

# Regulating the Advertising and Promotion of Tobacco Products: Where Are We Now?

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## ABSTRACT

Prior to 1995, the Food and Drug Administration (FDA) did not attempt to assert any regulatory control over tobacco products, nor did Congress promulgate any legislation affording FDA regulatory authority over tobacco products. However, in the mid-1990s, the Institute of Medicine and the Centers for Disease Control and Prevention performed studies that reflected an escalating use of tobacco products amongst adolescents and young people and indicated that approximately one out of every three young people using tobacco products would likely die prematurely as a result. These studies sparked a shift in FDA's regulatory position towards tobacco products, prompting an integrated and evolving regulatory system for their advertising and promotion which has helped to drastically reduce tobacco usage and dependency among all age groups, including adolescents and young people.

## I. INTRODUCTION

The Federal Food, Drug and Cosmetic Act (FDCA) grants the Food and Drug Administration (FDA) the authority to regulate drugs, devices, and combination products that constitute a combination of a drug, device, or biologic product.<sup>1</sup> Prior to 1995, FDA did not attempt to assert any regulatory control over tobacco products, nor did Congress promulgate any legislation affording FDA regulatory authority over tobacco products.<sup>2</sup> In fact, between 1965 and 1995, while Congress rejected several bills affording FDA such authority, Congress enacted six separate statutes addressing health concerns over tobacco use and creating a specific tobacco regulatory scheme.<sup>3</sup> Furthermore, during the 1970s and 1980s, FDA repeatedly asserted that the agency lacked jurisdiction under the FDCA to regulate tobacco products as customarily marketed, meaning without any therapeutic claims.<sup>4</sup> The consistency of FDA's

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<sup>1</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301-399i (2012).

<sup>2</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 130-31, 137-38 (2000).

<sup>3</sup> *Id.* at 137-38, 143-45.

<sup>4</sup> *Id.* at 151-53.

position bolstered the conclusion that, when Congress created a distinct regulatory scheme addressing tobacco in the context of health, Congress understood FDA to have no authority to regulate tobacco products and ratified that position.

However, after decades of avoiding the regulation of tobacco products, FDA's position changed in the mid-1990s. In 1994, the Institute of Medicine and the Centers for Disease Control and Prevention conducted studies and determined the following:

- Approximately three million American adolescents were smoking;
- an additional one million adolescent males used smokeless tobacco;
- one million young people became regular smokers each year;
- adolescents are very impressionable and therefore vulnerable to the sophisticated marketing techniques of tobacco companies;
- approximately one out of every three of these young people would likely die prematurely as a result; and
- anyone who does not begin to use tobacco products as a child or adolescent is unlikely to start as an adult.<sup>5</sup>

These studies demonstrated three significant correlations involving adolescents and tobacco product use: 1) advertising oriented towards adolescents increases the usage of tobacco products amongst adolescents; 2) using tobacco products as an adolescent increases a person's risk of health issues and premature death; and 3) if an individual does not use tobacco products as an adolescent, that person is unlikely to use tobacco products as an adult.<sup>6</sup> These findings centered around adolescents sparked a stark shift in FDA's regulatory position towards tobacco products and the agency's move towards creating an integrated and evolving regulatory system focused, in part, on the advertising and promotion of tobacco products. This regulatory system has since helped to drastically reduce tobacco usage and dependency among all age groups, including adolescents.<sup>7</sup>

## II. DRAMATIC CHANGE IN FDA'S REGULATORY POSITION

Under the FDCA, a drug is defined as:

- (A) articles recognized in the official United States Pharmacopoeia,<sup>1</sup> official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

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<sup>5</sup> *Executive Summary of the Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, FINDLAW FOR LEGAL PROS. (Mar. 26, 2008), <https://corporate.findlaw.com/litigation-disputes/executive-summary-of-the-regulations-restricting-the-sale-and.html> [<https://perma.cc/7PUR-MADT>].

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

<sup>7</sup> *Overall Tobacco Trends*, AM. LUNG ASS'N, <https://www.lung.org/research/trends-in-lung-disease/tobacco-trends-brief/overall-tobacco-trends> [<https://perma.cc/4KKQ-83JC>].

- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
- (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).<sup>8</sup>

Furthermore, the FDCA defines a device as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is[:]

- (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.<sup>9</sup>

In 1995, FDA determined nicotine was a drug and cigarettes and smokeless tobacco were drug delivery devices; therefore, FDA had jurisdiction under the FDCA to regulate tobacco products as customarily marketed without any therapeutic claims.<sup>10</sup> First, FDA determined “‘tobacco products affect the structure or function of the body’ because nicotine ‘has significant pharmacological effects.’”<sup>11</sup> Next, “the FDA determined that these effects were ‘intended’ under the FDCA because ‘they are so widely known and foreseeable that the effects may be deemed to have been intended by the manufacturer.’”<sup>12</sup> Finally, FDA concluded that “‘cigarettes and smokeless tobacco are ‘combination products’ because, in addition to containing nicotine, they include device components that deliver a controlled amount of nicotine to the body.’”<sup>13</sup>

Based upon this determination, FDA, on August 11, 1995, published proposed regulations governing the promotion, labeling, and accessibility of tobacco products to children and adolescents, intending to reduce the availability and attractiveness of tobacco products to children and adolescents, decrease the prevalence of addiction in

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<sup>8</sup> 21 U.S.C. § 321(g)(1).

<sup>9</sup> 21 U.S.C. § 321(h)(1).

<sup>10</sup> FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (2000).

