



Regulatory Options for Dissolvable Tobacco Products

Background

The tobacco industry has recently developed several novel products that have the potential to skirt many tobacco control laws, such as smoke-free laws or tax laws. Among the new products that the industry is aggressively marketing are flavored smokeless tobacco products that dissolve in the user's mouth and are commonly known as "dissolvables." The U.S. Food and Drug Administration (FDA) has taken the position that some dissolvables are not subject to federal regulation as "tobacco products"¹ and that restrictions in the Family Smoking Prevention and Tobacco Control Act, the federal law granting the FDA the authority to regulate tobacco products, do not apply to them. State and local governments, however, can regulate dissolvables in several different ways. This fact sheet provides a brief overview of dissolvable tobacco products, their health risks, regulatory gaps, and some approaches that state and local governments might consider to restrict their usage, pricing, and marketing.²

Product Description

Dissolvable tobacco products come in at least three forms: orbs, similar to breath mints; lozenges; strips, similar to breath strips; and sticks, shaped like long toothpicks. The convenient size, shape and flavoring of dissolvables makes them especially attractive to children and youth. In many instances, these products look and taste like candy. Also, because users do not need to spit out tobacco waste, and the products are smoke- and odor-free, dissolvable tobacco products can be used discretely. Their convenient size means they can be easily concealed – for example, in school – without being detected.³



Health Risks

Although studies on the health impact of smokeless tobacco products are ongoing, several health risks are associated with their use. The candy-like appearance and packaging of dissolvable tobacco products may make children more likely to try them. In addition to serving as a gateway tobacco product, the use of dissolvables can lead to oral cancer, gum disease, and nicotine addiction, and can increase the risk of cardiovascular disease, including heart attacks.⁴ Also, the size and shape of dissolvables makes them easy for children to ingest, which can lead to accidental poisoning.⁵

Regulatory Gaps & Options

Taxation

- Regulatory Gap:** Many state tax laws define tobacco products in a way that potentially excludes dissolvables. For example, laws that limit the definition of “tobacco products” to items that are smoked or chewed would arguably not apply to dissolvables; because the products dissolve in the user’s mouth and are neither smoked nor chewed, they may not fall into either of these categories.⁶ If dissolvables are not covered by state tobacco laws, they would not be subject to a tobacco tax. Also, even if a state’s tobacco tax laws do cover dissolvables, the tax rate may be substantially lower than that of more traditional tobacco products. Dissolvables may be subject to a percentage-of-wholesale-price tax (also known as an *ad valorem* tax), rather than a fixed excise tax, which is often applied to traditional tobacco products and is considerably higher. Lower tax rates make dissolvable tobacco products considerably cheaper, increasing their appeal to minors.⁷
- Regulatory Options:** The Family Smoking Tobacco and Prevention Control Act⁸ (Tobacco Control Act) expressly preserves the authority of state and local governments to levy taxes on tobacco products.⁹ State and local governments could broaden or clarify existing definitions of tobacco products in their tax laws to ensure that dissolvables are covered and taxed at rates comparable to those applied to traditional tobacco products.

Coupons, Discounts, & Rebates

- Regulatory Gap:** Tobacco manufacturers use coupons and other price-related incentives to make novel tobacco products such as dissolvables more attractive to consumers, particularly young people.¹⁰ Numerous studies have shown that youth are particularly sensitive to increases in the price of tobacco products.¹¹ The Surgeon General has concluded that the tobacco industry’s extensive use of price-related marketing practices has led to higher rates of tobacco use among young people than would have occurred in the absence of these practices.¹²
- Regulatory Options:** The Tobacco Control Act preserves state and local government authority to regulate the sale and distribution of tobacco products, including their price.¹³ Local and state governments could consider restricting or prohibiting the redemption of coupons for dissolvables and similar tobacco products in retail stores, or restricting other tobacco price-related marketing practices, such as price discounts to tobacco retailers and wholesalers, tobacco retailer incentive programs, and retail value-added deals (e.g., buy-one-get-one-free offers).¹⁴

While legal challenges to such policies can be anticipated in light of the tobacco industry’s heavy investment in price-related marketing strategies, a federal district court has recently upheld a local law prohibiting the sale of discounted tobacco products.¹⁵ 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.¹⁶ 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 was not preempted by federal or state law.¹⁷

Although this decision has been appealed, and even if upheld, would not be controlling in all jurisdictions, its promising initial result may help support similar state or local laws to prohibit the deeply discounted sale of emerging tobacco products like dissolvables.

