



## Regulatory Options for Electronic Cigarettes

### Background

Electronic cigarettes (“e-cigarettes”) are often described as “electronic nicotine delivery systems” in scientific literature. These products, which often resemble cigarettes, cigars, or pipes, are designed to deliver nicotine or other substances to users in the form of a vapor. Many public health organizations support regulating e-cigarettes to reduce youth initiation to nicotine and tobacco products, protect the health of their users, and promote enforcement of smoke-free laws. This fact sheet provides a brief overview of e-cigarettes, their potential health risks, gaps in current federal and state regulation, and some approaches that state and local governments might consider to regulate their use, pricing, sale, and marketing.

### Product Description

No standard definition or formulation of an e-cigarette exists: in fact, designs and ingredients vary by manufacturer.<sup>1</sup> Generally, however, e-cigarettes consist of battery-powered heating elements and replaceable cartridges that contain nicotine or other chemicals, and an atomizer that, when heated, converts the contents of the cartridge into a vapor that users inhale. Proponents of e-cigarettes, including some in the public health community, view them as less hazardous alternatives to combustible cigarettes. Others see them as gateway products to tobacco use and nicotine addiction and support their restriction, or even removal, from the market.



### Health Risks

The U.S. Food and Drug Administration (FDA) and many leading public health organizations have expressed concern about the lack of clinical studies on the potential health risks posed by e-cigarettes and the way these products are marketed without appropriate health warnings or legal age restrictions.<sup>2</sup> In 2009, for example, the FDA warned that “laboratory analysis of electronic cigarette samples has found that they contain carcinogens and toxic chemicals such as diethylene glycol, an ingredient used in antifreeze.”<sup>3</sup> In October 2012, the World Medical Association stated that “[d]ue to the lack of rigorous chemical and animal studies, as well as clinical trials on commercially available e-cigarettes, neither their value as therapeutic aids for smoking cessation

nor their safety as cigarette replacements is established.”<sup>4</sup> In recent years, litigation between the FDA and e-cigarette manufacturers arising from concerns about their safety and regulatory status resulted in a temporary restriction on the importation of e-cigarettes into the United States.<sup>5</sup> As a result of a 2010 ruling by the U.S. Court of Appeals for the D.C. Circuit,<sup>6</sup> in April 2011 the FDA announced that it will regulate e-cigarettes as tobacco products under the Family Smoking Prevention and Tobacco Control Act<sup>7</sup> – the federal law granting the FDA the authority to regulate tobacco products – “unless they are marketed for therapeutic purposes, in which case they are regulated as drugs and/or devices.”<sup>8</sup> As of February 2013, however, the FDA has not yet regulated e-cigarettes as tobacco products. For that reason, it has become more of a priority for many state and local governments to consider regulatory options for electronic cigarettes.

## Regulatory Gaps & Options

### Taxation

- **Regulatory Gap:** Many state tax laws define the term “tobacco products” in a way that excludes e-cigarettes. Although the FDA has said it will regulate electronic cigarettes as tobacco products, it is not clear whether every product marketed as an e-cigarette contains tobacco, or even nicotine derived from tobacco.<sup>9</sup>
- **Regulatory Options:** The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) expressly preserves the authority of state and local governments to levy taxes on tobacco products.<sup>10</sup> Since e-cigarettes are a different type of product, containing electronic parts and synthetically-derived ingredients, existing tobacco tax laws may not be well-suited to them.<sup>11</sup> Some states have addressed this issue by clarifying the definition of “tobacco products” in their tax codes so e-cigarettes are considered tobacco products for taxation purposes.<sup>12</sup> Unless the FDA determines that e-cigarettes have genuine therapeutic uses, other states might consider, in the meantime, taxing e-cigarettes in a way that complements their existing cigarette and tobacco product taxes.<sup>13</sup>

### Coupons, Discounts, & Rebates

- **Regulatory Gap:** Tobacco manufacturers use coupons and other price-related incentives to make products such as e-cigarettes more attractive to consumers, particularly young people.<sup>14</sup> Coupons and other price discounts for electronic cigarettes are utilized in the retail environment and discounted e-cigarettes are extensively promoted online.
- **Regulatory Options:** Local and state governments could consider restricting or prohibiting the retail redemption of coupons for tobacco products, including e-cigarettes and similar nicotine delivery systems, or restricting other price-related practices in the retail environment, such as payments from e-cigarette manufacturers and distributors to retailers resulting in price discounts; tobacco retailer incentive programs; and retail value-added deals (e.g., buy-one-get-one-free offers).<sup>15</sup>

