



## SPEECH REGULATION AND TOBACCO HARM REDUCTION

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Introduction..... 103

I. ENDS and Vaping Products..... 107

II. Regulating Cigarettes and Deemed Tobacco Products..... 116

III. Regulating Health-Related Information about Tobacco Products..... 125

IV. The Public Health Consequences of Regulating Health-Related Claims.... 129

V. What About the First Amendment? ..... 132

Conclusion ..... 137

### INTRODUCTION

Regulatory constraints on the provision of truthful information to consumers about tobacco products may be having deadly consequences. Different types of tobacco products present different degrees of risk, yet a substantial proportion of consumers are unaware of these differences.<sup>1</sup> Existing regulations governing tobacco products limit the ability of manufacturers to address these misperceptions. As a consequence, well-intentioned public health regulations may be undermining the protection of public health.

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<sup>1</sup> See Jacob James Rich & Jonathan H. Adler, *Uneducating Americans on Vaping*, 46 REGUL. 38 (2023) (discussing consumer misperceptions about the relative risk of different types of tobacco products).

Regulation of commercial speech is a major component of federal regulation of tobacco products. Even before the enactment of the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”),<sup>2</sup> Congress authorized cigarette warning labels and the regulation of cigarette advertisements.<sup>3</sup> In 2009, this legislation expanded the regulation of speech, imposed a permitting regime for comparative health claims of alternative tobacco products and subjected cigarette alternatives, such as electronic nicotine delivery systems (ENDS) and other vaping products, to the same regulatory regime as cigarettes.<sup>4</sup>

Federal regulation of tobacco company speech was adopted to counteract tobacco industry misinformation and manipulation of consumers.<sup>5</sup> Controlling the advertisement, promotion, and labeling of tobacco products was embraced as a central element of reducing smoking rates and youth initiation in particular.<sup>6</sup> While the regulation of tobacco advertising and labeling was considered an important public health measure, it was nonetheless subject to First Amendment scrutiny.<sup>7</sup>

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<sup>2</sup> 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>3</sup> See, e.g., Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331–1340; Public Health Cigarette Smoking Act of 1969, 15 U.S.C. 1331; Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984) (codified in 15 U.S.C. §§ 4401–4408). On the history of tobacco regulation, see generally Bruce Yandle, Joseph A. Rotondi, Andrew P. Morriss & Andrew Dorchak, *Bootleggers, Baptists & Televangelists: Regulating Tobacco by Litigation*, 2008 U. ILL. L. REV. 1225, 1259 (2008) (summarizing history of tobacco regulation).

<sup>4</sup> See *infra* Part II.

<sup>5</sup> See U.S. DEP’T OF HEALTH & HUM. SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 8 (2016), <https://perma.cc/RZQ9-G78H>.

<sup>6</sup> *Id.* at 9.

<sup>7</sup> See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (holding the First Amendment restricts regulation of outdoor advertisements for smokeless tobacco and cigars); *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012) (holding regulations requiring tobacco companies to include warning labels on tobacco packaging and advertising did not violate the First Amendment); *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012) (vacating FDA’s graphic warning requirement on cigarette packaging); *Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013) (holding Providence, RI’s restriction on discounting tobacco products with coupons and multipack discounts falls outside of the First Amendment); *Philip Morris USA, Inc. v. City & County of San Francisco*, 345 F. App’x 276 (9th Cir. 2009) (holding a San Francisco ordinance limiting the sale locations of cigarettes did not violate the First Amend-

Since the adoption of federal tobacco legislation, the Food and Drug Administration (FDA) has asserted regulatory authority over ENDS and other vaping products as “tobacco products,” subjecting them to the same regulatory regime as cigarettes and other traditional forms of tobacco products.<sup>8</sup> This includes labeling requirements and regulations governing tobacco product advertising. It also includes restrictions on providing consumers with truthful, and potentially life-saving, information about the relative risks of competing products.<sup>9</sup>

While ENDS are now subject to the same federal regulatory regime as cigarettes, they do not pose the same risks. ENDS and other vaping products pose far less danger to users than combustible tobacco products, such as cigarettes.<sup>10</sup> Yet recent polling shows that most consumers have a poor understanding of the relative risks of tobacco products, and that this public misunderstanding is getting worse.<sup>11</sup> Barring producers from informing consumers about the relative risks of vaping products and their potential to help smokers quit smoking eliminates a potentially powerful tool for consumer education. Measures to prevent fraudulent or misleading marketing claims may be necessary, but current restrictions go so far as to outlaw the promotion of information acknowledged by the regulators themselves.

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ment); *Rockwood v. City of Burlington*, 21 F. Supp. 2d 411 (D. Vt. 1998) (First Amendment challenge to a law restricting advertisement of tobacco products in convenience stores); *Penn Advertising v. Mayor & City Council*, 63 F.3d 1318 (4th Cir. 1995) (First Amendment challenge to an ordinance prohibiting outdoor cigarette advertisement); Yandle et al., *supra* note 3, at 1229 (explaining the bootlegger’s tactical advantage of accepting some restrictions on alcohol sales).

<sup>8</sup> See *Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R. §§ 1100, 1140, 1143) (“Deeming Rule”).

<sup>9</sup> See *infra* Part III.

<sup>10</sup> See, e.g., Amy Fairchild, Cheryl Heaton, James Curran, David Abrams & Ronald Bayer, *Evidence, Alarm, and the Debate Over E-Cigarettes*, 366 *SCI.* 1318, 1319 (2019) (“In the case of adult smokers, there is solid scientific evidence that vaping nicotine is much safer than smoking.”); David J.K. Balfour, Neal L. Benowitz, Suzanne M. Colby, Dorothy K. Hatsukami, Harry A. Lando, Scott J. Leischow, Caryn Lerman, Robin J. Mermelstein, Raymond Niaura, Kenneth A. Perkins, Ovide F. Pomerleau, Nancy A. Rigotti, Gary E. Swan, Kenneth E. Warner & Robert West, *Balancing Consideration of the Risks and Benefits of E-Cigarettes*, 111 *AM. J. PUB. HEALTH* 1661, 1662 (2021) (noting scientific bodies that have concluded ENDS are “far less harmful” than combustible cigarettes). See also *infra* Part I.

<sup>11</sup> See *infra* notes 139–42 and accompanying text.

Current restraints on truthful health information that could help or encourage smokers to quit are not only constitutionally dubious, they may undermine the protection of public health as well.

Part I of this essay describes what is currently understood about the relative health risks of ENDS and other vaping products, particularly as compared to combustible cigarettes. While uncertainties remain about the long-term risks posed by ENDS, the weight of existing scientific and medical evidence suggests that such products pose less risks to consumers and bystanders than cigarettes. The FDA concurs in this assessment. There is also strong evidence that such products can help smokers reduce their cigarette consumption and are more effective aids to smoking cessation than available FDA-approved alternatives.

Part II of this essay describes the current regulatory regime governing tobacco products and how this regime has been applied to ENDS and other vaping products. Under the Tobacco Control Act and the FDA's subsequent decision to deem ENDS as tobacco products, such products require FDA approval before they may be sold, much like drugs and medical devices. They are also subject to specific regulation under statutory provisions governing "modified risk tobacco products" if any relative risk claims are made about such products, and, in some cases, even being treated as drugs or devices under the Federal Food, Drug and Cosmetic Act (FDCA).

Part III of this essay explains how the FDA's regulatory regime hampers the ability of ENDS manufacturers to inform consumers about the relative risks of their products and the potential use of ENDS as smoking cessation aids. Under current law, ENDS producers must also obtain FDA approval before making any comparative risk claims, such as claiming that such products are less dangerous than cigarettes. Further, if ENDS manufacturers wish to inform smokers that ENDS may assist in smoking cessation, they must seek FDA approval for their products as drugs or devices. Even though such claims are accepted as true by the FDA, such speech is prohibited without prior FDA approval. In practice, this means that ENDS producers face greater restrictions on speech about their products than do other regulated entities, such as makers of nutritional supplements. These regulatory constraints hamper public health efforts and are constitutionally dubious.

Part IV explains why this regulation of health claims may be having serious negative consequences for public health. A majority of consumers, including current cigarette smokers, are misinformed about the relative risks posed by various nicotine products. Such public misunderstanding appears to be getting worse.

Part V explains why the current regulation of speech about the relative risks of ENDS and other vaping products is highly questionable under current commercial speech jurisprudence insofar as the FDA is prohibiting the communication of truthful information about such products. Even though product claims are subject to less demanding constitutional scrutiny than restrictions on political speech, existing restrictions are not sufficiently tailored to fit the government's interest in promoting health. Greater recognition and protection of the speech rights of ENDS producers is not only required under existing First Amendment jurisprudence, it would also likely benefit public health.

#### I. ENDS AND VAPING PRODUCTS

Electronic cigarettes, also known as “electronic nicotine delivery systems” (ENDS) or vapes, have been marketed in the United States since 2006.<sup>12</sup> Such products typically consist of a battery-powered atomizer, electronic components, and a cartridge that holds a liquid solution.<sup>13</sup> ENDS come in a variety of forms, including both disposable and rechargeable models, as well as modular products—vapors, tanks, and mods (VTMs)—that consumers may mix and match, then fill with the vaping fluid of their choice.<sup>14</sup> The CDC reports that disposable e-cigarettes ac-

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<sup>12</sup> See Peter Hajek, Jean-Francois Etter, Neal Benowitz, Thomas Eissenberg & Hayden McRobbie, *Electronic Cigarettes: Review of Use, Content, Safety, Effects on Smokers and Potential for Harm and Benefit*, 109 *ADDICTION* 1801 (2014); Barbara Demick, *A High Tech Approach to Getting a Nicotine Fix*, *L.A. TIMES* (Apr. 25, 2009). Although not developed for retail sale until the 21st 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>13</sup> See Riccardo Polosa, Brad Rodu, Pasquale Caponnetto, Marilena Maglia & Cirino Raciti, *A Fresh Look at Tobacco Harm Reduction: The Case for the Electronic Cigarette*, 10 *HARM REDUCTION J.* 19, 23 (2013); Chitra Dinakar & George T. O'Connor, *The Health Effects of Electronic Cigarettes*, 375 *NEW ENG. J. MED.* 1372, 1372–73 (2016).

<sup>14</sup> The two types of e-cigarette devices are also characterized as “closed system” and “open system,” respectively. See *Nicopure Labs, LLC v. FDA*, 266 F. Supp.3d 360, 377 (D.D.C. 2017).

counted for just over half of unit sales from brick-and-mortar retailers during December 2022, with pre-filled cartridges making up most of the rest.<sup>15</sup> Reliable data for online retailers, vape shops, and tobacco retailers is unavailable.<sup>16</sup> This makes it difficult to determine the volume of sales for vaping fluids used with VTMs.