Free Samples

- Regulatory Gap:** Under the Tobacco Control Act, tobacco manufacturers, distributors, and retailers are generally restricted from distributing free samples of “cigarettes, smokeless tobacco or other tobacco products.”¹⁸ Dissolvables that consist of ground tobacco would appear to fall under the Tobacco Control Act’s definition of “smokeless tobacco,” which presumably means the restriction on free samples would apply to them.¹⁹ However, as mentioned above, the FDA does not consider certain dissolvables with low nitrosamine levels to be tobacco products, and thus, free samples of these products can apparently be distributed.²⁰ Also, under an exception in the Tobacco Control Act, free samples of smokeless tobacco may be distributed in “qualified adult-only facilities” as that term is defined under federal regulations.²¹ The sample must be limited to one package containing 0.53 ounces of smokeless tobacco or eight individual portions of smokeless tobacco, whichever weighs less.²² Given the low weight of many dissolvable tobacco products, this provision could create a significant loophole.²³
- Regulatory Options:** Although the Tobacco Control Act allows limited free sampling of smokeless tobacco products, it expressly states that it does not affect the authority of a state or local government to prohibit or further restrict the distribution of free samples of smokeless tobacco.²⁴ State and local governments could prohibit the distribution of free samples of all non-cigarette tobacco products, including dissolvables, in all locations.²⁵

Minimum Pack Size

- Regulatory Gap:** Unlike cigarettes, which must be sold in packs of twenty,²⁶ the FDA does not require dissolvables to be sold in any minimum pack size. Some dissolvable tobacco products are sold in packages containing only five units. When dissolvables are sold in smaller quantities, their product price is considerably lower than packages of conventional tobacco products. As a result, these lower-priced products may have a direct appeal to minors.²⁷
- Regulatory Options:** To combat price disparities caused by small packs of dissolvables, and to ensure that these products have a price compatible with cigarettes, state and local governments could create a standard minimum pack size for dissolvables sold in their jurisdictions, thereby limiting the sale of dissolvables sold in small quantities.²⁸

Flavoring

- **Regulatory Gap:** Another disparity exists in the way flavored dissolvables 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.²⁹ This prohibition is limited to cigarettes, however, and does not apply to other tobacco products. Tobacco companies can continue to market flavored dissolvables, which come in cinnamon, citrus, mint and other flavors intended to appeal to youth.³⁰
- **Regulatory Options:** As noted above, the Tobacco Control Act clearly indicates that state and local governments can regulate the sale and distribution of tobacco products.

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.”³¹ 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.³² 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.³³

In early 2012, Providence, Rhode Island enacted a similar ordinance prohibiting the sale of flavored tobacco products, except in “smoking bars.”³⁴ 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.³⁵ 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.³⁶

Although both of these decisions are on appeal and, even if upheld, would not be precedential in all jurisdictions, New York City’s and Providence’s initial successes may help support similar state or local laws to prohibit or significantly restrict the sale of flavored dissolvable tobacco products.

Youth Access

- **Regulatory Gap:** Under federal law, retailers cannot “sell cigarettes or smokeless tobacco to any person younger than eighteen years of age.”³⁷ Although many

dissolvables would likely qualify as “smokeless tobacco” under federal law because they include ground tobacco, other dissolvables may be unregulated.³⁸ Also, many state and local youth access laws arguably do not include dissolvables because these laws are restricted to those products that are chewed or smoked.

- **Regulatory Options:** State and local governments could consider passing stronger, more comprehensive youth access laws to include dissolvables, and also raising the minimum age to purchase such products.³⁹

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

- **Regulatory Gap:** The Federal Cigarette Labeling and Advertising Act⁴⁰ 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 dissolvables, regulate the advertising or promotion of dissolvables, and regulate the sale of dissolvables without risking federal preemption concerns.
- **Regulatory Options:** To determine the most effective options for regulating the sale and marketing of dissolvables 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,⁴¹ imposing marketing restrictions, and prohibiting the sale of all dissolvable tobacco products.⁴² Although federal statutes should not pose a barrier for state and local policies restricting the sale and marketing of dissolvables, 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.⁴³ 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 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.

Last Updated: February 2013

Notes

¹ Letters from Dr. Lawrence R. Deyton M.D., Dir., Ctr. for Tobacco Products, to Paul Perito, Star Scientific, Inc. (March 17, 2011). See also Molly Peterson, *Star Scientific's Tobacco Lozenges Get Favorable FDA Ruling*, BLOOMBERG (Mar. 23, 2011), <http://www.bloomberg.com/news/print/2011-03-23/star-scientific-gets-favorable-fda-ruling-on-tobacco-lozenges.html>.