While legal challenges to such policies can be anticipated in light of the e-cigarette industry's investment in price-related marketing strategies, a federal district court has recently upheld a local law prohibiting the sale of discounted tobacco products.<sup>16</sup> In early 2012, Providence, Rhode Island enacted an ordinance prohibiting licensed tobacco dealers from selling discounted tobacco products through coupon redemption and multi-pack offers.<sup>17</sup> Tobacco industry stakeholders challenged the law on First Amendment and federal and state preemption grounds. In December 2012, a federal district court upheld the pricing ordinance, concluding that its prohibition against certain industry price discounting practices did not violate the First Amendment, and also was not preempted by federal or state law.<sup>18</sup>

Although this decision has been appealed, and even if upheld, would not be controlling in all jurisdictions, Providence's promising early results may help support similar state or local laws to prohibit the deeply discounted sale of emerging tobacco products like e-cigarettes.

### Free Samples

- **Regulatory Gap:** Under the Tobacco Control Act, tobacco manufacturers are restricted from distributing free samples of "cigarettes, smokeless tobacco or other tobacco products."<sup>19</sup> At present, this restriction does not apply to e-cigarettes. Although the FDA has indicated that it intends to regulate electronic cigarettes as tobacco products, the agency has yet to issue regulations asserting jurisdiction over e-cigarettes or extending the Act's prohibition on free samples to electronic cigarettes.<sup>20</sup>
- **Regulatory Options:** State and local governments could prohibit the distribution of all free samples of tobacco products, including e-cigarettes and other nicotine delivery systems.<sup>21</sup>

### Flavoring

- **Regulatory Gap:** Another disparity exists in the way flavored e-cigarette cartridges are regulated versus flavored cigarettes. Under the Tobacco Control Act, tobacco companies are prohibited from producing cigarettes containing any characterizing flavor other than tobacco or menthol.<sup>22</sup> This prohibition is limited to flavored cigarettes, however. E-cigarette manufacturers can continue to market e-cigarette cartridges in a variety of candy-like flavors that appeal to youth (such as bubble gum, chocolate, and mint),<sup>23</sup> and sell them at mall kiosks, where young people often congregate, as well as online, where safeguards against youth access can be breached more easily than in face-to-face purchases.
- **Regulatory Options:** Although the Tobacco Control Act prohibits state and local governments from establishing tobacco product standards relating to the manufacture of tobacco products, it expressly preserves the authority of state and local governments to regulate the sale and distribution of tobacco products.<sup>24</sup>

In 2009, New York City enacted an ordinance prohibiting the sale of flavored non-cigarette tobacco products with a characterizing flavor other than menthol, mint, or wintergreen, except in certain “tobacco bars.”<sup>25</sup> Smokeless tobacco companies sued the city, arguing that the ordinance imposed manufacturing standards on their products in conflict with federal law. In 2010, the federal district court for the Southern District of New York ruled in favor of the city, denying the tobacco companies’ request to delay enforcement of the law.<sup>26</sup> The court stated that the Tobacco Control Act gives the federal government exclusive authority over tobacco product manufacturing standards, but preserves state and local authority to regulate the sale and distribution of tobacco products. The court then found that the New York City ordinance was a sales restriction, not a product standard. In 2011, the court affirmed the reasoning of its previous decision and dismissed the complaint.<sup>27</sup>

In early 2012, Providence, Rhode Island enacted a similar ordinance prohibiting the sale of flavored tobacco products, except in “smoking bars.”<sup>28</sup> Several tobacco industry stakeholders sued the city, arguing that the ordinance was preempted by the Tobacco Control Act because it attempted to establish a product standard, and also violated the First Amendment because it limited their ability to describe their products. Like the New York court, the federal district court in Rhode Island concluded that the ordinance was a sales restriction, not a product standard, and thus was not preempted under the Tobacco Control Act.<sup>29</sup> The court also concluded that Providence’s ordinance did not limit the plaintiffs’ First Amendment rights, finding that it was simply an economic regulation on the sale of a particular product.<sup>30</sup>