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>17</sup> Instead, e-cigarettes heat and vaporize a propylene-glycol or glycerol solution that typically contains nicotine and some sort of flavoring.<sup>18</sup> Users inhale the vapor as a cigarette user might inhale smoke. For this reason, e-cigarette use is referred to as “vaping,” and ENDS are increasingly referred to as “vapes.”

ENDS have proven to be a disruptive technology, threatening the market for traditional tobacco products as well as for other nicotine products.<sup>19</sup> Initially manufactured and distributed by small firms, ENDS are now made and sold by a range of firms, including the major tobacco companies, which have both acquired ENDS producers and developed their own vaping products.<sup>20</sup> And, like other disruptive

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<sup>15</sup> See Fatma Romeh M. Ali, Andrew B. Seidenberg, Elisha Crane, Elizabeth Seaman, Michael A. Tynan & Kristy Marynak, *E-Cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020–2022*, 72 MORBIDITY & MORTALITY WKLY. REP. 672 (2023).

<sup>16</sup> See Alex C. Liber, Maryam Faraji, Radhika Ranganathan & Abigail S. Friedman, *How Complete Are Tobacco Sales Data? Assessing The Comprehensiveness of US Tobacco Product Retail Sales Data Through Comparisons to Excise Tax Collections*, NICOTINE & TOBACCO RSCH. (Nov. 2, 2023), <https://perma.cc/75VR-BWUC> (discussing limitations of ENDS sales data, especially as compared to cigarette sales data).

<sup>17</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 13, 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>18</sup> See Polosa et al., *supra* note 13, at 22; Dinakar & O’Connor, *supra* note 13, at 1374; Caroline Franck, Kristian B. Filion, Jonathan Kimmelman, Roland Grad & Mark J. Eisenberg, *Ethical Considerations of E-cigarette Use for Tobacco Harm Reduction*, 17 RESPIRATORY RSCH. 53, 54–55 (2016). While most e-cigarette fluids contain nicotine, nicotine-free fluids are also available.

<sup>19</sup> See Jonathan H. Adler, Andrew P. Morriss, Roger E. Meiners & Bruce Yandle, *Baptists, Bootleggers & Electronic Cigarettes*, 33 YALE J. ON REG. 313, 334 (2016).

<sup>20</sup> See generally Greta Hsu, Jessica Y. Sun & Shu-Hong Zhu, *Evolution of Electronic Cigarette Brands From 2013–2014 to 2016–2017: Analysis of Brand Websites*, 20 J. MED. INTERNET RSCH. e80 (2018).

technologies, ENDS have become the subject of regulation, some of which is encouraged by incumbent firms seeking to suppress or constrain competition.<sup>21</sup>

ENDS are still a relatively new technology and their rate of product evolution has been quite rapid.<sup>22</sup> As a consequence, the long-term health consequences of ENDS usage remain unknown and currently unknowable.<sup>23</sup> Nonetheless, the majority of medical and scientific institutions that have considered the question have concluded that ENDS are significantly safer to consume than conventional cigarettes.<sup>24</sup> A 2018 National Academies of Sciences report, for instance, found there is “conclusive evidence that completely substituting e-cigarettes for combustible cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.”<sup>25</sup> It further found that “there is moderate evidence that second-hand exposure to nicotine and particulates is lower from e-cigarettes compared with combustible tobacco cigarettes.”<sup>26</sup> The FDA has likewise acknowledged that “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” since ENDS do not contain tar and other carcinogens found in combustible tobacco products.<sup>27</sup> Although the FDA warned that e-cigarettes pose similar addiction risks as combustible tobacco products, the agency justified its relative risk distinction because “the effects from nicotine exposure by inhalation are likely not responsible for the high prevalence of tobacco-related death and disease in this country.”<sup>28</sup>

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<sup>21</sup> See Adler et al., *supra* note 19.

<sup>22</sup> *Id.* at 337.

<sup>23</sup> See Balfour et al., *supra* note 10, at 1662 (noting the lack of data on long-term health effects).

<sup>24</sup> *Id.* (noting the conclusions of the National Academies of Sciences, Engineering and Medicine and the British Royal College of Physicians).

<sup>25</sup> NAT’L ACADS. OF SCIS. ENG’G & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 11 (David L. Eaton, Leslie Y. Kwan & Kathleen Stratton eds., 2018).

<sup>26</sup> *Id.*; see also Lion Shahab, Maciej L Goniewicz, Benjamin C Blount, Jamie Brown, Ann McNeill, K Udeni Alwis, June Feng, Lanqing Wang & Robert West, *Nicotine, Carcinogen, and Toxicant Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users*, 166 ANNALS INTERNAL MED. 390 (2017).

<sup>27</sup> See Deeming Rule, *supra* note 8, at 28981.

<sup>28</sup> *Id.* (citing H.L. Waldrum, O.G. Nilsen, T. Nilsen, H. Rørvik, V. Syversen, A. K. Sanvik, O. A. Haugen, S. H. Torp & E. Brenna, *Long-Term Effects of Inhaled Nicotine*, 58 LIFE SCI. 1339 (1996); M.

Even those medical institutions concerned about the possibility of encouraging youth or non-smokers to use vaping products have acknowledged the difference in risk between ENDS and cigarettes. Johns Hopkins Medicine, for instance, explicitly states “[v]aping is less harmful than smoking, but it’s still not safe” in an article for the general public.<sup>29</sup> A similar type of article published by the Mayo Clinic echoed this sentiment, claiming “[e-cigarettes are] probably safer than cigarettes for sure, but they are not safe.”<sup>30</sup>

Public health authorities in the United Kingdom have been less equivocal. After a comprehensive review of the available literature, Public Health England (the research arm of the United Kingdom’s Department of Health and Social Care) concluded that e-cigarettes are significantly less harmful than other tobacco products, cigarettes in particular.<sup>31</sup> Specifically, Public Health England, after conducting their own assessment of the available evidence, concurred with an international expert panel’s estimate that e-cigarettes pose no more than five percent of the risk presented by tobacco cigarettes to users and secondhand bystanders.<sup>32</sup>

These conclusions are based upon an abundance of research in the medical literature showing that vaping products have significantly safer short-term outcomes. For example, a 2017 study published in the *Annals of Internal Medicine* concluded that former smokers who had completely switched to ENDS showed significantly

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A. Russell, *Low-Tar Medium-Nicotine Cigarettes: A New Approach to Safer Smoking*, 1 BRIT. MED. J. 1430 (1976)).

<sup>29</sup> See Michael Joseph Blaha, *5 Vaping Facts You Need to Know*, JOHNS HOPKINS MED., <https://perma.cc/FKG8-LNXX>.

<sup>30</sup> See Deb Balzer, *Vaping Unknowns: Mayo Clinic Expert Answers Questions About Vaping*, MAYO CLINIC NEWS NETWORK (Aug. 29, 2019), <https://perma.cc/K44P-CNLF>.

<sup>31</sup> See A. MCNEILL, L.S. BROSE, R. CALDER, S.C. HITCHMAN, P. HAJEK & H. MCROBBIE, PUB. HEALTH ENG., PUBL’N NO. 2015260, E-CIGARETTES: AN EVIDENCE UPDATE 76 (2015), <https://perma.cc/T7MA-3MWS> (“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.”); U.K. OFF. FOR HEALTH IMPROVEMENT & DISPARITIES, NICOTINE VAPING IN ENGLAND: 2022 EVIDENCE UPDATE (Sept. 29, 2022), <https://perma.cc/P42D-2LTY>.

<sup>32</sup> See David J. Nutt, Lawrence D. Phillips, David Balfour, H. Valerie Curran, Martin Dockrell, Jonathan Foulds, Karl Fagerstrom, Kgosile Letlape, Anders Milton, Riccardo Polosa, John Ramsey & David Sweanor, *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, 20 EUR. ADDICTION RSCH. 218 (2014). The 2015 Public Health UK report concluded this was a “reasonable estimate.” MCNEILL ET AL., *supra* note 31.



lower levels of carcinogens in their salivary and urinary samples compared to current smokers.<sup>33</sup> Subsequent research supported these results, finding that the levels of carcinogens found in the blood samples of former smokers who had completely switched to e-cigarettes closely reflected those of people who had never used tobacco within a year of cessation.<sup>34</sup> Indeed, a study published in *Tobacco Control* estimated that if every American smoker switched to e-cigarettes over a ten-year period, approximately 6.6 million premature deaths from tobacco would be avoided.<sup>35</sup>

Among all of the public health considerations for e-cigarettes, the implications for pregnant mothers and their children might be the most visible. It is well established that smoking during pregnancy leads to adverse outcomes such as low birth weights,<sup>36</sup> complications that lead to miscarriages and premature births,<sup>37</sup> and obesity during childhood.<sup>38</sup> Some of these effects may be related to nicotine exposure in utero or other factors, but most of the research connects these adverse outcomes to mothers inhaling carbon monoxide in the smoke from combustible tobacco

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<sup>33</sup> See Lion Shahab, Maciej L. Goniewicz, Benjamin C. Blount, Jamie Brown, Ann McNeill, K Udeni Alwis, June Feng, Lanqing Wang & Robert West, *Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users*, 166 ANNALS INTERNAL MED. 390 (2017).

<sup>34</sup> See Maciej L. Goniewicz, Danielle M. Smith, Kathryn C. Edwards, Benjamin C. Blout, Kathleen L. Caldwell, Jun Feng, Lanqing Wang, Carol Christensen, Bridget Ambrose, Nicolette Borek, Dana van Bommel, Karen Konkell, Gladys Erives, Cassandra A. Stanton, Elizabeth Lambert, Heather L. Kimmel, Dorothy Hatsukami, Stephen S. Hecht, Raymond S. Niaura, Mark Travers, Charles Lawrence & Andrew J. Hyland, *Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes*, 1 JAMA NETWORK OPEN (Dec. 14, 2018), <https://perma.cc/H3XX-T3QX>.

<sup>35</sup> See David T. Levy, Ron Borland, Eric N. Lindblom, Maciej L. Goniewicz, Rafael Meza, Theodore R. Holford, Zhe Yuan, Yuing Luo, Richard J. O'Connor, Raymond Niaura & David B. Abrams, *Potential Deaths Averted in USA by Replacing Cigarettes with E-Cigarettes*, 27 TOBACCO CONTROL 18 (2018).

<sup>36</sup> See M. S. Kramer, *Determinants of Low Birth Weight: Methodological Assessment and Meta-Analysis*, 65 BULL. WORLD HEALTH ORG. 663 (1987).

<sup>37</sup> See Anne Castles, E. Kathleen Adams, Cathy L. Melvin, Christopher Kelsch & Matthew L. Boulton, *Effects of Smoking During Pregnancy: Five Meta-Analyses*, 16 AM. J. PREVENTATIVE MED. 208 (1999).