<sup>11</sup> *Id.* at 127.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

future generations, and decrease the incidence of tobacco-related deaths and disease.<sup>14</sup> After a public comment period, on August 28, 1996, FDA issued a set of final regulations entitled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.”<sup>15</sup>

In response to FDA’s new regulations, Brown & Williamson Tobacco Corporation and a group of tobacco manufacturers, retailers, and advertisers filed the case of *Food and Drug Administration v. Brown & Williamson Tobacco Corporation*, challenging FDA’s authority under the FDCA to regulate tobacco products as customarily marketed without any therapeutic claims.<sup>16</sup> On March 21, 2000, when considering the FDCA as a whole, prior legislation addressing tobacco products, FDA’s position prior to 1995, and the economic and political significance of the regulations at issue, the Supreme Court held that “Congress ha[d] not given the FDA the authority to regulate tobacco products as customarily marketed.”<sup>17</sup>

### III. FDA’S REGULATORY CONTROL

After the holding in the *Brown & Williamson* case, Congress made numerous attempts to enact a statute affording FDA the authority to regulate tobacco products prior to enacting the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) on June 22, 2009.<sup>18</sup> The Tobacco Control Act grants FDA regulatory authority over tobacco products, authorizes FDA to promulgate regulations dealing with tobacco product advertising and marketing, and amended the Federal Cigarette Labeling and Advertising Act.<sup>19</sup> Section 901(b) of the Tobacco Control Act states that Chapter IX of the FDCA “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 chapter.”<sup>20</sup> Therefore, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco are automatically tobacco products over which FDA has regulatory authority, but before FDA can assert control over other tobacco products, FDA must promulgate applicable regulations.<sup>21</sup> While FDA subsequently, in 2010, issued rules substantially similar to the 1996 rules prohibiting the sale of cigarettes and smokeless tobacco to individuals under 18 and imposing specific marketing, labeling, and advertising requirements (“2010

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<sup>14</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 60 Fed. Reg. 41,314 (proposed Aug. 11, 1995) (to be codified at 40 C.F.R. pts. 801, 803, 804, 897).

<sup>15</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996) (to be codified at 40 C.F.R. pts. 801, 803, 804, 807, 820, 897).

<sup>16</sup> *Brown & Williamson Tobacco Corp.*, 529 U.S. 120.

<sup>17</sup> *Id.* at 161.

<sup>18</sup> Arlen W. Langvardt, *Tobacco Advertising and the First Amendment: Striking the Right Balance*, 5 WM. & MARY BUS. L. REV. 331, 342–43 (2014), <https://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=1073&context=wmlr> [<https://perma.cc/NPY8-BLY3>].

<sup>19</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776, 1786 (2009).

<sup>20</sup> 21 U.S.C. § 387a(b) (2019).

<sup>21</sup> 123 Stat. at 1786 (2009).

Implementing Regulations”), FDA did not, under the deeming provision, expand upon the tobacco products over which FDA exercised regulatory jurisdiction.<sup>22</sup>

Instead of promulgating regulations under the Tobacco Control Act to regulate e-cigarettes, in 2010, FDA asserted that e-cigarettes appeared to be adulterated, misbranded, or unapproved drug-device combinations under the FDCA and ordered a shipment of NJOY’s e-cigarettes be denied entry into the United States.<sup>23</sup> *Sottera, Inc.*, which was doing business as NJOY, joined Smoking Everywhere in the case of *Sottera, Inc. v. U.S. Food & Drug Administration*, arguing FDA can regulate e-cigarettes, as they proposed to market them, only under the Tobacco Control Act, “claiming that the Supreme Court’s opinion in the case of *Brown & Williamson* foreclosed [the] FDCA[’s] drug/device jurisdiction over tobacco products marketed without claims of therapeutic effect.”<sup>24</sup> On December 7, 2010, the *Sottera* court agreed, holding the *Brown & Williamson* case and the Tobacco Control Act establish that, while FDA can regulate tobacco products marketed for therapeutic purposes under the FDCA’s drug/device provisions, FDA cannot regulate customarily marketed tobacco products under those provisions.<sup>25</sup> However, the court further held FDA can regulate customarily marketed tobacco products under the Tobacco Control Act.<sup>26</sup> Therefore, the *Sottera* case clarifies that tobacco products as customarily marketed are regulated under the Tobacco Control Act, not the FDCA, and FDA has latitude to determine what constitutes “other tobacco products” within the limitations of the Tobacco Control Act.

On May 10, 2016, almost six years after the *Sottera* case, FDA finally published rules under the deeming provisions of the Tobacco Control Act entitled “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” (the Deeming Rules), wherein FDA deemed all tobacco products, except accessories, subject to the Tobacco Control Act and FDA’s 2010 Implementing Regulations.<sup>27</sup> Furthermore, FDA deemed tobacco products to specifically include currently marketed products, such as dissolvables not already regulated by FDA, gels, waterpipe tobacco, electronic nicotine delivery systems known as ENDS (including e-cigarettes, e-hookah, e-cigar, vape pens, advanced refillable personal vaporizers, and electronic pipes), cigars, and pipe tobacco.<sup>28</sup> Almost immediately, manufacturers and importers of these products, especially ENDS products and premium cigar manufacturers, began challenging the validity of the

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<sup>22</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 75 Fed. Reg. 13,225 (2010) (to be codified at 21 C.F.R. pt. 1140).

<sup>23</sup> *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010).

<sup>24</sup> *Id.* at 893.