Although both of these decisions are on appeal and, even if upheld, would not be precedential in all jurisdictions, their promising initial results may help support similar state or local laws to prohibit or restrict the sale of flavored tobacco products, including flavored e-cigarettes

### Youth Access

- **Regulatory Gap:** Under federal law, retailers cannot “sell cigarettes or smokeless tobacco to any person younger than eighteen years of age.”<sup>31</sup> As explained above, the FDA has yet to assert jurisdiction over electronic cigarettes and extend restrictions like this to e-cigarettes. Also, many state and local youth access laws do not include e-cigarettes.<sup>32</sup>
- **Regulatory Options:** State and local governments could consider passing stronger, more comprehensive youth access laws to prohibit the sale of e-cigarettes to minors, require these products to be kept behind the counter, allow them to be sold only in places adults are permitted to enter, or raise the minimum legal age to purchase them.<sup>33</sup>

### Use Restrictions

- **Regulatory Gap:** Many smoke-free laws define the act of “smoking” as inhaling or carrying a lighted tobacco or plant product intended for inhalation. E-cigarettes, which

are not burned, but “vaped,” are generally not covered under these laws. Using e-cigarettes in public may lead conventional smokers to assume that smoking is permitted in such locations and nonsmokers to believe that a smoke-free law is being violated. Because of this, several health organizations recommend that the use of electronic cigarettes be prohibited in public places and workplaces.<sup>34</sup>

- **Regulatory Options:** Local and state governments could include e-cigarettes in their smoke- and tobacco-free restrictions by revising definitions of “smoking” or “tobacco products” to expressly cover e-cigarettes and other electronic nicotine delivery systems.

### Point-of-Sale Warnings, Marketing Restrictions, & Broad Sales Prohibitions

- **Regulatory Gap:** The Federal Cigarette Labeling and Advertising Act<sup>35</sup> limits the authority of state and local governments to regulate the advertising and promotion of cigarettes; however, no federal statute limits the authority of local or state governments to regulate the advertising and promotion of non-cigarette tobacco products. In addition, as discussed above, the Tobacco Control Act expressly preserves state and local government authority to regulate the sale of tobacco products. Therefore, state and local governments are able to warn consumers of the dangers of using electronic cigarettes, regulate the advertising or promotion of e-cigarettes, and regulate the sale of e-cigarettes without risking federal preemption concerns.
- **Regulatory Options:** To determine the most effective options for regulating the sale and marketing of e-cigarettes or for warning consumers about the use of these products, state and local governments need to analyze their jurisdiction-specific needs, priorities, and goals. Possible policy options include posting health warnings at the point-of-sale,<sup>36</sup> imposing marketing restrictions, and prohibiting the sale of all electronic cigarettes.<sup>37</sup> Although federal statutes should not pose a barrier for state and local policies restricting the sale and marketing of e-cigarettes, such laws will most certainly be challenged on the basis that they violate state or federal constitutional provisions related to free speech or interstate commerce.<sup>38</sup> Although it is important to work with an attorney when pursuing any policy options, the legal issues surrounding the First Amendment are complicated, and jurisdictions must consult with legal counsel before pursuing these types of policies.

### Contact Us

Please feel free to contact the Tobacco Control Legal Consortium at (651) 290-7506 or [publichealthlaw@wmitchell.edu](mailto:publichealthlaw@wmitchell.edu) with any questions about the information included in this fact sheet or to discuss local concerns you may have about implementing these policy options.

*The Tobacco Control Legal Consortium provides information and technical assistance on issues related to tobacco and public health. The Consortium does not provide legal representation or advice. This document should not be considered legal advice or a substitute for obtaining legal advice from an attorney who can represent you. We recommend that you consult with local legal counsel before attempting to implement any of these measures.*

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## Notes

<sup>1</sup> World Med. Ass'n, *Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems* (Oct. 2012), available at <http://www.wma.net/en/30publications/10policies/e19/>.

<sup>2</sup> U.S. Food and Drug Admin., *Electronic Cigarettes*, <http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm> (last visited Feb. 8, 2013).