<sup>38</sup> See E. Oken, E.B. Levitan & M.W. Gillman, *Maternal Smoking During Pregnancy and Child Overweight: Systematic Review and Meta-Analysis*, 32 INT'L J. OBESITY 201 (2008).

products, such as conventional cigarettes.<sup>39</sup> This would suggest that the harm to mothers and their children would be reduced if smoking mothers switched to ENDS.

Research on ENDS usage during pregnancy has shown stark differences in risks. A study reviewing the outcomes of 129 live births at Coombe Women and Infants University Hospital in Ireland among women who exclusively used e-cigarettes, for example, found that their babies' measurements were similar to the babies of nonsmokers and larger than those of cigarette smokers, with no cases of serious maternal or infant morbidity.<sup>40</sup> These results have been continuously replicated, including a study in *The Lancet's* eClinicalMedicine that found "[b]irth outcomes, namely birthweight, gestation and head circumference, did not differ for e-cigarette exposed infants compared with infants who were not prenatally exposed to nicotine. Cigarette exposed infants had a significantly lower birthweight . . . and reduced head circumference . . . in comparison to non-exposed infants."<sup>41</sup> Some adverse outcomes for infants, such as decreased motor maturity, have been correlated with e-cigarette use during pregnancy.<sup>42</sup> But almost all studies on the topic conclude that ENDS use during pregnancy is substantially preferable to smoking.<sup>43</sup>

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<sup>39</sup> See Anna Merklinger-Gruchala, Grazyna Jasienska & Maria Kapiszewska, *Parity Conditions the Risk for Low Birth Weight After Maternal Exposure to Air Pollution*, 63 *BIODEMOGRAPHY & SOC. BIOLOGY* 71 (2017).

<sup>40</sup> See Brendan P. McDonnell, Evan Bergin & Carmen Regan, *Electronic Cigarette Use in Pregnancy Is Not Associated with Low Birth Weight or Preterm Delivery*, 220 *AM. J. OBSTETRICS & GYNECOLOGY* S137 (2019).

<sup>41</sup> See Suzanne Froggatt, Nadja Reissland & Judith Covey, *The Effects of Prenatal Cigarette and E-Cigarette Exposure on Infant Neurobehaviour: A Comparison to a Control Group*, 28 *ECLINICALMED.* 100602 (2020).

<sup>42</sup> *Id.*; CDC DIVISION OF REPRODUCTIVE HEALTH, *E-CIGARETTES AND PREGNANCY* (Feb. 25, 2019), <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/substance-abuse/e-cigarettes-pregnancy.htm>.

<sup>43</sup> There is also some research suggesting that indoor vaping restrictions may increase infant mortality, likely due to an increase in smoking. See Michael Cooper & Michael F. Pesko, *The Effect of E-Cigarette Indoor Vaping Restrictions on Infant Mortality*, *S. ECON. J.* (2022), <https://perma.cc/SUD3-XT6W>.

Since only about half of women who smoke quit smoking during pregnancy,<sup>44</sup> such research has led Public Health England to encourage the use of e-cigarettes by female smokers during pregnancy who are otherwise unable to quit.<sup>45</sup> This approach began in 2019 and has been followed by a 33.7% percent drop in the percentage of women who are known smokers at the time of birth in England as of Q4 2023.<sup>46</sup> ENDS were a common nicotine replacement tool among mothers during this period and were occasionally provided by government maternity services free of charge.<sup>47</sup>

In addition to being safer than conventional cigarettes, ENDS also appear to be a more effective tool for smoking reduction and cessation than available alternatives, including FDA-approved nicotine replacement therapies. *The New England Journal of Medicine (NEJM)* published a randomized controlled trial (RCT) comparing the effectiveness of e-cigarettes to a patient's choice of nicotine-replacement products (like nicotine gum and patches) that had been approved by the UK's Medicines and Healthcare products Regulatory Agency for smoking cessation, finding

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<sup>44</sup> See Am. Coll. of Obstetricians & Gynecologists, Comm. on Obstetric Prac., Committee Opinion No. 807, *Tobacco and Nicotine Cessation during Pregnancy*, 135 OBSTETRICS & GYNECOLOGY e221 (2020) (“[A]pproximately 54% of women who smoke before pregnancy quit smoking directly before or during pregnancy”).

<sup>45</sup> See ANN MCNEILL, LEONIE S. BROSE, ROBERT CALDER, LINDA BAULD & DEBBIE ROBSON, PUB. HEALTH ENG., PUB'N NO. GW-1118, VAPING IN ENGLAND: AN EVIDENCE UPDATE INCLUDING MENTAL HEALTH AND PREGNANCY (2020), <https://perma.cc/CYJ6-9P63>.

<sup>46</sup> See WALT TRELOAR, NAT'L HEALTH SERV. ENG., STATISTICS ON WOMEN'S SMOKING STATUS AT TIME OF DELIVERY: ENGLAND, QUARTER 4, 2023-24 (2024), <https://perma.cc/CWC5-L622>.

<sup>47</sup> See Ross Thomson, Sue Cooper, John Waldron, Efe Mamuzo, Lisa McDaid, Joanne Emery, Lucy Phillips, Felix Naughton & Tim Coleman, *Smoking Cessation Support for Pregnant Women Provided by English Stop Smoking Services and National Health Service Trusts: A Survey*, 19 INT'L. J. ENV'T RSCH. & PUB. HEALTH 1634 (2022); compare with K. Bowker, S. Lewis, L. Phillips, S. Orton, M. Ussher, F. Naughton, L. Bauld, T. Coleman, L. Sinclair, H. McRobbie, A. Khan & S. Cooper, *Pregnant Women's Use of E-Cigarettes in the UK: A Cross-Sectional Survey*, 128 BJOG 984 (2021). Due to the COVID-19 pandemic, it has been difficult to estimate the public health benefits of these interventions, but the UK's current tobacco control plan intends to “[r]educ[e] the prevalence of smoking in pregnancy from 10.7% to 6.0% or less by the end of 2022” with the help of e-cigarettes. U.K. DEP'T OF HEALTH & SOC. CARE, TOBACCO CONTROL DELIVERY PLAN 2017–2022, at 1 (June 2018), <https://perma.cc/RWV8-T78M>; U.K. DEP'T OF HEALTH & SOC. CARE, TOWARDS A SMOKE-FREE GENERATION: TOBACCO CONTROL PLAN FOR ENGLAND (July 18, 2017), <https://perma.cc/LUV5-G8PQ>.

that e-cigarettes were approximately twice as effective.<sup>48</sup> A subsequent literature review by the Cochrane Library of RCTs and randomized cross-over trials published as of January 2020 supported the *NEJM*'s results, concluding that e-cigarettes were approximately 70% more effective in supporting smokers with quitting than traditional nicotine-replacement products.<sup>49</sup> This review was recently updated with new studies in 2024 and confirmed the previous results.<sup>50</sup> Such research motivated another *NEJM* RCT, which concluded that adding free e-cigarette access to standard-of-care counseling in Switzerland substantially improved smoking cessation rates without worsening health risks among current cigarette users who intended to quit smoking.<sup>51</sup>

Amid promising findings that suggest ENDS may be the most effective tool for smoking cessation, critics argue that ENDS may also increase the overall rate of nicotine addiction, especially among youth. According to estimates from the National Youth Tobacco Survey (NYTS), 2018 and 2019 saw the first sharp increases

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<sup>48</sup> Peter Hajek, Anna Phillips-Waller, Dunja Przulj, Francesca Pesola, Katie Myers Smith, Natalie Bisal, Jinshuo Li, Steve Parrot, Peter Sasieni, Lynne Dawkins, Louise Ross, Maciej Goniewicz, Qi Wu & Hayden J. McRobbie, *A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy*, 380 *NEW ENG. J. MED.* 629 (2019).

<sup>49</sup> Jamie Hartmann-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodoulou, Caitlin Notley, Nancy A. Rigotti, Tari Turner, Ailsa R. Butler, Thomas R. Fanshawe & Peter Hajek, *Electronic Cigarettes for Smoking Cessation*, *COCHRANE DATABASE SYSTEMATIC REVIEWS*. (2020), <https://perma.cc/A35E-U5SU>.

<sup>50</sup> Jamie Hartmann-Boyce, Nicola Lindson, Alisa R. Butler, Hayden McRobbie, Chris Bullen, Rachna Begh, Annika Theodoulou, Caitlin Notley, Nancy A. Rigotti, Tari Turner, Thomas R. Fanshawe & Peter Hajek, *Electronic Cigarettes for Smoking Cessation*, *COCHRANE DATABASE SYSTEMATIC REVIEWS*. (2022), <https://perma.cc/9U3T-SR49>.

<sup>51</sup> Reto Auer, Anna Schoeni, Jean-Paul Humair, Isabelle Jacot-Sadowski, Ivan Berlin, Mirah J. Stuber, Moa Lina Haller, Rodrigo Casagrande Tango, Anja Frei, Alexandra Strassmann, Philip Bruggmann, Florent Baty, Martin Brutsche, Kali Tal, Stéphanie Baggio, Julian Jakob, Nicolas Sambiagio, Nancy B. Hopf, Martin Feller, Nicolas Rodondi & Aurélie Berthet, *Electronic Nicotine-Delivery Systems for Smoking Cessation*, 390 *NEW ENG. J. MED.* 601 (2024); *see also* Nancy A. Rigotti, *Electronic Cigarettes for Smoking Cessation—Have We Reached a Tipping Point?*, 390 *NEW ENG. J. MED.* 664 (2024).

of “any tobacco product use” among adolescents in approximately 20 years.<sup>52</sup> Despite decreases in cigarette use and negligible increases in other smokeless tobacco use among teens in both years, past-30-day nicotine product use among high schoolers had surged over 50% almost entirely due to ENDS between 2017 and 2019.<sup>53</sup> This event was largely blamed on JUUL Labs Inc. for allegedly targeting youth with its social media advertising campaign.<sup>54</sup> However, subsequent FDA compliance actions broadly targeted the entire ENDS market, including e-liquid advertising for VTM products that were not commonly used among youth.<sup>55</sup>

Although youth exposure to nicotine is a legitimate concern of regulators, the fear that the uptake of ENDS might promote other tobacco product usage has not been substantiated. Although research has found that teen users of ENDS are more likely to try combustible cigarettes than other teens,<sup>56</sup> research also suggests that e-cigarette access is associated with further declines in youth smoking.<sup>57</sup> Additionally,

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<sup>52</sup> See Ruoyan Sun, David Mendez & Kenneth E. Warner, *Trends in Nicotine Product Use Among US Adolescents, 1999–2020*, 4 JAMA NETWORK OPEN (2021), <https://perma.cc/6KHC-E58H>.

<sup>53</sup> See *id.*; SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2019 NATIONAL SURVEY ON DRUG USE AND HEALTH B-15 (Sept. 2020), <https://perma.cc/P9MU-9YUP>.