<sup>25</sup> *Id.* at 898–99.

<sup>26</sup> *Id.*

<sup>27</sup> Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,973 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143) [hereinafter Deeming Rule].

<sup>28</sup> *Id.* at 28,976.

Deeming Rules and the scope of the marketing and promotional aspects of the Tobacco Control Act, FDA's 2010 Implementation Regulations, and the Deeming Rules.

A week after FDA published the Deeming Rules, Nicopure Labs, LLC and other manufacturers of ENDS products challenged the Deeming Rules' application to ENDS products, arguing the provisions violated their First Amendment rights to free speech and FDA acted arbitrarily in violation of the Administrative Procedure Act.<sup>29</sup> On December 10, 2019, in the case of *Nicopure Labs, LLC v. U.S. Food and Drug Administration*, a U.S. District Court of Appeals for the District of Columbia affirmed FDA's ability to regulate ENDS products as set forth in the Deeming Rules and the Tobacco Control Act, noting that "it is entirely rational and nonarbitrary to apply to e-cigarettes the [Tobacco Control] Act's baseline requirement that, before *any* new tobacco product may be marketed, its manufacturer must show FDA that selling it is consistent with the public health."<sup>30</sup>

The publication of the Deeming Rules in 2016 also sparked controversy in the cigar industry, as an initial proposal for the deeming rules in 2014 contained a proposed option exempting premium cigars from the rules while the 2016 Deeming Rules made no such distinction.<sup>31</sup> The proposed distinction of premium cigars in the 2014 draft appears to be a continuation of the historic distinction that premium cigars are fundamentally different from cigarettes, little cigars, and other tobacco products<sup>32</sup> because premium cigars do not appeal to children or adolescents, are too expensive for children or adolescents, are generally only occasionally smoked, and are not marketed to impressionable children or adolescents.<sup>33</sup> However, the fact that an increasing number of cigarette manufacturers were classifying and marketing their products as cigars to avoid certain regulations,<sup>34</sup> along with health concerns attributed to these products, contributed to the elimination of the distinction in the 2016 Deeming Rules.<sup>35</sup>

Consequently, on July 15, 2016, the Cigar Association of America filed a Complaint for Declaratory and Injunctive Relief in the U.S. District Court of the District of Columbia against FDA challenging various aspects of the Deeming Rules, including FDA's regulatory jurisdiction, asserting FDA's decision to regulate all cigars rather than exempting premium cigars was "arbitrary and capricious" in violation of the

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<sup>29</sup> *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 271 (D.C. Cir. 2019).

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

<sup>31</sup> *See* Deeming Rule, 81 Fed. Reg. at 28,981–82.

<sup>32</sup> For example, the Federal Cigarette Labeling and Advertising Act of 1965 as amended by the Little Cigar Act of 1973 applies to cigarettes and little cigars, but premium cigars are outside the definition of little cigars. The Federal Cigarette Labeling and Advertising Act was amended a second time in 1986 by the Comprehensive Smokeless Tobacco Health Education Act to include smokeless tobacco. Even though cigars have been around for centuries, the Tobacco Control Act in 2009 automatically applies to just cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, and FDA was granted the authority to promulgate applicable regulations encompassing other tobacco products.

<sup>33</sup> Deeming Rule, 81 Fed. Reg. at 29,022, 29,024.

<sup>34</sup> Cristine D. Delnevo, Mary Hrywna, Daniel P. Gioenco, Erin J. Miller Lo & Richard J. O'Connor, *Close, But No Cigar: Certain Cigars Are Pseudo-Cigarettes Designed to Evade Regulation*, 26 TOBACCO CONTROL 349 (2017).

<sup>35</sup> Deeming Rule, 81 Fed. Reg. at 28,973–76.

Administrative Procedures Act.<sup>36</sup> The August 19, 2020 Memorandum Opinion and Order in the case of *Cigar Association of America v. U.S. Food and Drug Administration* offers a glimpse into the potential long-term outcome of this legal struggle, as the court ruled in favor of FDA on four issues concerning the Deeming Rules as they apply to cigars and pipe tobacco, but held FDA “arbitrarily failed to address commenters’ suggestions that the FDA create a streamlined substantial equivalence process for premium cigars . . . , remand[ed] the Final Deeming Rule to the FDA to consider developing a streamlined substantial equivalence process for premium cigars, [and] . . . enjoin[ed] the FDA from enforcing the premarket review requirements against premium cigars . . . .”<sup>37</sup> While this litigation is ongoing, making any prediction of the final resolution murky at best, the court appears to be drawing a distinction between cigars and premium cigars consistent with the historic regulatory treatment of both and FDA’s continued contemplation of regulating premium cigars differently from other cigars.

#### IV. THE CURRENT STATE OF TOBACCO PRODUCT ADVERTISING AND PROMOTION

The expansive nature of the term “tobacco products” as set forth in the Tobacco Control Act and the Deeming Rules, in addition to the corresponding regulations implemented by FDA, subject tobacco products to numerous new marketing and promotional regulations beyond the array of previously existing restrictions.

##### A. Advertising Medium Restrictions

Through the years, the ability of tobacco product manufacturers to advertise their products on various public advertising and marketing mediums has become more and more limited with the passage of time.

