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Options for State and Local Governments to Regulate Non-Cigarette Tobacco Products*

*Michael Freiberg**

I. INTRODUCTION

When most tobacco control laws were drafted, smoking was a national scourge. In 1965, when Congress adopted the Federal Cigarette Labeling and Advertising Act,¹ the adult smoking rate in the United States was 42.4 percent.² When the major cigarette manufacturers signed the Master Settlement Agreement in 1998,³ the adult smoking rate was still high at 24.7 percent.⁴ In contrast, the rate of smokeless tobacco use among young adults in the same year was 5.4 percent.⁵

Smoking rates have decreased since their peak in the mid-twentieth

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*Michael Freiberg, J.D., is a Staff Attorney with the Public Health Law Center in St. Paul, Minnesota. He is also an Adjunct Professor at the William Mitchell College of Law, teaching courses in Legislation and Public Health Law. He has served on the City Council of Golden Valley, Minnesota, since 2004. He has a B.A. from Georgetown University and a J.D. from the William Mitchell College of Law.

1. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended 15 U.S.C. §§ 1331-1341).

2. CTRS. FOR DISEASE CONTROL & PREVENTION, TRENDS IN CURRENT CIGARETTE SMOKING AMONG HIGH SCHOOL STUDENTS AND ADULTS, UNITED STATES, 1965–2009 (2010), http://www.cdc.gov/tobacco/data_statistics/tables/trends/cig_smoking/index.htm (last visited Aug. 2, 2011).

3. The Master Settlement Agreement settled lawsuits brought by forty-six state attorneys general and the major cigarette manufacturers to recover health care costs associated with cigarette use. TOBACCO MASTER SETTLEMENT AGREEMENT (1998), *available at* <http://ag.ca.gov/tobacco/pdf/1msa.pdf>.

4. CTRS. FOR DISEASE CONTROL & PREVENTION, CIGARETTE SMOKING AMONG ADULTS, UNITED STATES, 1998, (2000), <http://cdc.gov/mmwr/preview/mmwrhtml/mm4939a1.htm> (last visited Sept. 6, 2011).

5. U.S. DEP'T OF HEALTH & HUMAN SERVS., TABLE 2.1: PERCENTAGES REPORTING PAST MONTH USE OF CIGARETTES AND SMOKELESS TOBACCO, BY AGE GROUP: 1994 TO 1999 PAPI (1999), <http://www.oas.samhsa.gov/NHSDA/tobacco/appendixb.htm> (last visited Aug. 2, 2011).

century.⁶ However, there has been no commensurate decrease in the use rate of non-cigarette tobacco products,⁷ often called other tobacco products or OTPs.⁸ Indeed, recent studies have shown an increase in the use of such products,⁹ including novel products such as snus, hookah, little cigars, and electronic cigarettes.¹⁰ In fact, the increased diversity of products may be partly responsible for the alarming rates of tobacco use among U.S. teenagers. It is no coincidence that major U.S. tobacco companies are now selling OTPs – including dissolvable tobacco products and snus – under their most popular cigarette brand names,¹¹ are contemplating entering the market for electronic cigarettes,¹² and have substantially increased the amount spent on marketing these products.¹³

With all of these novel tobacco and nicotine products available, it is important that tobacco control laws be written broadly so that these products are not excluded. Failure to enact comprehensive laws poses

6. See Karen C. Sokol, *Smoking Abroad and Smokeless at Home: Holding the Tobacco Industry Accountable in a New Era*, 13 N.Y.U. J. LEGIS. & PUB. POL'Y 81, 108, 121 (2010).

7. See, e.g., MINN. DEP'T OF HEALTH, TEENS AND TOBACCO IN MINNESOTA, THE VIEW FROM 2008 (2008), available at <http://www.health.state.mn.us/divs/chs/tobacco/execsummary07.pdf> (“While cigarette smoking has declined since 2000, there has been no change since 2000 in the percentage of students smoking cigars or little cigars or using smokeless tobacco.”).

8. It should be acknowledged that this term is not a perfect fit for the five products discussed in this article. As will be explained, electronic cigarettes, at least arguably, do not contain tobacco – rather, they may contain a synthetic form of nicotine – and some non-tobacco herbal products may be smoked in water pipes. However, the term “OTPs” is in common use among public health advocates and it will be used in this article as a shorthand term that includes products such as electronic cigarettes and products smoked in water pipes.

9. E.g., MINN. DEP'T OF HEALTH, MINNESOTA ADULT TOBACCO SURVEY, TOBACCO USE IN MINNESOTA, 2010 UPDATE 3-9 (2011), available at <http://mnadulthoodsurvey.org/> (“Between 2007 and 2010, Minnesotans’ current use of any noncigarette tobacco products increased from 6.1±0.8 percent to 7.5±0.8 percent . . .”); L.D. JOHNSTON, ET AL., SMOKING STOPS DECLINING AND SHOWS SIGNS OF INCREASING AMONG YOUNGER TEENS (2010), available at <http://www.monitoringthefuture.org/pressreleases/10cigpr.pdf>; Sokol, *supra* note 6, at 118.