<sup>54</sup> See Robert K. Jackler, Cindy Chau, Brook D. Getachew, Mackenzie M. Whitcomb, Jeffrey Lee-Heidenreich, Alexander M. Bhatt, Sophia H.S. Kim-O’Sullivan, Zachary A. Hoffman, Laurie M. Jackler & Divya Ramamurthi, *JUUL Advertising Over Its First Three Years on the Market* (Stanford Rsch. into the Impact of Tobacco Advert., Research Paper, 2019), <https://perma.cc/95MQ-GW5C>.

<sup>55</sup> Statement, Scott Gottlieb, Comm’r, U.S. Food & Drug Admin., Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes (Nov. 15, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access>.

<sup>56</sup> See Kaitlyn M. Berry, Jessica L. Fetterman, Emelia J. Benjamin, Aruni Bhatnagar, Jessica L. Barrington-Trimis, Adam M. Leventhal & Andrew Stokes, *Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths*, 2 JAMA NETWORK OPEN (2019), <https://perma.cc/4SRP-C4Y2>.

<sup>57</sup> See, e.g., Rahi Abouk, Charles Courtemanche, Dhaval Dave, Bo Feng, Abigail S. Friedman, Johanna Catherine Maclean, Michael F. Pesko, Joseph J. Sabia & Samuel Safford, *Intended and Unintended Effects of E-Cigarette Taxes on Youth Tobacco Use*, 87 J. HEALTH ECON. 102720 (2023); Michael F. Pesko & Janet M. Currie, *E-Cigarette Minimum Legal Sale Age Laws and Traditional Cigarette Use Among Rural Pregnant Teenagers*, 66 J. HEALTH ECON. 71 (2020); Abigail S. Friedman,

trends in nicotine use among youth<sup>58</sup> and adults<sup>59</sup> have recently trended towards historic lows, with high school nicotine use hitting its lowest rate in 2023 since data have been collected. With little variation in restrictive marketing regulations, it is not clear how various forms of ENDS advertising would affect the size of the nicotine product market.

## II. REGULATING CIGARETTES AND DEEMED TOBACCO PRODUCTS

Today, tobacco products are heavily regulated in the United States, but this is a relatively recent development. For most of the twentieth century, the tobacco industry was largely unregulated.<sup>60</sup> Comprehensive regulation of tobacco products did not begin until the passage of federal legislation in 2009.

For over forty years, the federal government regulated tobacco advertising and promotion, with little regulation of the tobacco products themselves. After publication of the Surgeon General's 1964 report on the harms of cigarette smoking,<sup>61</sup> the Federal Trade Commission (FTC) sought to require dramatic warning labels on

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*A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California*, 175 JAMA PEDIATRICS 863 (2021).

<sup>58</sup> See Sun et al., *supra* note 52.

<sup>59</sup> See Monica E. Cornelius, Caitlin G. Loretan, Ahmed Jamal, Brittany C. Davis Lynn, Margaret Mayer, Iris C. Alcantara & Linda Neff, *Tobacco Product Use Among Adults—United States, 2021*, 72 MORTALITY & MORBIDITY WEEKLY REP. 475 (2023) (noting 2021 marked “the lowest smoking prevalence recorded since 1965”).

<sup>60</sup> See generally Peter D. Jacobson, Jeffery Wasserman & John R. Anderson, *Historical Overview of Tobacco Legislation and Regulation*, 53 J. SOC. ISSUES 75 (1997). For a useful history of tobacco regulation and litigation, see also Yandle et al., *supra* note 3; RICHARD KLUGER, *ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* (1996). 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>61</sup> See DEP'T OF HEALTH, EDUC. & WELFARE, PUB'N NO. 1103, *SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE* (1964), <https://perma.cc/2H24-NQGS>.

cigarette packages.<sup>62</sup> Congress responded by mandating milder warnings, preempting state-level efforts to require more explicit warnings.<sup>63</sup> A few years later—also in response to more aggressive agency initiatives—Congress prohibited cigarette and cigar advertising on television.<sup>64</sup>

In 1996, the FDA sought to regulate cigarettes and other tobacco products under the FDCA.<sup>65</sup> According to the FDA, nicotine constituted a “drug” and cigarettes and smokeless tobacco products should be considered “drug delivery devices” under the Act.<sup>66</sup> On this basis, the FDA asserted regulatory jurisdiction over tobacco products and sought to regulate tobacco advertising and promotion pursuant to its extant regulatory authorities. 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.<sup>67</sup>

This effort to regulate tobacco products under the FDCA would not last long. The major tobacco companies filed suit and ultimately prevailed in the Supreme

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<sup>62</sup> Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8324, 8326 (July 29, 1965) (to be codified at 16 C.F.R. § 408).

<sup>63</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 3, at 1249–51; see also Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 513–15 (1992).

<sup>64</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. §§ 1331–1338); 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 REGUL. 35 (1986); see also John E. Calfee, *Cigarette Advertising, Health Information and Regulation Before 1970* (Fed. Trade Comm’n, Working Paper No. 134, 1985), <https://perma.cc/4XKC-N4ZZ>.

<sup>65</sup> See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44396, 44418 (Aug. 28, 1996).

<sup>66</sup> *Id.* at 44397, 44402.

<sup>67</sup> See George J. Annas, *Cowboys, Camels, and the First Amendment: The FDA’s Restrictions on Tobacco Advertising*, 335 NEW ENG. J. MED. 1779, 1779–80 (1996).

Court.<sup>68</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>69</sup> In the view of the Court's majority, the history of federal legislation concerning tobacco made clear that Congress had no intention of subjecting cigarettes and other tobacco products to FDA regulation, let alone of creating the potential for the FDA to prohibit tobacco products because cigarettes could not be deemed "safe and effective" when used as intended.<sup>70</sup>

While the major cigarette producers had initially opposed the FDA's efforts to regulate tobacco products under the FDCA, they soon had a change of heart. Waves of litigation, including coordinate suits filed by state attorneys general and the resulting Master Settlement Agreement, changed the incentives faced by the cigarette companies.<sup>71</sup> Philip Morris, in particular, sought federal legislation to expressly authorize FDA regulation of tobacco products.<sup>72</sup> The nation's largest cigarette producer stood to benefit from federal regulation that would both suppress competition within the industry and provide insulation from future tort litigation.<sup>73</sup>

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"),<sup>74</sup> which gave the FDA formal authority to regulate cigarettes and other tobacco products, including those "made or derived from"

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<sup>68</sup> See *FDA v. Brown & Williamson Tobacco Co.*, 529 U.S. 120 (2000).

<sup>69</sup> *Id.* at 126 ("Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products.").

<sup>70</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.").

<sup>71</sup> See Yandle et al., *supra* note 3, at 1270–71.

<sup>72</sup> See P.A. McDaniel & R.E. Malone, *Understanding Philip Morris's Pursuit of US Government Regulation of Tobacco*, 14 *TOBACCO CONTROL* 193 (2005).

<sup>73</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/moneybox/2002/07/smoke\\_screen.html](http://www.slate.com/articles/business/moneybox/2002/07/smoke_screen.html); see also Duff Wilson, *Philip Morris's Support Casts Shadow Over a Bill to Limit Tobacco*, *N.Y. TIMES* (Mar. 31, 2009) (calling the resulting law "the tobacco regulation that Philip Morris can live with.").

<sup>74</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.).



tobacco.<sup>75</sup> The Tobacco Control Act imposes regulatory restrictions on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.<sup>76</sup> It also provided the FDA the authority to reach other tobacco products, including pipes and cigars and some smoking alternatives that compete with tobacco but that could not be regulated under other existing authorities.<sup>77</sup>

The Tobacco Control 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>78</sup> The Tobacco Control Act requires tobacco companies to disclose their product contents<sup>79</sup> and authorizes the FDA to set tobacco product standards.<sup>80</sup> The Act further provides for more explicit warning labels on tobacco products,<sup>81</sup> imposes stringent limits on tobacco product advertising and promotion,<sup>82</sup> and limits the use of flavoring in cigarettes.<sup>83</sup> It also adopts additional controls to prevent tobacco sales to minors.<sup>84</sup>

Significant for product development and innovation, the Act requires manufacturers to obtain premarket approval for new tobacco products. Products marketed prior to February 15, 2007 and their substantial equivalents are grandfathered and exempt from the premarket approval requirement.<sup>85</sup> The FDA, for its part, enforces this rule strictly, and has concluded that even relatively modest changes in

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<sup>75</sup> For an overview of the Tobacco Control Act, see C. STEPHEN REDHEAD & VANESSA K. BURROWS, CONG. RSCH SERV., R40475, FDA TOBACCO REGULATION: THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009 (2009), <https://perma.cc/6JMB-W9ZK>.

<sup>76</sup> See 21 U.S.C. § 387a(b).

<sup>77</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>78</sup> See 21 U.S.C. § 387e (Center); 21 U.S.C. § 387s (fees).

<sup>79</sup> See 21 U.S.C. §§ 387d, 387i.

<sup>80</sup> See 21 U.S.C. § 387g.

<sup>81</sup> See 15 U.S.C. § 1333 (requiring one of nine warning labels, such as “Cigarettes are addictive.”)

<sup>82</sup> See 21 U.S.C. §§ 387f, 387k(g).

<sup>83</sup> See 21 U.S.C. § 387g(a)(1)(A).

<sup>84</sup> See 21 U.S.C. §§ 387f(d)(5) (making it unlawful for a retailer to sell a tobacco product to a person younger than 21).

<sup>85</sup> See 21 U.S.C. § 387j. Approximately 11,000 combustible tobacco products are grandfathered under these regulations and are not subject to any FDA approval requirement. See Brian F. Yagi,

product design or packaging will be sufficient to identify a product as a new tobacco product and one that is not substantially equivalent to a product already on the market.<sup>86</sup> The Act further authorizes the FDA to “deem” other “tobacco products” to be subject to the Act’s regulatory requirements.<sup>87</sup>

In May 2016, the FDA finalized regulations “deeming” e-cigarettes and other vaping products to be “tobacco products” subject to regulation under the Tobacco Control Act.<sup>88</sup> In reaching this decision, the FDA determined that e-cigarettes “should be regulated due to their potential for public harm.”<sup>89</sup> According to the agency, regulating e-cigarettes and similar products “is necessary to learn more about that potential.”<sup>90</sup> This rule applies to all such products, including their components and parts,<sup>91</sup> as well as to new products that may be used to deliver nicotine or tobacco in the future.<sup>92</sup>

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Boris Lushniak & Brian J. Miller, *Appropriate for the Protection of Public Health: Why We Need Electronic Nicotine Delivery System Product Standards*, 78 FOOD & DRUG L.J. 16, 17 (2023).

<sup>86</sup> See FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: DEMONSTRATING THE SUBSTANTIAL EQUIVALENCE OF A NEW TOBACCO PRODUCT: RESPONSES TO FREQUENTLY ASKED QUESTIONS (3d ed. 2016), <https://perma.cc/5PSH-EUSN>.