<sup>3</sup> U.S. Food & Drug Admin., *Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by the FDA*, <http://www.fda.gov/newsevents/publichealthfocus/ucm173146.htm> (last visited Feb. 8, 2013).

<sup>4</sup> See World Med. Ass'n, *supra* note 1.

<sup>5</sup> *Sottera v. Food & Drug Admin.*, 627 F.3d 891, 893 (D.C. Cir. 2010).

<sup>6</sup> *Sottera*, 627 F.3d at 893 (holding that e-cigarettes and other nicotine-containing products are not drugs or devices unless they are marketed for therapeutic purposes, but that other nicotine-containing products can be regulated as “tobacco products” under the Federal Food, Drug, and Cosmetic Act).

<sup>7</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended in relevant part at 21 U.S.C. §§ 301, 321, 387), available at [www.govtrack.us/congress/bills/111/hr1256/text](http://www.govtrack.us/congress/bills/111/hr1256/text).

<sup>8</sup> See Letter from Lawrence Deyton, Dep't Director, Food & Drug Admin., to Stakeholders, *Regulation of E-Cigarettes and Other Tobacco Products* (Apr. 25, 2011), available at <http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm>.

<sup>9</sup> See Michael Freiberg, *Options for State and Local Governments to Regulate Non-Cigarette Tobacco Products*, 21 ANNALS OF HEALTH LAW 407, 412 (2012), available at <http://publichealthlawcenter.org/sites/default/files/resources/phlc-lreview-freiberg-regulating-otp-2012.pdf>.

<sup>10</sup> 21 U.S.C. § 387p(a)(1).

<sup>11</sup> See Freiberg, *supra* note 9, at 421.

<sup>12</sup> See, e.g., 2010 Minn. Laws ch. 305 § 2, available at <https://www.revisor.mn.gov/data/revisor/law/2010/0/2010-305.pdf>.

<sup>13</sup> See Freiberg, *supra* note 9, at 418, 421.

<sup>14</sup> U.S. Dep't of Health & Human Servs., *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 522-30 (2012), available at <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf>.

<sup>15</sup> See, e.g., Marlo Miura, Tobacco Control Legal Consortium, *Regulating Tobacco Product Pricing: Guidelines for State and Local Governments* (2010), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-pricing-2010.pdf>; Tobacco Control Legal Consortium, *Price-Related Promotions for Tobacco Products: An Introduction to Key Terms and Concepts* (2011), available at [http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-pricerelatedpromotions-2011\\_0.pdf](http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-pricerelatedpromotions-2011_0.pdf).

<sup>16</sup> *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, No. 12-96-ML, 2012 WL 6128707 (D.R.I. Dec. 12, 2012).

<sup>17</sup> PROVIDENCE, R.I. CODE §§ 14-300, 14-303.

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<sup>18</sup> Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, 2012 WL 6128707 at \*5-7, 11.

<sup>19</sup> 21 C.F.R. § 1140.16(d)(1).

<sup>20</sup> The Tobacco Control Act immediately gave the FDA the authority to regulate cigarettes, roll your own, and smokeless tobacco and “any other tobacco products that the Secretary by regulation deems to be subject to” the Act. The Act includes a broad definition of tobacco products that would appear to include e-cigarettes and any other tobacco product that is currently on the market. However, in order to regulate those products, the FDA has to issue a regulation that deems them subject to the Act. After indicating in 2011 that it intended to issue the regulations later that year, the FDA did not issue the regulations in 2011 or 2012. In January 2013, the U.S. Department of Health and Human Services (HHS) published its Unified Regulatory Agenda, which indicates that the FDA intends to issue a notice of proposed rulemaking regarding its authority to deem other tobacco products subject to its jurisdiction in April 2013. U.S. Dep't of Health & Human Services, Regulatory Agenda, 78 Fed. Reg. 1574, 1579 (Jan. 8, 2013), available at <http://www.gpo.gov/fdsys/pkg/FR-2013-01-08/pdf/2012-31671.pdf>.

<sup>21</sup> See, e.g., Tobacco Control Legal Consortium, *Tobacco Coupon Regulations and Sampling Restrictions – Tips and Tools* (2011), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-tobcouponregsandsampling-2011.pdf>.