##### 1. Public Health Cigarette Smoking Act

In 1970, the Public Health Cigarette Smoking Act amended the Federal Cigarette Labeling and Advertising Act (FCLAA) to prohibit the advertising of cigarettes on television and radio effective on January 1, 1971.<sup>38</sup> Six radio companies challenged the constitutionality of the Public Health Cigarette Smoking Act in the case of *Capital Broadcasting Company v. Mitchell*, asserting that Section 6 violated the First Amendment by prohibiting the dissemination of information with respect to a lawfully sold product.<sup>39</sup> On October 14, 1971, the U.S. District Court of the District of Columbia held “Congress has the power to prohibit the advertising of cigarettes in any media. The validity of other, similar advertising regulations concerning . . . federal

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<sup>36</sup> Complaint for Declaratory and Injunctive Relief at 32–33, *Cigar Ass’n of Am. v. FDA*, No 1:16-cv-01460 (D.D.C. July 15, 2016), <https://www.scribd.com/document/318395733/Lawsuit-Vsf-Da> [<https://perma.cc/8ZX2-U2FD>].

<sup>37</sup> Memorandum Opinion and Order at 38, *Cigar Ass’n of Am. v. FDA*, No 1:16-cv-01460 (D.D.C. Aug. 19, 2020), <https://www.scribd.com/document/472997516/Show-Public-Doc-2> [<https://perma.cc/58MN-HUHB>].

<sup>38</sup> Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87, 89 (1970).

<sup>39</sup> *Cap. Broad. Co. v. Mitchell*, 333 F. Supp. 582, 583 (D.D.C. 1971).

regulatory agencies has been repeatedly upheld whether the agency be the FCC, the FTC, or the SEC . . . .”<sup>40</sup>

The ban on television and radio advertising was extended to little cigars by the Little Cigar Act of 1973, which amended the FCLAA to include little cigars,<sup>41</sup> and to smokeless tobacco via the Comprehensive Smokeless Tobacco Health Education Act of 1986.<sup>42</sup> To date, the FCLAA has not been extended beyond cigarettes, little cigars, and smokeless tobacco. Additionally, the 2016 Deeming Rules do not restrict the advertising and marketing of ENDS and other new tobacco products on television or radio, except that these products are now subject to FDA action for false, misleading, or unauthorized modified risk claims.<sup>43</sup> Therefore, a significant regulatory gap currently exists with the advertising and promotion of ENDS and other new tobacco products, as these products can be advertised on television and radio.

## 2. *Tobacco Master Settlement Agreement*

On November 23, 1998, attorneys general from forty-six states, the District of Columbia, and the United States territories signed a contractual agreement called the Master Settlement Agreement with the four major cigarette manufacturers,<sup>44</sup>—Philip Morris USA Inc., R.J. Reynolds Tobacco Company, Brown & Williamson Tobacco Corporation, and Lorillard Tobacco Company—to settle state lawsuits to recover the costs, borne by Medicaid and other public programs, of treating smoking-related illnesses.<sup>45</sup> In exchange for the participating states and territories, but not individual citizens, releasing the participating manufacturers from past and future legal claims for costs incurred by the states, District of Columbia, and United States territories for smoking-related illnesses and deaths and for equitable relief, the participating manufacturers agreed to make annual payments in perpetuity and accept certain restrictions on tobacco product advertising, marketing, and promotion, including, but not limited to:

- limiting each company to brand name sponsorship of one sporting or cultural event a year, excluding concerts, team sports, events with a significant youth audience, or events with underage contestants;
- banning public transit advertising;

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<sup>40</sup> *Id.* at 584.

<sup>41</sup> Little Cigar Act of 1973, Pub. L. No. 93–109, 87 Stat. 352 (1973).

<sup>42</sup> Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99–252, § 3(f), 100 Stat. 30 (1986).

<sup>43</sup> See TOBACCO CONTROL LEGAL CONSORTIUM, THE DEEMING REGULATION: FDA AUTHORITY OVER E-CIGARETTES, CIGARS, AND OTHER TOBACCO PRODUCTS 2 (2016), <https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fda-deemingreg-regulation-authority-Dec2016.pdf> [<https://perma.cc/RV9L-ZHY6>].

<sup>44</sup> *Master Settlement Agreement*, PUB. HEALTH L. CTR., <https://www.publichealthlawcenter.org/topics/commercial-tobacco-control/commercial-tobacco-control-litigation/master-settlement-agreement> [<https://perma.cc/2PDA-M42Q>].

<sup>45</sup> See *The Master Settlement Agreement*, NEV. ATT’Y GEN. AARON D. FORD, [https://ag.nv.gov/Hot\\_Topics/Issue/Master\\_Settlement\\_Agreement/](https://ag.nv.gov/Hot_Topics/Issue/Master_Settlement_Agreement/) [<https://perma.cc/JM5E-EGCE>] [hereinafter NEV. ATT’Y GEN. AARON D. FORD].



- banning outdoor billboard advertising, excluding billboard advertising for brand name sponsored events;
- limiting advertising outside retail stores to signs no bigger than 14 sq. ft.;
- banning company payments to promote cigarettes in various media, including movies and TV;
- limiting free samples of cigarettes to adult-only facilities; and
- banning non-cigarette apparel with brand name logos except at brand name sponsored events.<sup>46</sup>

Since the Master Settlement Agreement's execution, forty-one additional tobacco companies have joined the Agreement.<sup>47</sup> Therefore, the Master Settlement Agreement essentially bans outdoor, billboard, and public transportation advertising of cigarettes in forty-six states, the District of Columbia, and the United States territories.<sup>48</sup> Restrictions in Mississippi, Florida, Texas, and Minnesota, the four states that settled with the manufacturers before the Master Settlement Agreement, vary according to the state's specific settlement with the manufacturers.<sup>49</sup>