<sup>87</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 further 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>88</sup> Deeming Rule, *supra* note 8.

<sup>89</sup> *Id.* at 28983.

<sup>90</sup> *Id.* at 28984.

<sup>91</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 29074.

<sup>92</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 28976.

In deeming e-cigarettes as being 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>93</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 if such liquids were not intended to be combined with nicotine-containing liquids.<sup>94</sup> In July 2017, a federal district court rejected a legal challenge to the broad scope of the FDA’s rule<sup>95</sup> and this decision was upheld on appeal.<sup>96</sup>

With the deeming rule, the FDA effectively extended the Tobacco Control 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 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>97</sup> This rule is likely to produce significant consolidation within the e-cigarette industry, in no small part because the pre-market approval requirement stands as a significant barrier to entry. As with prior tobacco regulation, this is likely to benefit larger corporations, including tobacco companies that seek to operate within the ENDS market, while

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<sup>93</sup> *Id.* at 28976; *see also* 21 U.S.C. § 387a (defining tobacco products); 21 U.S.C. § 321(rr)(1) (including products “containing nicotine from any source, that is intended for human consumption” in the definition of tobacco products).

<sup>94</sup> Deeming Rule, *supra* note 8, at 28995, 28974, 29032.

<sup>95</sup> *See Nicopure Labs LLC v. FDA*, 266 F. Supp. 3d 360, 421 (D.D.C. 2017), *aff’d*, 944 F.3d 267 (D.C. Cir. 2019).

<sup>96</sup> *Nicopure Labs LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019); *see also Cigar Ass’n of Am. v. FDA*, 964 F.3d 56 (D.C. Cir. 2020) (holding the Deeming Rule did not give adequate notice of health warning requirements on cigar packaging.).

In separate litigation, the U.S. Court of Appeals for the D.C. Circuit rejected a challenge to the 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. Dep’t of Transp.*, 863 F.3d 911 (D.C. Cir. 2017).

<sup>97</sup> *See Deeming Rule, supra* note 8, at 28974. *See also Tripp Mickle, FDA Cloud Hangs Over Vape Shops*, WALL ST. J. (July 7, 2015).

simultaneously reducing innovation and the harm-reduction potential of e-cigarettes.<sup>98</sup>

While acknowledging the evidence that e-cigarettes are in all likelihood less harmful than combustible 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>99</sup>

Thus far, the FDA has rejected the vast majority of PMTA submissions made by manufacturers of ENDS and other vaping products. Out of almost 26 million PMTA applications submitted as of March 2023,<sup>100</sup> the FDA has only authorized forty-five products, approximately half of which are ENDS.<sup>101</sup> On June 21, 2024, FDA authorized four additional PMTAs, the first flavored (menthol) products to receive approval since the May 14, 2022 deadline for products already on the market.<sup>102</sup> Only three companies (R.J. Reynolds Vapor Co., NJOY, and Logic Technology Development) have had their vapor products approved.<sup>103</sup> Several companies have gone to court, challenging the FDA’s denial of their product applications as

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<sup>98</sup> See Adler et al., *supra* note 19.

<sup>99</sup> See Deeming Rule, *supra* note 8, at 28976.

<sup>100</sup> See Press Release, U.S. Food & Drug Admin., FDA Makes Determinations on More than 99% of the 26 Million Tobacco Products for Which Applications Were Submitted (Mar. 15, 2023), <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted>.

<sup>101</sup> See Press Release, U.S. Food & Drug Admin., Premarket Tobacco Product Marketing Granted Orders (Mar. 28, 2024), <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>. Note that the FDA defines individual products quite narrowly.

<sup>102</sup> See Press Release, U.S. Food & Drug Admin., FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review (June 21, 2024), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-four-menthol-flavored-e-cigarette-products-after-extensive-scientific>.

<sup>103</sup> Philip Morris has also obtained approval for several heated, but non-combusted, tobacco products called “HeatSticks” or iQOS. *Id.*

arbitrary and capricious. As of this writing, most of these challenges have failed.<sup>104</sup> Others have prompted the FDA to reconsider its initial denials.<sup>105</sup>

Although the FDA originally estimated that the average initial cost of a PMTA would be approximately \$131,643 for an e-liquid and \$466,563 for an ENDS delivery system,<sup>106</sup> companies that have successfully acquired approval have reported their costs to range between \$5 and \$8 million per product.<sup>107</sup> Such barriers to entry will likely limit competition from smaller companies, and may have motivated much of the tobacco industry's support for legislation like the Tobacco Control Act.<sup>108</sup>

Of particular concern for speech regulation and public health, the Tobacco Control Act also regulates “modified risk tobacco products” (MRTPs). Specifically,

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<sup>104</sup> See *Lotus Vaping Techs., LLC v. FDA*, 73 F.4th 657 (9th Cir. 2023) (rejecting challenge to FDA denial of premarket tobacco product application); *Magellan Technology Inc. v. FDA*, 70 F.4th 622 (2nd Cir. 2023) (same); *Liquid Labs LLC v. FDA*, 52 F.4th 533 (3d Cir. 2022) (same); *Gripum LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022) (same); *Avail Vapor, LLC. v. FDA*, 55 F.4th 409 (4th Cir. 2022) (same); *Prohibition Juice Co. v. United States FDA*, 45 F.4th 8 (D.C. Cir. 2022) (same); *Breeze Smoke, LLC v. FDA*, 18 F.4th 499 (6th Cir. 2021) (same). *But see* *Wages & White Lion Invs. LLC. v. FDA*, 90 F.4th 357 (5th Cir. 2024) (en banc) (holding FDA denial of premarket tobacco applications was arbitrary and capricious); *Bidi Vapor LLC v. FDA*, 47 F.4th 1191 (11th Cir. 2022) (same).

<sup>105</sup> See *FDA Rescinds Previously Disclosed Marketing Denial Order for Turning Point Brands' Vapor Products*, BUSINESSWIRE (Oct. 11, 2021), <https://www.businesswire.com/news/home/20211011005139/en/FDA-Rescinds-Previously-Disclosed-Marketing-Denial-Order-for-Turning-Point-Brands%E2%80%99-Vapor-Products>; Christina Jewett, *F.D.A. Lets Juul Appeal Ban and Stay on the Market During a Review*, N.Y. TIMES (July 6, 2022) (reporting FDA granted administrative stay of marketing denial order due to “scientific issues” after U.S. Court of Appeals for the D.C. Circuit granted Juul’s request for temporary administrative stay).

<sup>106</sup> See U.S. FOOD & DRUG ADMIN., 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 88, 90 (May 2015), <https://perma.cc/GHK6-7VG2>.

<sup>107</sup> See FED. TRADE COMM’N, CORRECTED POST-TRIAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW OF RESPONDENTS ALTRIA GROUP, INC. AND JUUL LABS, INC. 24 (Sept. 26, 2021), <https://perma.cc/SX5S-U7U5>.

<sup>108</sup> See P. A. McDaniel & R. E. Malone, *Understanding Philip Morris’s Pursuit of US Government Regulation of Tobacco*, 14 TOBACCO CONTROL 193 (2005); Yandle et al., *supra* note 3.

the Act prohibits the marketing and sale of MRTPs without prior FDA approval.<sup>109</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>110</sup> It further creates an application process for MRTPs, somewhat similar to the approval process for new drugs and devices.<sup>111</sup> As the FDA noted in the deeming rule, the prohibition on selling “modified risk” tobacco products “applies automatically to deemed products.”<sup>112</sup> This means that, even once approved as tobacco products, ENDS cannot be promoted as a less harmful or less risky alternative to cigarettes without going through an additional approval process.<sup>113</sup>

As of December 1, 2023, the FDA has only approved sixteen MRTP applications.<sup>114</sup> Most approved products have been smokeless tobacco products, such as eight types of snus (an oral smokeless tobacco product that is usually placed between the lip and gum) produced by Swedish Match and one type of Copenhagen snuff.<sup>115</sup> Others include heated tobacco products made by Philip Morris, known as iQOS or “Heatsticks,” and low-nicotine cigarettes that are equally as harmful as conventional combustible cigarettes but may now be advertised as containing less nicotine than regular cigarettes.<sup>116</sup> As of this writing, no ENDS have been approved as MRTPs.

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<sup>109</sup> See 21 U.S.C. § 387k(a).

<sup>110</sup> See 21 U.S.C. § 387k(b)(1).

<sup>111</sup> See 21 U.S.C. § 387k(g).

<sup>112</sup> Deeming Rule, *supra* note 8, at 29039.

<sup>113</sup> See Yagi et al., *supra* note 85, at 33 (noting that the FDA determined it would not accept MRTP applications for products that had not yet received premarket approval).

<sup>114</sup> See *Modified Risk Tobacco Products*, U.S. FOOD & DRUG ADMIN. (Mar. 31, 2024), <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products#summary>.

<sup>115</sup> On the lower risk posed by snus, see Elizabeth Clarke, Keith Thompson, Sarah Weaver, Joseph Thompson & Grant O’Connell, *SNUS: A Compelling Harm Reduction Alternative to Cigarettes*, 16 HARM REDUCTION J. 62 (2019); see also Brad Rodu & Carl V. Phillips, *Switching to Smokeless Tobacco as a Smoking Cessation Method: Evidence from the 2000 National Health Interview Survey*, 5 HARM REDUCTION J. 18 (2008).

<sup>116</sup> *Modified Risk Granted Orders*, U.S. FOOD & DRUG ADMIN. (Mar. 16, 2023), <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-granted-orders>.

### III. REGULATING HEALTH-RELATED INFORMATION ABOUT TOBACCO PRODUCTS

The FDA has acknowledged that ENDS pose less risks to users than do combustible tobacco products. “Vaping is not as dangerous as combustible tobacco,” according to FDA Commissioner Robert Califf.<sup>117</sup> “We know that in general, e-cigarette have lower risks than a conventional cigarette,” said Brian King, Director of the FDA’s Center for Tobacco Products in 2023.<sup>118</sup> As his predecessor, Mitch Zeller, explained:

E-cigarettes . . . compared to cigarettes have far fewer harmful compounds in the vapor . . . [W]e still have more than 30 million addicted adult cigarette smokers. Almost all of whom are concerned about their health and have some interest in quitting. So, if a typical pack-a-day cigarette smoker could completely substitute all of his or her cigarettes with e-cigarettes, there’s no question that that person, that hypothetical pack-a-day smoker, would be reducing their risk compared to continuing to smoke a pack of cigarettes every day.<sup>119</sup>

More formally, in the *Federal Register*, the FDA has acknowledged that “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>120</sup> Also according to the FDA, “several studies support the notion that the quantity of toxicants [in e-cig vapor] is significantly less than those in tobacco cigarettes and tobacco smoke and similar to those contained in recognized nicotine-replacement therapies.”<sup>121</sup>

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<sup>117</sup> *A Conversation with the FDA’s Robert Califf*, WALL ST. J. (Mar. 6, 2023).