² For more detailed information, see Michael Freiberg, *Options for State and Local Governments to Regulate Non-Cigarette Tobacco Products*, 21 ANNALS HEALTH L. 407 (2012).

³ Campaign for Tobacco-Free Kids, *The Danger from Dissolvable Tobacco and Other Smokeless Tobacco Products* (2012), available at <http://www.tobaccofreekids.org/research/factsheets/pdf/0363.pdf>.

⁴ See U.S. Food & Drug Admin., *Health Effects of Dissolvable Tobacco Products* (2012), available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM288283.pdf>; Karen C. Sokol, *Smoking Abroad and Smokeless at Home: Holding the Tobacco Industry Accountable in a New Era*, 18 N.Y.U. J. LEGIS. & PUB. POL'Y 81, 114-15 (2010). According to a 2008 World Health Organization's International Agency for Research on Cancer study, smokeless tobacco users have an 80 percent higher risk of developing oral cancer and a 60 percent higher risk of developing pancreatic and esophageal cancer. Paolo Boffetta et al., *Smokeless Tobacco and Cancer*, 9 LANCET 667-75 (2008).

⁵ Greg Connolly et al., *Unintentional Child Poisonings Through Ingestion of Conventional and Novel Tobacco Products*, 125 PEDIATRICS 896, (2010), available at <http://pediatrics.aappublications.org/content/early/2010/04/19/peds.2009-2835.abstract>.

⁶ Freiberg, *supra* note 2, at 417.

⁷ *Id.* at 420 (noting that applying a weight-based tax of \$1.00 per ounce to a pack of 15 Camel Orbs would amount to taxation of less than \$0.01 per dose).

⁸ 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.

⁹ 21 U.S.C. § 387p(a)(1).

¹⁰ 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>. See also Tobacco Control Legal Consortium, *Cause and Effect: Tobacco Marketing Increases Youth Tobacco Use – Findings from the 2012 Surgeon General's Report on Youth and Young Adult Tobacco Use* 20 (2012), <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-SGReport-Findings-Youth-Marketing-2012.pdf>.

¹¹ U.S. Dep't of Health & Human Servs., *supra* note 10, at 528, 530.

¹² *Id.* at 530.

¹³ 21 U.S.C. § 387p(a)(1). See Marlo Miura, Tobacco Control Legal Consortium, *Regulating Tobacco Product Pricing: Guidelines for State and Local Governments* 5 (2010), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-pricing-2010.pdf>.

¹⁴ See Tobacco Control Legal Consortium, *Cause and Effect*, *supra* note 10, at 27-28; Miura, *supra* note 13. See also 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.

¹⁵ 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).

¹⁶ PROVIDENCE, R.I. CODE §§ 14-300, 14-303.

¹⁷ Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, 2012 WL 6128707 at *5-7, 11.

¹⁸ 21 C.F.R. § 1140.16(d)(1).

¹⁹ Freiberg, *supra* note 2, at 425-26. See also Public Health Law and Policy & Tobacco Control Legal Consortium, Comments on the FDA's "Draft Guidance for Industry: Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents" (May 20, 2011), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-fdacommments-cigarsinsamplingrestrictions-2011.pdf>.

²⁰ See sources cited *supra* note 1; Freiberg, *supra* note 2, at 423.

²¹ 21 U.S.C. § 387a-1(a)(2)(G)(d)(2)(A); 21 C.F.R. § 1140.16(d)(2)(iii)(A)-(F).

²² 21 C.F.R. § 1140.16(d)(2)(iv).

²³ Freiberg, *supra* note 2, at 424.

²⁴ 21 U.S.C. § 387a-1(a)(2)(G)(d)(2)(B).

²⁵ 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>.

²⁶ 21 C.F.R. § 1140.16(b).

²⁷ See, e.g., Tobacco Control Legal Consortium, *Regulating Tobacco Products Based on Pack Size* (2012), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regulating-packsizes-2012.pdf>.

²⁸ Freiberg, *supra* note 2, at 428.

²⁹ 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).

³⁰ 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>.

³¹ 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.").

³² 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).

³³ 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).

³⁴ PROVIDENCE, R.I. CODE §§ 14-308, 14-309, and 14-310.

³⁵ 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).

³⁶ *Id.* at *8.

³⁷ 21 C.F.R. § 1140.14(a).

³⁸ Freiberg, *supra* note 2, at 434.

³⁹ See 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.

⁴⁰ 15 U.S.C. § 1331 *et seq.*

⁴¹ See 23-34 94th 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 dissolvable tobacco products, the FCLAA would not apply. However, the law would almost certainly be challenged on First Amendment grounds.

⁴² Freiberg, *supra* note 2, at 438.

⁴³ 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>.