### 3. *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*

As stated hereinabove, the Tobacco Control Act granted FDA the authority to issue rules and regulations, and on June 22, 2010, the Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (2010 Implementing Regulations) became effective instituting the following advertising or promotion medium restrictions:

- the prohibition of tobacco brand name sponsorship of any athletic, musical, or other social or cultural event, or any team or entry in those events;
- the prohibition of gifts or other items in exchange for buying cigarettes or smokeless tobacco products;
- the requirement that audio advertisements use only words with no music or sound effects;
- the prohibition of the sale or distribution of items, such as hats and tee shirts, with tobacco brands or logos;
- the prohibition of free samples of cigarettes; and

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<sup>46</sup> See MASTER SETTLEMENT AGREEMENT (July 2014), <https://11i23g1as25g1r8so11ozniw-wpengine.netdna-ssl.com/wp-content/uploads/2020/09/MSA.pdf> [<https://perma.cc/6FXY-UJD6>].

<sup>47</sup> NEV. ATT'Y GEN. AARON D. FORD, *supra* note 45.

<sup>48</sup> See MASTER SETTLEMENT AGREEMENT, *supra* note 46.

<sup>49</sup> NEV. ATT'Y GEN. AARON D. FORD, *supra* note 45.

- the prohibition of the sale of cigarettes and smokeless tobacco in vending machines, self-service displays, or other impersonal modes of sales, except in very limited situations.<sup>50</sup>

On August 31, 2009, in the case of *Discount Tobacco City Lottery v. United States Food and Drug Administration*, six tobacco manufacturers challenged the constitutionality of the Tobacco Control Act and the 2010 Implementing Regulations, alleging the restrictions on tobacco advertising and marketing violated their First Amendment rights.<sup>51</sup> A three-judge panel in the Sixth Circuit upheld the above-referenced advertising and promotional restrictions, ruling the First Amendment is not violated by a regulatory restriction if the restriction advances a “substantial” governmental interest and is “not more extensive than is necessary to serve that interest.”<sup>52</sup> In applying this standard, the court opined “[t]here can be no doubt that the government has a significant interest in preventing juvenile smoking and in warning the general public about the harms associated with the use of tobacco products.”<sup>53</sup>

The 2010 Implementing Regulations were limited to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco<sup>54</sup> until FDA finally published the 2016 Deeming Rules, making these advertising restrictions applicable to all tobacco products.<sup>55</sup>

#### B. *Additional Advertising and Promotion Restrictions Designed to Protect Children and Adolescents*

The Master Settlement Agreement and the 2010 Implementing Regulations contain additional advertising and promotion restrictions designed to protect children and adolescents from the potential health harms of tobacco and nicotine addiction. The Master Settlement Agreement specifically prohibits cigarette companies from targeting youth in the advertising, promotion, or marketing of their products; bans the use of cartoons in advertising; and bans gifts of non-cigarette items to youth in exchange for cigarettes.<sup>56</sup> The 2010 Implementing Regulations limits advertising in publications with significant teen readership to black text on white background only

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<sup>50</sup> 21 C.F.R. §§ 1140.10–.16 (2016); Regulation Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco, U.S. FOOD & DRUG ADMIN., <https://web.archive.org/web/20101021195458/https://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/RegsRestrictingSale/default.htm> (last updated Aug. 6, 2010) [<https://perma.cc/A4DJ-FN4T>].

<sup>51</sup> Complaint for Declaratory Judgment and Injunctive Relief at 4–5, *Discount Tobacco City & Lottery v. United States*, Case 1:09-cv-00117-JHM-ERG (W.D. Ky. Aug. 31, 2009), <https://ia800207.us.archive.org/9/items/gov.uscourts.kywd.70736/gov.uscourts.kywd.70736.1.0.pdf> [<https://perma.cc/84Q6-S6AU>].

<sup>52</sup> *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509, 517–18, 522–23 (6th Cir. 2012).

<sup>53</sup> *Id.* at 519.

<sup>54</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 75 Fed. Reg. 13,225, 13,230 (Mar. 19, 2010) (codified at 21 C.F.R. § 1140.14(a)(1)).

<sup>55</sup> Deeming Rule, 81 Fed. Reg. at 28,973.

<sup>56</sup> MASTER SETTLEMENT AGREEMENT, *supra* note 46, at 18–19, 26.

and prohibits the sale of cigarettes and smokeless tobacco to people under 18.<sup>57</sup> The Deeming Rules expanded these restrictions to all tobacco products,<sup>58</sup> and the Tobacco 21 legislation increased the age restriction to 21 years old.<sup>59</sup>

### C. *Point of Sale Advertising and Promotion Restrictions*

The Tobacco Control Act provides state and local governments with the ability to enact additional restrictions covering tobacco product advertising and marketing,<sup>60</sup> which consists of state and local laws, ordinances, licensing, and zoning.<sup>61</sup> Furthermore, under the FCLAA, as amended by the Tobacco Control Act, state and local governments can impose specific bans or restrictions on the time, place, and manner, but not the content, of the advertising or promotion of any cigarettes.<sup>62</sup>

While each state or local government varies in the restrictions it places on tobacco product advertising and promotion, state and local governments use three basic approaches:

- restricting all advertising without regard to its content;
- restricting the time, place, or manner of tobacco advertisements;
- restricting the content, messages, or imagery within some tobacco advertisements.<sup>63</sup>

Licensing, zoning, and conditional use permits have a direct and huge impact on the tobacco industry, as the tobacco industry spent nearly 80% of the industry's marketing expenditures for cigarettes and smokeless tobacco in 2019 in the retail environment.<sup>64</sup> These three mechanisms are the regulatory controls local governments use to control "the density of tobacco retailers [in certain areas], the types of retailers that can sell tobacco, and the location of tobacco retailers."<sup>65</sup>

As of 2020, thirty-nine states require a license for over-the-counter tobacco sales.<sup>66</sup> These states typically require a business to obtain and maintain a tobacco retail license from the city or county before a business can sell and continue selling tobacco

<sup>57</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 75 Fed. Reg. 13,225, 13,230, 13,232 (Mar. 19, 2010) (codified at 21 C.F.R. § 1140.14(a)(1)).