<sup>118</sup> Am. Vapor Mfrs., *The Future of Vaping in the US: A Conversation with FDA’s Dr. Brian King*, YOUTUBE (Feb. 24, 2023), <https://perma.cc/SX8K-QZA9>; see also Nicholas Florko, *FDA’s Top Tobacco Regulator Is Ready to Talk About the Benefits of E-Cigs Versus Cigarettes*, STATNEWS (Feb. 24, 2023), <https://perma.cc/5B8T-RXHS>.

<sup>119</sup> See U.S. FDA, *FDA Insight: E-Cigarettes and the National Youth Tobacco Survey*, Sept. 15, 2020, <https://www.fda.gov/news-events/fda-insight/fda-insight-e-cigarettes-and-national-youth-tobacco-survey>.

<sup>120</sup> See Deeming Rule, *supra* note 8, at 28981.

<sup>121</sup> See Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142, 23157 (proposed Apr. 25, 2014) (to be codified at 21 C.F.R. §§ 1100, 1140, 1143).

The FDA has also acknowledged that such products may help some smokers quit. As King noted, “there is a growing body of literature that has shown that people are using e-cigarettes to quit smoking completely.”<sup>122</sup> The FDA has also made this observation in the *Federal Register*, noting that “there is emerging data that some individual smokers may potentially use ENDS to transition away from combustible tobacco products.”<sup>123</sup> Under existing law and FDA policy, however, ENDS manufacturers may not communicate any of the above information without first getting FDA approval to communicate such messages, which would require them to submit to a lengthy and costly authorization process at the very least, if their application is not denied altogether.

As noted above, the Tobacco Control Act creates a special approval process for MRTPs that is distinct from the approval process for “new” tobacco products. What constitutes an MRTP? The statute 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>124</sup> In other words, a producer that seeks to make a less-dangerous tobacco product is subject to additional regulatory constraints if they wish to market the product on that basis.

The statute goes on to define what qualifies as being “sold or distributed” for such purposes quite capaciously. It includes any labeling or marketing which represents “explicitly or implicitly” that:

1. the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
2. the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
3. the tobacco product or its smoke does not contain or is free of a substance.<sup>125</sup>

Thus, the Tobacco Control Act bars the seller of a vaping product from telling consumers that its products “produce no smoke, only vapor” or that it contains

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<sup>122</sup> Am. Vapor Mfrs., *supra* note 117.

<sup>123</sup> See Deeming Rule, *supra* note 8, at 29037.

<sup>124</sup> 21 U.S.C. § 387k(b)(1).

<sup>125</sup> See 21 U.S.C. § 387k(b)(2)(A)(i).



lower levels of specified contaminants or nicotine. Such factually true claims may not be made without first obtaining MRTP-level approval. As interpreted by the FDA, this also applies to claims such as “healthier alternative to smoking,” even though the FDA does not dispute the truth of this claim.<sup>126</sup> As the agency explained in a follow-up rulemaking designed to clarify the scope of FDA regulation on 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>127</sup>

The Tobacco Control Act, by its terms and as interpreted by the FDA, bars manufacturers from engaging in marketing or labeling that provides factual information regarding health to consumers, potentially including information about product or vapor contents, in addition to comparative risk claims.

As for the potential for smokers to use ENDS as a way to reduce or quit smoking, the FDA’s position is that communicating such messages requires the manufacturer to obtain FDA approval for its product as a medical drug, device, or combination product. Under a January 2017 regulation, 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 symptoms” is “subject to regulation as a drug, device, or combination product.”<sup>128</sup> According to the FDA, “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>129</sup>

As with modified risk claims, the FDA has adopted a fairly broad conception of what sorts of claims about the use of ENDS products would trigger the approval

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<sup>126</sup> 21 C.F.R. §§ 201, 801, 1100 (2017).

<sup>127</sup> Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses,” 82 Fed. Reg. 2193, 2212 (Jan. 9, 2017) (“Clarification Rule”).

<sup>128</sup> *Id.* at 2194; 21 C.F.R. § 1100.5(a).

<sup>129</sup> Deeming Rule, *supra* note 8, at 29036.

requirement or could trigger regulation of an e-cigarette as a medical product. According to the FDA, “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>130</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.” As with the regulation of medical devices, the FDA also made clear that in determining the “intended use” of a product, the FDA may look at “‘any . . . relevant source,’ including but not limited to the product’s labeling, promotional claims, and advertising.”<sup>131</sup>

The FDA has closely guarded the right to make relative health claims. At the beginning of 2019, JUUL launched its “make the switch” campaign, which targeted current cigarette smokers.<sup>132</sup> One ad noted that “the average smoker tries to quit over 30 times” and urged adult smokers to “make the switch.”<sup>133</sup> Although JUUL never made a specific relative risk claim, the FDA considered the company’s marketed statements such as “[JUUL is] a smart, really well thought-out alternative to smoking” tantamount to communicating “less harmful than cigarettes.”<sup>134</sup> Moreover, the FDA sent the company a Warning Letter claiming “JUUL has marketed JUUL products as modified risk tobacco products” without an appropriate FDA order authorizing such claims.<sup>135</sup>

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<sup>130</sup> Clarification Rule, *supra* note 127, at 2205. The FDA expressly notes that these are just illustrative examples and not an exclusive list. *Id.* at 2205 n.14.

<sup>131</sup> *Id.* at 2195.

<sup>132</sup> Brian Jenssen, *JUUL Ad Campaign “Targets Adult Smokers,” But New Research Shows Youth-Focused Past*, POLICYLAB (May 17, 2019), <https://perma.cc/MZ4N-VZXT>.

<sup>133</sup> See *New JUUL Labs Adult Education Campaign*, JUUL LABS (Jan. 8, 2019), <https://perma.cc/423D-BZDG>.

<sup>134</sup> Letter from Mitchell Zeller, Director, Ctr. for Tobacco Products, U.S. Food & Drug Admin., to Kevin Burns, CEO, JUUL Labs, Inc. (Sept. 9, 2019), <https://www.fda.gov/media/130859/download>.

<sup>135</sup> *Id.*; Letter from Ann Simoneau, Director, Off. of Compliance & Enf’t, Ctr. for Tobacco Products, U.S. Food & Drug Admin., to Kevin Burns, CEO, JUUL Labs, Inc. (Sept. 9, 2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/juul-labs-inc-590950-09092019>.

Under the FDA’s interpretation of its own authority, a manufacturer could be penalized 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 for its specific product. (The FDA acknowledges that such a prohibition may raise First Amendment concerns, but this has not changed the FDA’s legal position.<sup>136</sup>) Any such efforts to encourage or facilitate smoking cessation are only allowed if first approved by the FDA—and subjecting simple, truthful marketing claims to FDA approval is not a way to get the message out. The FDA itself has also failed to educate current smokers on relative risks.<sup>137</sup> If there is going to be competition in educating adults, and smokers in particular, about the relative risks of nicotine products, it must occur in a dynamic, competitive marketplace. Such discovery is not compatible with government-imposed prior restraints on what sorts of truthful claims manufacturers are allowed to make.

#### IV. THE PUBLIC HEALTH CONSEQUENCES OF REGULATING HEALTH-RELATED CLAIMS

The FDA may be aware that ENDS pose less risks to users than combustible tobacco products, and that ENDS may be a more effective way to reduce or quit smoking, but many Americans are not. Indeed, since the FDA endeavored to regulate ENDS under the Tobacco Control Act, public ignorance of the relative risks of competing tobacco products has gotten worse, while those with a financial interest in educating the public about the relative benefits of vaping over smoking have been prevented from communicating that message, resulting in harm to smokers in particular.<sup>138</sup>

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<sup>136</sup> Clarification Rule, *supra* note 127, 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).

<sup>137</sup> See, e.g., *The Real Cost E-Cigarette Prevention Campaign*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/real-cost-campaign/real-cost-e-cigarette-prevention-campaign> (public education campaign highlighting risks of vaping and not providing comparative risk information); U.S. FOOD AND DRUG ADMIN., FDA LAUNCHES NEW CAMPAIGN: “THE REAL COST” YOUTH E-CIGARETTE PREVENTION CAMPAIGN (May 1, 2020), <https://perma.cc/E5P4-NEM2> (describing campaign to highlight “potential health risks” of vaping).

<sup>138</sup> See Rich & Adler, *supra* note 1.

Recent surveys show that a majority of Americans have inaccurate views about the relative risks of vaping products. According to one study of changing perceptions of harm from ENDS use versus combustible cigarette use, “[f]rom 2012 to 2017, the proportion of US adults who perceived e-cigarettes as less harmful than cigarettes decreased significantly” and that “during the same time period, the perception of e-cigarettes to be equally or more harmful than cigarettes increased significantly.”<sup>139</sup> Interestingly enough, the study found the greatest change between 2012 and 2015. And it was in April 2014 that the FDA formally proposed regulating e-cigarettes as tobacco products.

Since then, public misperceptions have only gotten worse. In 2016, respondents rejected the proposition that “vaping is healthier than traditional cigarettes” by a margin of 47 percent to 32 percent in Reuters–Ipsos polling.<sup>140</sup> By 2019, the same proposition was rejected 63 percent to 23 percent. A similar shift was observed on the question of whether “vaping is a good way to help people quit smoking.”<sup>141</sup> Respondents rejected that proposition 43 percent to 37 percent in 2016 and 58 percent to 29 percent in 2019.<sup>142</sup> According to one 2020 survey of adults, for example, approximately 35.6% believed that e-cigarettes were “as harmful” as conventional cigarettes, while 28.3% believed that e-cigarettes were “more harmful” than conventional cigarettes, marking the first year that a majority of Americans rejected the claim that ENDS are less dangerous than cigarettes.<sup>143</sup>

Public misunderstanding of the relative risks of vaping products is concerning because such knowledge affects the willingness of smokers to use or try ENDS to reduce and quit smoking. Current smokers who believe ENDS are less harmful than

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<sup>139</sup> Jidong Huang, Bo Feng, Scott R. Weaver, Terry F. Pechacek, Paul Slovic & Michael P. Eriksen, *Changing Perceptions of Harm of E-Cigarette vs Cigarette Use Among Adults in 2 US National Surveys From 2012 to 2017*, 2 JAMA NETWORK OPEN 7, 15 (2019).

<sup>140</sup> CHRIS KAHN & ALLY J. LEVINE, REUTERS, BETTER THAN CIGARETTES? (2019), <https://perma.cc/6PQM-HSNQ>.