<sup>22</sup> See U.S. Food & Drug Admin., Flavored Tobacco, <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/default.htm> (last visited Feb. 8, 2013) (containing links to resources related to 2009 law prohibiting the manufacture and sale of cigarettes containing certain characterizing flavors).

<sup>23</sup> Minutes, U.S. Food & Drug Admin., Ctr. for Tobacco Products, Tobacco Products Scientific Advisory Committee Meeting, Dissolvable Tobacco Products Session, Testimony of Curtis Wright (July 21, 2011), available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM270282.pdf>.

<sup>24</sup> 21 U.S.C. § 387p(a)(1). See Tobacco Control Legal Consortium, *Federal Regulation of Tobacco: Impact on State and Local Authority* (2009), available at <http://www.publichealthlawcenter.org/sites/default/files/fda-1.pdf>.

<sup>25</sup> N.Y.C. CODE § 17-713, 715 (prohibiting the sale of smokeless tobacco products that have as a component part tastes or aromas relating to "any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb or spice.").

<sup>26</sup> U.S. Smokeless Tobacco Mfg. Co. v. City of New York, 703 F. Supp. 2d 329, 344-45 (S.D.N.Y. 2010) (denying plaintiffs' motion for a preliminary injunction, finding them unlikely to prevail on the merits of their federal preemption claim; concluding that the Tobacco Control Act gives the federal government the exclusive authority to regulate the manufacture of tobacco products, while reserving to the states the power to regulate the sale and distribution of tobacco products).

<sup>27</sup> U.S. Smokeless Tobacco Mfg. Co. v. City of New York, No. 09 Civ. 10511, 2011 WL 5569431 (S.D.N.Y. Nov. 15, 2011) (affirming reasoning of preliminary injunction order that the ordinance is an allowable sales restriction, denying plaintiffs' motion for summary judgment, granting defendant's cross-motion for summary judgment, and dismissing the complaint).

<sup>28</sup> PROVIDENCE, R.I. CODE §§ 14-308, 14-309, and 14-310.

<sup>29</sup> Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, No. 12-96-ML, 2012 WL 6128707 at \*12-13 (D.R.I. Dec. 12, 2012).

<sup>30</sup> *Id.* at \*8.

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<sup>31</sup> 21 C.F.R. § 1140.14(a).

<sup>32</sup> Freiberg, *supra* note 9, at 434.

<sup>33</sup> See Tobacco Control Legal Consortium, *Regulating E-Cigarettes – Tips and Tools* (2011) (including select U.S. legislation and policies regulating e-cigarettes), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regecigs-2011.pdf>; Tobacco Control Legal Consortium, *Raising the Minimum Legal Sale Age for Tobacco and Related Products* (2012), available at [http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-minimumlegal-saleage-2012\\_0.pdf](http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-minimumlegal-saleage-2012_0.pdf).

<sup>34</sup> See, e.g., Americans for Nonsmokers' Rights, *Model Ordinance Prohibiting Smoking in All Workplaces and Public Places* 7 (2011), available at <http://www.no-smoke.org/pdf/modelordinance.pdf>.

<sup>35</sup> 15 U.S.C. § 1331 *et seq.*

<sup>36</sup> See 23-34 94<sup>th</sup> St. Grocery Corp. v. New York City Bd. of Health, 685 F.3d 174, 183-85 (2d Cir. 2012) (affirming a district court decision ruling that New York City may not require cigarette retailers to post graphic health warnings next to cash registers or adjacent to cigarette displays, on the grounds that the Federal Cigarette Labeling and Advertising Act prevents state or local governments from adopting laws that affect the content of tobacco retailers' and manufacturers' promotional efforts). The challenged warning signs depicted the health impacts of smoking and contained the message "quit smoking today." It should be noted that if a jurisdiction adopted graphic point-of-sale warning requirements applying to non-cigarette tobacco products such as electronic cigarettes, the FCLAA would not apply. However, the law would almost certainly be challenged on First Amendment grounds.

<sup>37</sup> Freiberg, *supra* note 9, at 438.

<sup>38</sup> For additional information, see the Tobacco Control Legal Consortium's publications on First Amendment and Commerce Clause issues in the regulation of tobacco products, available at <http://publichealthlawcenter.org/topics/special-collections/federal-regulation-tobacco-collection>.