<sup>58</sup> See Deeming Rule, 81 Fed. Reg.

<sup>59</sup> Further Consolidated Appropriations Act, 2020, Pub. L. No. 116–94, div. N § 603, 133 Stat. 2534, (codified at 21 U.S.C. § 387f(d)(3)(A)(ii)).

<sup>60</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, § 916, 123 Stat. 1776, 1823–24 (2009) (codified at 21 U.S.C. § 387p).

<sup>61</sup> See *Licensing, Zoning, and Retailer Density*, COUNTERTOBACCO.ORG, <https://countertobacco.org/policy/licensing-and-zoning/> [<https://perma.cc/GW34-MZ9M?type=image>].

<sup>62</sup> Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334(c) (2019).

<sup>63</sup> TOBACCO CONTROL LEGAL CONSORTIUM, RESTRICTING TOBACCO ADVERTISING (2011), <https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-guide-restricttobadvert-2011.pdf> [<https://perma.cc/XH6A-4PD4>].

<sup>64</sup> *The War in the Store*, COUNTERTOBACCO.ORG, <https://countertobacco.org/the-war-in-the-store/> (last visited October 24, 2021) [<https://perma.cc/DHA6-AQXX?type=image>].

<sup>65</sup> *Licensing, Zoning, and Retailer Density*, *supra* note 61.

<sup>66</sup> *Id.*

products.<sup>67</sup> Licensing requirements in some states incorporate advertising and promotion restrictions.<sup>68</sup>

Local governments use zoning laws and conditional use permits to regulate land use, keep compatible land uses together, and keep incompatible land uses separated. Zoning laws and conditional use permits are used by local governments to prevent tobacco retailers from operating in certain zones, limit the number of tobacco retailers in certain zones, and restrict tobacco retailers from operating in certain zones.<sup>69</sup> Some common advertising and promotional restrictions in zoning laws and conditional use permits are signage restrictions and proximity restrictions to schools and churches.<sup>70</sup>

#### *D. Labeling*

The FCLAA has required warnings on cigarette labeling since 1965,<sup>71</sup> and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) has required warnings on smokeless tobacco labeling since 1986.<sup>72</sup> The Tobacco Control Act amended both of these Acts in Sections 201 and 204, respectively,<sup>73</sup> and in conjunction with FDA's 2010 Implementing Regulations and the Deeming Rules, extended warning and labeling requirements to far more tobacco products than ever before.<sup>74</sup>

##### *I. Warning Statement*

Under the FCLAA, cigarette packaging and advertising must contain one of the following warnings, which must be randomly displayed in an alternating quarterly sequence:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

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<sup>67</sup> *Id.*

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

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-1340).

<sup>72</sup> Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30 (1986) (codified as amended at 15 U.S.C. §§ 4401-4408).

<sup>73</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, §§ 201, 204, 123 Stat. 1776, 1842-45, 1846-48 (2009) (codified as amended at 15 U.S.C. §§ 1333, 4402).

<sup>74</sup> Deeming Rule, 81 Fed. Reg. at 28,974.

- WARNING: Quitting smoking now greatly reduces serious risks to your health.<sup>75</sup>

Under the CSTHEA, smokeless tobacco packaging and advertising requires one of the following warnings:

- WARNING: This product can cause mouth cancer.
- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: Smokeless tobacco is addictive.<sup>76</sup>

Currently, under the Deeming Rules as codified in the Code of Federal Regulations, labeling and advertising for cigarette tobacco, roll-your-own tobacco, ENDS, and other covered tobacco products must display the following warning on the two principal display panels: “WARNING: This product contains nicotine. Nicotine is an addictive chemical.”<sup>77</sup> Cigars and pipe tobacco are exempt from the warning requirements as a result of the U.S. District Court of the District of Columbia entering a Final Judgment and Order on September 11, 2020, in the case of *Cigar Association of America v. U.S. Food and Drug Administration*, “vacat[ing] and remand[ing] the Final Deeming Rule’s warning requirements for cigars and pipe tobacco” to FDA for revision.<sup>78</sup>

These required warning statements must also meet certain requirements with respect to font, text, size, placement, and formatting on package labels and advertisements.<sup>79</sup>

## 2. Other Labeling Requirements

The Tobacco Control Act also prohibits the labeling or advertising of tobacco products to contain the terms “light,” “low,” “mild,” or similar descriptors, as they mislead the public into thinking the tobacco products cause fewer health problems than other tobacco products.<sup>80</sup> Furthermore, labeling must contain the name and place of business of the manufacturer, packer, or distributor; quantity of the contents in terms of weight, measure, or numerical count; percentage of domestic and foreign grown tobacco in the tobacco product; and a statement that sale is only allowed in the United States.<sup>81</sup>

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<sup>75</sup> Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333(a)(1) & 15 U.S.C. § 1333(c)(1)–(c)(2).