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

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

<sup>143</sup> Priti Bandi, Samuel Asare, Anuja Majmundar, Nigar Nargis, Ahmedin Jemal & Stacey A. Fedewa, *Relative Harm Perceptions of E-Cigarettes Versus Cigarettes, U.S. Adults, 2018–2020*, 63 AM. J. PREV. MED. 186 (2022).

cigarettes are twice as likely to completely switch to vaping.<sup>144</sup> Similarly, dual e-cigarette and combustible cigarette users who perceive e-cigarettes as less harmful than cigarettes have triple the odds of becoming exclusive e-cigarette users.<sup>145</sup> Research also suggests these misperceptions about the relative risks of tobacco products are shared by many physicians, which could influence the advice that doctors give their patients who smoke.<sup>146</sup> Thus, FDA rules against comparative claims is depriving the public and professionals of truthful information that could be used by smokers to improve their health.

Those supporting the FDA's approach may contend that such measures are justified to discourage the use of nicotine-containing products by non-users, which could ultimately lead to more people smoking than would have otherwise. However well-intentioned, we believe this is misguided. Existing empirical research suggests that ENDS and combustible cigarettes are economic substitutes, particularly among youth. Although smoking has generally dropped among all age groups over the past two decades,<sup>147</sup> observational studies show that increases in e-cigarette sales are followed by faster reductions in conventional cigarette sales. According to one recent study, an e-cigarette tax in Minnesota that consequently reduced e-cigarette sales prevented approximately 32,400 smokers from quitting, which the authors further estimate would have prevented 1.8 million smokers from quitting nationwide if the tax had been levied across the country.<sup>148</sup> Further city-level research

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<sup>144</sup> See Sooyong Kim, Saul Shiffman & Mark A. Sembower, *US Adult Smokers' Perceived Relative Risk on ENDS and Its Effects on Their Transitions Between Cigarettes and ENDS*, 22 BMC PUB. HEALTH 1771 (2022).

<sup>145</sup> See Alexander Persoskie, Erin Keely O'Brien & Karl Poonai, *Perceived Relative Harm of Using E-cigarettes Predicts Future Product Switching Among U.S. Adult Cigarette and E-Cigarette Dual Users*, 114 ADDICTION 2197 (2019).

<sup>146</sup> See Michael B. Steinberg, Michelle T. Bover Manderski, Olivia A. Wackowski, Binu Singh, Andrew A. Strasser & Cristine D. Delnevo, *Nicotine Risk Misperception Among U.S. Physicians*, 36 J. GEN. INTERNAL MED. 3888 (2020).

<sup>147</sup> SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2020 NATIONAL SURVEY ON DRUG USE AND HEALTH (Oct. 25, 2021), <https://perma.cc/SNC9-AL6Q>.

<sup>148</sup> Henry Saffer, Daniel Dench, Michael Grossman & Dhaval Dave, *E-Cigarettes and Adult Smoking: Evidence from Minnesota*, 60 J. RISK & UNCERTAINTY 207 (2020); Abouk et al., *supra* note 57; Michael F. Pesko & Janet M. Currie, *E-Cigarette Minimum Legal Sale Age Laws and Traditional Cigarette Use Among Rural Pregnant Teenagers*, 66 J. HEALTH ECON. 71 (2020).

published in *JAMA Pediatrics* shows that a comprehensive tobacco flavor ban (including vapor products) led to more youth smoking in San Francisco.<sup>149</sup> These sorts of studies show that efforts to constrain or discourage ENDS use can increase cigarette consumption, something that should be of significant concern for public health.<sup>150</sup>

## V. WHAT ABOUT THE FIRST AMENDMENT?

The federal government's current approach to truthful claims about the relative risks and risk-reduction benefits of ENDS is not only bad public health policy, but also at odds with existing First Amendment jurisprudence. Advertising, labeling, and other speech about products receives First Amendment protection as commercial speech, even when the products at issue are regulated by the FDA.<sup>151</sup> This includes tobacco-related labeling and advertising,<sup>152</sup> and includes health-related claims about products and services.<sup>153</sup> While the protection that such claims get is

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<sup>149</sup> Friedman, *supra* note 57.

<sup>150</sup> See also Abigail S. Friedman, Alex C. Liber, Alyssa Crippen & Michael F. Pesko, *E-Cigarettes Flavor Restrictions' Effects on Tobacco Product Sales* (Feb. 1, 2024), <https://perma.cc/6PBH-7XRN> (finding restrictions on ENDS can lead to smoking increases).

<sup>151</sup> See Richard A. Samp, *Courts Are Arriving at a Consensus on Food and Drug Administration Speech Regulation*, 58 FOOD & DRUG L.J. 313, 314 (2003) (“[E]very major lawsuit challenging FDA speech restrictions has proceeded under the assumption that the speech in question is commercial in character.”); see also Nathan Cortez, *Can Speech by FDA-Regulated Firms Ever Be Noncommercial?*, 37 AM. J.L. & MED. 388 (2011).

<sup>152</sup> See *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001). Of note, in *Lorillard* the tobacco companies had sought even greater protection for their advertising. As considered by the Court, the question was less whether such advertising would be protected as it was how much protection it would receive, and some justices questioned whether existing commercial speech doctrine was sufficiently protective. See *id.* at 571 (Kennedy, J., concurring in part and concurring in the judgment); *id.* at 572 (Thomas, J., concurring in part and concurring in the judgment).

<sup>153</sup> The Supreme Court initially defined commercial speech as that speech which “propose[s] a commercial transaction” *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976). Subsequent opinions have expanded the definition to include information about products and services offered by the manufacturer or seller for the purpose of encouraging the purchase of the good or service in question, even if such communication or advertising includes health-related information. See *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 67 (1983). See also *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (applying commercial speech doctrine to FDA regulation advertising about compounded drugs).

less robust than core protected speech, it is still significant.<sup>154</sup> Over the past several decades, the Supreme Court has repeatedly reaffirmed that commercial speech receives meaningful constitutional protection.<sup>155</sup> While government measures to prevent fraud or the luring of unwitting consumers are permissible, the First Amendment makes it more difficult for the government to suppress or restrict the provision of truthful information to consumers.<sup>156</sup>

The formal test applied to the regulation of commercial speech was articulated in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.<sup>157</sup> The Court in *Central Hudson* established a four-part test. First, in order to qualify for protection, the speech must concern lawful activity and not be fraudulent or inherently misleading.<sup>158</sup> Second, courts consider whether the government has asserted a “substantial” governmental interest, such as preventing consumer deception or protecting public health.<sup>159</sup> Third, if so, courts then consider whether the regulation

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<sup>154</sup> See *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 579 (2011) (“[T]he government’s legitimate interest in protecting consumers from commercial harms explains why commercial speech can be subject to greater governmental regulation than noncommercial speech.” (internal quotation marks omitted)); *Thompson*, 535 U.S. at 374 (noting the *Central Hudson* test applied to commercial speech is “significantly stricter than the rational basis test”).

<sup>155</sup> See, e.g., *Sorrell*, 564 U.S. 552; *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249–50 (2010); *Lorillard*, 533 U.S. at 565–71 (2001); *Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173, 195–96 (1999); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 516 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 491 (1995). As some commentators have noted, in some recent cases, the Court has “seemed to suggest that commercial speech has parity with pure (noncommercial) speech,” though it has not said as much. Barbara J. Evans, *The First Amendment Right to Speak about the Human Genome*, 16 U. PA. J. CONST. L. 549, 587 (2014). See also Rodney A. Smolla, *Afterword: Free the Fortune 500! The Debate over Corporate Speech and the First Amendment*, 54 CASE W. RES. L. REV. 1277, 1292 (2004) (“Examination of actual case decisions demonstrates that the trajectory of modern commercial speech law has been an accelerating rise of protection for advertising.”).

<sup>156</sup> In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, Justice Blackmun explained that it was “a matter of public interest” that consumer decisions “in the aggregate, be intelligent and well informed,” and that this makes “the free flow of commercial information . . . indispensable.” 425 U.S. 748, 765 (1976).

<sup>157</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557 (1980).

<sup>158</sup> *Id.* at 566.

<sup>159</sup> *Id.*

“directly advances” the government’s asserted interest<sup>160</sup> and, fourth, whether it is “more extensive than is necessary to serve that interest.”<sup>161</sup>

In *Lorillard Tobacco Co. v. Reilly*, the Supreme Court applied the *Central Hudson* test to regulations limiting tobacco product advertising, and readily concluded that only the latter two prongs of the test were at issue because the products discussed were legal, but the government indisputably had a substantial interest in preventing youth smoking.<sup>162</sup> The Court explained that these prongs still required careful examination of the advertising restrictions in question because “tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products.”<sup>163</sup> The same is true in the case of ENDS and other vaping products.

FDA-approved ENDS are lawful products and factually truthful claims about such products, such as those that the FDA itself has made, are not inherently misleading. The federal government has a substantial interest in protecting public health, which can justify regulation of ENDS for the purposes of informing consumers about potential risks, preventing youth consumption, preventing nicotine addiction, and preventing consumers from being misled.<sup>164</sup> As with the tobacco advertising at issue in *Lorillard*, however, this does not mean that the FDA can lawfully suppress, let alone prohibit, the communication of truthful information by manufacturers. The “compelling” nature of the state’s interest in preventing youth smoking in *Lorillard* did not absolve it of the need to observe First Amendment

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<sup>160</sup> *Id.*

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

<sup>162</sup> See *Lorillard*, 533 U.S. at 555 (“Only the last two steps of *Central Hudson*’s four-part analysis are at issue here.”).

<sup>163</sup> *Id.* at 564.

<sup>164</sup> See Lawrence O. Gostin & Gail H. Javitt, *Health Promotion and the First Amendment: Government Control of the Informational Environment*, 79 MILBANK Q. 547, 568 (2001) (noting that protection of public health is a substantial governmental interest).



limits on state regulation.<sup>165</sup> Consumers also have a significant interest in information about the health consequences of the products available to them in the marketplace.

The third and fourth prongs of the *Central Hudson* test constrain the government's ability to adopt overbroad or poorly justified restrictions on commercial speech. Rote invocation of "public health" is insufficient to justify restrictions on truthful commercial speech. The government must be able to show that such restrictions advance the asserted interest "in a direct and material way."<sup>166</sup> This burden is "not satisfied by mere speculation or conjecture."<sup>167</sup> Rather, the government "must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree."<sup>168</sup> And while courts often defer to federal agency claims about scientific matters within their expertise, it is unclear that such deference should be shown when governmental actions are subject to heightened constitutional scrutiny.<sup>169</sup>

The Supreme Court has "rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."<sup>170</sup> If the government is concerned that consumers might be misled if information is incomplete, there are other steps that can be taken that impose less of a burden on speech, such as the requirement of disclaimers or additional disclosures. The consideration of such alternatives is required to satisfy the fourth prong of *Central Hudson*. As the U.S. Court of Appeals for the D.C. Circuit explained in

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<sup>165</sup> *Lorillard*, 533 U.S. at 564; *see also* *Reno v. ACLU*, 521 U.S. 844, 875 (1997) ("[T]he governmental interest in protecting children from harmful materials . . . does not justify an unnecessarily broad suppression of speech addressed to adults.").