<sup>76</sup> Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. § 4402(a)(1) (2019).

<sup>77</sup> Required Warning Statement Regarding Addictiveness of Nicotine, 21 C.F.R. § 1143.3(a)–(b) (2021).

<sup>78</sup> Final Judgment & Order at 3, *Cigar Ass’n of Am. v. FDA*, No. 1:16-cv-01460 (D.D.C. Sept. 11, 2020), <https://www.bloomberglaw.com/public/desktop/document/CIGARASSOCIATIONOFAMERICAetalvUNITEDSTATESFOODANDDRUGADMINISTRATI/1?1605998284> [<https://perma.cc/29UY-YPQ2>].

<sup>79</sup> 15 U.S.C. § 4402; 21 C.F.R. § 1143.3(a)(2), (b)(2); 15 U.S.C. § 1333(a)–(b).

<sup>80</sup> 21 U.S.C. § 387k(2)(A)(ii) (2019); *See generally* 21 U.S.C. § 387k(2)(A).

<sup>81</sup> 21 U.S.C. § 387c(a)(2) (2019).

### E. Graphic Warnings

The Tobacco Control Act directs FDA to issue regulations requiring new text and color graphic health warnings depicting the negative health consequences of cigarette smoking, and ever since, these graphic warnings have been challenged by the tobacco industry. Before FDA even issued regulations, the Tobacco Control Act's required graphic health warnings were first challenged in the *Discount Tobacco City Lottery* case, wherein the court ruled the graphic warnings did not violate the First Amendment because the graphic warnings were reasonably related to the government's legitimate interest of protecting consumers from deceptive practices.<sup>82</sup>

Shortly after FDA promulgated the final rules requiring nine text warnings and graphic pictures to be printed on cigarette packs, cartons, and advertisements, the tobacco industry challenged the specific graphic health warnings in FDA's rules in the case of *R.J. Reynolds v. U.S. Food and Drug Administration*.<sup>83</sup> The *R.J. Reynolds* court held FDA failed to demonstrate that the graphic warning rules and requirements would directly advance FDA's interest in reducing smoking rates; therefore, the graphic health warnings violated the First Amendment, and the court directed FDA to draft new warnings complying with constitutional standards.<sup>84</sup>

After being compelled to issue new graphic health warnings by the U.S. District Court of the Southern Division of Maryland in the case of *American Academy of Pediatrics v. U.S. Food and Drug Administration*,<sup>85</sup> FDA finally issued new graphic health warnings on March 18, 2020. FDA's new rules, entitled "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements," require compliance beginning on June 18, 2021 with eleven new health warnings on cigarette packs, cartons, and advertisements, consisting of text warning statements accompanied by graphic color images.<sup>86</sup> Two cases—*R.J. Reynolds v. U.S. Food and Drug Administration*<sup>87</sup> (hereinafter, *R.J. Reynolds* 2020) and *Philip Morris USA Inc., et al. v. U.S. Food and Drug Administration et al.*<sup>88</sup>—have already been filed challenging the new graphic health warnings. The Complaint in the *R.J. Reynolds* 2020 case alleges the Tobacco Control Act's requirement that FDA issue graphic health warnings rules violates the First Amendment, the rules are arbitrary and capricious as FDA failed to undertake an appropriate cost-benefit analysis, the proposed rules violate the Tobacco Control Act by changing the language of the textual warning and the number of warnings, and FDA would violate the Tobacco Control Act by requiring companies to implement the new textual warnings prior to legal resolution of the graphic warnings rules.<sup>89</sup> The Complaint in the *Philip Morris* case alleges several First Amendment defects including, but not limited to, FDA's failure to meet the strict standards required

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<sup>82</sup> *Id.* at 562–66.

<sup>83</sup> *R.J. Reynolds v. FDA*, 696 F.3d 1205, 1222 (D.C. Cir. 2012).

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

<sup>85</sup> *Memorandum & Order, American Acad. of Pediatrics v. FDA*, No. 1:16-cv-11985 (D. Mass. Sept. 5, 2018)

<sup>86</sup> Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 53,15638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141).

<sup>87</sup> Complaint, *R.J. Reynolds v. FDA*, No. 6:20-cv-00176 (E.D. Tex., filed Apr. 3, 2020).

<sup>88</sup> Complaint, *Philip Morris USA Inc. v. FDA*, No. 1:20-cv-01181 (D.D.C., filed May 6, 2020).

<sup>89</sup> Complaint, *R.J. Reynolds*, *supra* note 87.

for an agency to compel speech through the mandated warnings, the warnings are misleading by distorting the likelihood of suffering specific smoking-related consequences, the size of the mandated warnings are unduly burdensome in violation of the First Amendment, and the requirement for cigarette manufacturers to obtain pre-approval of their labeling and advertising plans violates First Amendment speech protections.<sup>90</sup>

While an immense amount of uncertainty surrounds the graphic health warning requirements and compliance with the requirements has been delayed until October 11, 2022, via a court order entered in the *R.J. Reynolds* 2020 case,<sup>91</sup> graphic health warnings will most likely be a requirement in some form. The final form will probably take years of litigation between FDA and the tobacco industry to determine, given the extreme differences in the two sides' objectives—FDA attempting to protect the health of the general public and the tobacco industry attempting to protect a multi-billion-dollar industry.