<sup>166</sup> *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995); *see also* *Edenfield v. Fane*, 507 U.S. 761 (1993) ("A governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.").

<sup>167</sup> *Id.* at 487.

<sup>168</sup> *Edenfield*, 507 U.S. at 770–71.

<sup>169</sup> *See* Jonathan H. Adler, *Super Deference and Heightened Scrutiny*, 74 FLA. L. REV. 268 (2022) (explaining why deference to agency scientific determinations is incompatible with heightened scrutiny).

<sup>170</sup> *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002).

the context of FDA regulation of nutritional supplements, “when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a ‘far less restrictive’ means.”<sup>171</sup> Similarly, insofar as the government is concerned about advertising directed at minors, this does not relieve the government of meeting its burden under *Central Hudson*.<sup>172</sup>

In *Pearson v. Shalala*, the D.C. Circuit found “dubious” the FDA’s argument that “health claims ‘lacking significant scientific agreement’ are *inherently* misleading.”<sup>173</sup> In that case, the FDA was concerned about health claims concerning nutritional supplements, about which there was not a wealth of medical research. Accepting the FDA’s assertion that such claims were not based upon a scientific consensus, the court still rejected the FDA’s “paternalistic assumption” that consumers would necessarily be misled by such information.<sup>174</sup> Instead of prohibiting such claims, the D.C. Circuit suggested, the FDA had to at least consider how such information could be presented to consumers with appropriate qualifications or disclaimers.<sup>175</sup>

Unlike the nutritional supplements at issue in *Pearson*, the most relevant health-related claims about ENDS have already been embraced by the FDA. At least with regard to such claims, it would seem fantastical for the FDA to argue that such information could not be presented to consumers without misleading them. Like other tobacco products, ENDS must already be sold with FDA-prescribed warning labels.<sup>176</sup> This ensures that consumers are made aware of the FDA’s concerns about

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<sup>171</sup> *Pearson v. Shalala*, 164 F.3d 650, 658 (D.C. Cir. 1999).

<sup>172</sup> See *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 561 (2001).

<sup>173</sup> *Pearson*, 164 F.3d at 655.

<sup>174</sup> *Id.* In subsequent cases, the D.C. Circuit has affirmed the federal government’s authority to prohibit health claims that are not substantiated by significant research. See *Bellion Spirits, LLC v. United States*, 7 F.4th 1201 (D.C. Cir. 2021).

<sup>175</sup> *Id.* at 659. See also *Evans*, *supra* note 155, at 605 (“*Pearson I* suggests that when a claim has considerable evidence to support it but the evidence is mixed or unclear, the proper approach is to disclose the uncertainty rather than ban the speech altogether.”).

<sup>176</sup> *Retailers: Chart of Required Warning Statements on Tobacco Product Packaging and Advertising*, U.S. FOOD AND DRUG ADMIN. (Aug. 13, 2018), <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/retailers-chart-required-warning-statements-tobacco-product-packaging-and-advertising>.

the risks of such products, such as the risk of nicotine addiction. The FDA could well require additional warnings to accompany truthful health claims, including a disclaimer that a manufacturer's claims have not been evaluated or endorsed by the FDA or that they are being made without the FDA's approval.<sup>177</sup> The FDA would also retain the ability to sanction companies that make false or unsubstantiated claims. The current policy of imposing a prior restraint on truthful claims about the relative health benefits of ENDS and other vaping products is not only poor health policy, it is difficult to reconcile with existing commercial speech precedent.

#### CONCLUSION

If Americans, and smokers in particular, do not understand the relative risks of combustible and non-combustible products, how can this be addressed? The traditional answer is better public health campaigns, meaning a concerted push for government agencies to develop and promote more balanced and accurate public health messages. We are skeptical of such approaches and believe that respecting free speech principles with regard to truthful information about the relative risks of tobacco products could help protect public health more effectively. Additionally, we prefer government public health campaigns that add context to the suppression of truthful health claims.

Better messaging from governmental authorities may be helpful, but it can only do so much, particularly at a time of reduced trust in authorities.<sup>178</sup> In the wake of the COVID-19 pandemic, public health authorities have taken a massive credibility hit. A 2021 poll by the Robert Wood Johnson Foundation and the Harvard T.H. Chan School of Public Health found that barely half of Americans put significant trust in the Centers for Disease Control and Prevention (CDC) and only 37 percent had much trust in the National Institutes of Health (NIH) or the FDA.<sup>179</sup> America

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<sup>177</sup> Of course, this might be an awkward disclaimer for the FDA to require if all a manufacturer were to do was quote the FDA's own statements. Note, also, that while the FDA could require a broad range of informational disclosures or disclaimers, its power to compel commercial speech is also subject to constitutional constraints. See Jonathan H. Adler, *Compelled Commercial Speech and the Consumer Right-to-Know*, 58 ARIZ. L. REV. 421 (2016).

<sup>178</sup> See Adler & Rich, *supra* note 1.

<sup>179</sup> ROBERT WOOD JOHNSON FOUND. & HARVARD T.H. CHAN SCH. OF PUB. HEALTH, THE PUBLIC'S PERSPECTIVE ON THE UNITED STATES PUBLIC HEALTH SYSTEM 5 (May 2021), <https://perma.cc/UT2A-XTZK>.

today is a low-trust environment, and governmental health authorities are not well-trusted by large swaths of the American population.<sup>180</sup>

The public health challenge is how to educate Americans, and smokers in particular, about the relative risks of ENDS compared to combustible cigarettes. More precisely, the challenge is to discover how to most effectively convey that information. And insofar as discovery is needed, competitive marketplace dynamics are more promising than governmental edicts issued from on high. As F.A. Hayek instructed, competition is “first and foremost a procedure for discovering facts.”<sup>181</sup>

If we want to discover how to teach consumers that ENDS are less dangerous than cigarettes and can help smokers quit, we want to harness self-interest and enable those who stand to benefit from the discovery of such knowledge to compete with each other. As Hayek further explained, “[c]ompetition as a discovery procedure must rely on the self-interest of the producers, that is it must allow them to use their knowledge for their purposes, because nobody else possesses the information on which they must base their decision.”<sup>182</sup> The problem, however, is that the existing regulatory regime makes it difficult—and in some cases illegal—for producers to attempt to educate their own consumers about the potential benefits and relative risks of their own products.

At present, ENDS manufacturers compete with each other, and against combustible tobacco products, across a range of product attributes, including price, convenience, taste, mouth feel, nicotine content, and aesthetics. By differentiating their products from others, they can hope to gain market share. The product attributes they cannot compete on, however, are health and safety. ENDS manufacturers are not allowed to make claims about the relative risks of their products as compared to other ENDS products, or even to combustible cigarettes, without first getting FDA approval. Nor do FDA regulations allow ENDS manufacturers to tell consumers that vaping might help them reduce or quit smoking, unless they wish to go through a lengthy process that is equivalent to new drug approval. Thus, ENDS

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

<sup>181</sup> F.A. Hayek, *Competition as a Discovery Procedure*, 5 Q.J. AUSTRIAN ECON. 9 (2002) (Marcellus S. Snow, trans.).

<sup>182</sup> FRIEDRICH A. HAYEK, *The Political Order of a Free People*, 3 LAW, LEGISLATION AND LIBERTY 70 (2013).

manufacturers are discouraged from competing on health and safety-related product attributes.

FDA restrictions on the ability of producers to differentiate their products through health and safety claims foreclose a potentially promising way to educate consumers about the potential health benefits of switching from smoking to vaping. Research on product marketing has shown the consumer benefits of allowing product manufacturers to make truthful and non-misleading health-related claims.<sup>183</sup> 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.

In the 1980s, Kellogg's launched a marketing campaign for All-Bran® cereal, emphasizing the National Cancer Institute's conclusion that high-fiber diets could reduce the risks of some cancers.<sup>184</sup> This initiative led to an increase in health claims about high-fiber foods, an increase in food product fiber content, and an increase in consumer fiber consumption.<sup>185</sup> Allowing firms to communicate the health benefits of their products led to both healthier products and healthier consumer choices.<sup>186</sup> Why would we not want there to be a similar dynamic for nicotine products? If Volvo can pitch its cars by highlighting their relative crashworthiness (which necessarily requires highlighting the risk of car crashes),<sup>187</sup> why should

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<sup>183</sup> See Press Release, Fed. Trade Comm'n, FTC to FDA: Allowing More, Truthful Health Claims for Food and Dietary Supplements Likely to Benefit Both Consumers and Competition (Jan. 29, 2004), <https://perma.cc/6XFG-DLA2>. See also J. Howard Beales, *Health Related Claims, the Market for Information, and the First Amendment*, 21 HEALTH MATRIX 7 (2011).

<sup>184</sup> See John E. Calfee & Janis K. Pappalardo, *Public Policy in Health Claims for Food*, 10 J. PUB. POL'Y & MKTG. 33 (1991); V.S. Freimuth, S.L. Hammond & J. A. Stein, *Health Advertising; Prevention for Profit*, 78 AM. J. PUB. HEALTH 557 (1988); Rebecca Tushnet, *It Depends on What the Meaning of "False" Is: Falsity and Misleadingness in Commercial Speech Doctrine*, 41 LOYOLA L.A. L. REV. 227 (2007).

<sup>185</sup> See Calfee & Pappalardo, *supra* note 184, at 39.

<sup>186</sup> *Id.*; A.S. Levy & R.C. Stokes, *Effects of a Health Promotion Advertising Campaign on Sales of Ready-to-Eat Cereals*, 102 PUB. HEALTH REP. 398 (1987).

<sup>187</sup> See Press Release, Volvo Car USA, Volvo XC90 Awarded Top Safety Rating by IIHS (Sept. 17, 2015), <https://perma.cc/9MZS-YZRY> (emphasizing crashworthiness of Volvo vehicles compared to other automakers' vehicles); Volvo Cars, *For Life—When You Feel Safe You Can Be Truly Free*, YOUTUBE (Feb. 13, 2023), <https://perma.cc/5GX3-Y3A6>.

ENDS manufacturers not be allowed to explain why their product is less dangerous than combustible alternatives?

It is certainly true that all nicotine products pose risks, but the risks are not equivalent. Allowing manufacturers to educate consumers about relative risks both makes product safety a more salient product characteristic and helps increase consumer knowledge. Barring ENDS manufacturers from explaining the relative health benefits of their products makes as much sense as prohibiting car makers from advertising about auto safety. Allowing ENDS manufacturers the ability to make their products more desirable than cigarettes on health grounds will give them a substantial incentive to figure out how to communicate that message to consumers, and to smokers in particular. While constraints on health-related information may be justified in some contexts, in the case of tobacco products, excessive (and arguably unconstitutional) constraints on speech are compromising public health.