### F. Social Media and Internet Influencers

The internet affords companies and individuals an opportunity to communicate to young people about tobacco products. According to the Pew Internet Project, 92% of teenagers use the internet daily, and 56% use the internet several times a day.<sup>92</sup> Tobacco product companies have noticed this internet usage by teenagers and young people, as tobacco product companies have significantly increased spending on company websites and internet marketing from \$8.3 million in 2006 to \$17.8 million in 2008.<sup>93</sup> Between 2009 and 2018, tobacco companies consistently spent over \$25 million per year on company websites and internet marketing.<sup>94</sup> Tobacco product companies are increasingly utilizing social media platforms, such as Instagram and YouTube, as well as internet influencers with followings consisting of adolescents and young people to market and promote various tobacco products.<sup>95</sup>

While tobacco product companies have been spending tens of millions of dollars advertising and promoting their products online, such as through influencers, social media platforms, and company websites, as well as refining their marketing and promotion techniques,<sup>96</sup> these activities have largely gone unregulated. However, FDA has grown concerned about social media and influencer marketing and promotion tactics. On March 17, 2021, FDA issued a letter to four ENDS companies—Aspire Vape Co., Joyetech, Vaporesso, and Vopoo—to determine their presence, reach, and

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<sup>90</sup> Complaint, *Philip Morris USA Inc.*, *supra* note 88.

<sup>91</sup> Order, *R.J. Reynolds v. FDA*, No. 6:20-cv-00176 (E.D. Tex. Aug. 18, 2021), Doc. No. 92.

<sup>92</sup> Laura Bach, *Tobacco Product Marketing on the Internet*, CAMPAIGN FOR TOBACCO-FREE KIDS 1 (Apr. 16, 2021), <https://www.tobaccofreekids.org/assets/factsheets/0081.pdf> [<https://perma.cc/DJQ2-D9BV>].

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

<sup>94</sup> *Id.*

<sup>95</sup> See Hannah Prokop, *FDA Asks ENDS Companies for Social Media Marketing Information*, CSP DAILY NEWS (Mar. 23, 2021), <https://www.cspdailynews.com/tobacco/fda-asks-ends-companies-social-media-marketing-information> [<https://perma.cc/6QBP-XR9T>] (discussing social media use by ENDS companies).

<sup>96</sup> Bach, *supra* note 92.

activity on social media platforms and their use of influencers.<sup>97</sup> FDA has provided these four companies with sixty days to provide the following information:

documents related to social media advertising and marketing plans, including planned content, cost of plans, plans to target specific audiences, and plans to restrict youth exposure and/or access to ads; use of partners, promoters, affiliates, influencers, bloggers, and/or brand ambassadors; and the number of followers and/or viewers broken out by age group, how the ages of followers and viewers are tracked and managed, and any actions taken to restrict youth-access and/or limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion in social media channels and a summary of the effectiveness of such actions.<sup>98</sup>

The information obtained will help FDA craft procedures for social media surveillance and help FDA develop strategies for reducing the exposure of adolescents and young people to the digital marketing and promotion of tobacco products, including potentially drafting applicable marketing and promotion regulations addressing the use of social media and internet influencers.<sup>99</sup>

## V. CONCLUSION

Over the last three decades, FDA has transitioned from avoiding the regulation of tobacco products to forming a comprehensive regulatory scheme designed to reduce the population's dependency on tobacco products and the associated health issues, in part, by increasingly focusing on the regulation of the advertising and marketing of tobacco products aimed at all age groups with an emphasis on adolescents.

While the tobacco industry continues to vigorously contest FDA's regulation of the advertising and marketing of tobacco products, and a resolution concerning graphic health warnings is likely years away, FDA's efforts, as a whole, have helped reduce the usage of tobacco products among all age groups. For example, from 2002 to 2018, the current use of any tobacco product decreased 43% among individuals from the age of 18 to 25; from 2011 to 2019, cigarette usage dropped from 15.8% of high school students to 5.8%; from 2002 to 2019, the current use of any tobacco product among middle school students decreased 6%; and from 2002 to 2018, the current usage of any tobacco product decreased 24% among individuals the age of 26 or older.<sup>100</sup>

As new and innovative advertising techniques are developed to market existing and emerging tobacco products, FDA's regulatory efforts need to continue to evolve to have similar and continued success in the future. One such tobacco product is e-cigarettes, as the usage of e-cigarettes has drastically increased among high school

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<sup>97</sup> See Press Release, U.S. Food & Drug Admin., FDA in Brief: FDA Requires Four E-Cigarette Brands to Provide Critical Information on Social Media Practices (Mar. 17, 2021), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-requires-four-e-cigarette-brands-provide-critical-information-social-media-practices> [<https://perma.cc/N2V8-6NTQ>].

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

<sup>99</sup> *Id.*

<sup>100</sup> *Overall Tobacco Trends*, *supra* note 7.



students from 1.5% in 2011 to 27.5% in 2019.<sup>101</sup> While this increase may partially be attributed to the infancy and novelty of e-cigarettes in the market, some of the increase may also be explained by the gaps in some of the current advertising and marketing regulations, such as the regulations restricting television and radio advertising and marketing not applying to ENDS and other new tobacco products and the lack of regulations regarding the use of social media, such as Instagram and YouTube, and internet influencers to market and promote tobacco products. As FDA continues to strive to achieve the goals the agency set forth in 1995 when FDA first began attempting to regulate tobacco products, a key to FDA's success will be the agency's continued flexibility and ability to adapt to the regulatory challenges presented by new and innovative ways of advertising and promoting existing and emerging tobacco products.

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<sup>101</sup> *Id.*