10. E.g., MINNESOTA ADULT TOBACCO SURVEY, *supra* note 9, at 3-9 (discussing different forms of non-cigarette tobacco being used).

11. Sokol, *supra* note 6, at 110-112; see also Sy Kraft, *Big Tobacco Scrambles For Smokeless Products With New Bans Looming*, MED. NEWS TODAY (May 28, 2011), <http://www.medicalnewstoday.com/articles/226787.php>.

12. *Philip Morris Eying Electronic-Cigarette Market?*, CSP DAILY NEWS (Nov. 25, 2009), <http://www.cspnet.com/news/tobacco/articles/philip-morris-eying-electronic-cigarette-market>; see also Melissa Korn, *Philip Morris International Buys Nicotine Aerosol Technology*, DOW JONES NEWSWIRE (May 26, 2011), <http://www.foxbusiness.com/markets/2011/05/26/Philip-morris-international-buys-nicotine-aerosol-technology/>.

13. *FTC Releases Reports on Cigarette and Smokeless Tobacco Advertising and Promotion*, FED. TRADE COMMISSION (July 29, 2011), <http://ftc.gov/opa/2011/07/tobacco.shtm>.

serious risks to public health, from tobacco initiation¹⁴ to the continuation of tobacco use by smokers and other tobacco users who may otherwise try to quit.¹⁵

When President Obama signed the Family Smoking Prevention and Tobacco Control Act (TCA)¹⁶ into law on June 22, 2009, it marked a new era of extensive federal regulation of tobacco products. The Food and Drug Administration (FDA) is now the agency responsible for tobacco regulation, with public health serving as its lodestar.¹⁷ As this article discusses, however, this law still leaves some gaps in regulation.

As an initial matter, most of the law applies only to four classes of products: cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.¹⁸ This means that products such as electronic cigarettes, cigars, and water pipes are not yet regulated by the FDA, although the agency has the authority to assert jurisdiction over such products through regulation.¹⁹ As this paper will demonstrate, parts of the law exclude some OTPs that fall into these four regulated categories.²⁰

Although these gaps are troubling, they create an opportunity for state and local governments to fill these regulatory holes until the FDA chooses to exercise jurisdiction over all OTPs. Indeed, states should regulate OTPs in the absence of FDA regulation. State and local governments are often viewed as a “laboratory” where strong policy can be adopted.²¹ State and local regulation can also serve as an impetus for the FDA to advance its mission of public health. Unfortunately, many state and local laws also fail to account for OTPs, increasing the appeal of and access to the products and jeopardizing public health.²² Now, more than ever, it is critical that tobacco control laws – whether at the federal, state, or local level – sensibly regulate

14. See, e.g., Scott L. Tomar, et al., *Is Smokeless Tobacco Use an Appropriate Public Health Strategy for Reducing Societal Harm from Cigarette Smoking?*, 6 INT’L J. OF ENVTL. RES. & PUB. HEALTH 10, 16 (2009) (“[T]he preponderance of evidence suggests that [smokeless tobacco] use is a predictor of cigarette smoking in the United States.”).

15. Annette K McClave-Regan & Judy Berkowitz, *Smokers Who Are Also Using Smokeless Tobacco Products in the US: A National Assessment of Characteristics, Behaviours and Beliefs of ‘Dual Users’*, 3 TOBACCO CONTROL 239, 239 (2011).

16. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

17. 21 U.S.C.A. § 387f(d)(1) (West 2009).

18. *Id.* § 387a(b).

19. *Id.*

20. See, e.g., *id.* § 387g(a)(1)(A) (prohibition on characterizing flavors applies only to cigarettes).

21. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

22. See generally, MARLO MIURA, TOBACCO CONTROL LEGAL CONSORTIUM, REGULATING TOBACCO PRODUCT PRICING: GUIDELINES FOR STATE AND LOCAL GOVERNMENTS (2010), available at <http://www.publichealthlawcenter.org/sites/default/files/Resources/tclc-fs-pricing-2010.pdf>; see *infra* pp. 11-19.

all tobacco and nicotine products, while exempting products that can genuinely advance public health goals such as smoking cessation.

This article will examine deficiencies in many federal, state, and local tobacco control laws relating to OTPs, using five products as case studies. These weaknesses increase the likelihood that OTPs will be used by youth and that current tobacco users will continue to use tobacco. This article will focus on areas which are ripe for regulation at the state and local level. The tobacco control laws in Minnesota, which offer a unique perspective on the regulation of OTPs, will be highlighted in this discussion. In 2010, the Minnesota Legislature updated the state's tobacco laws by enacting the Tobacco Modernization and Compliance Act of 2010 (TMCA).²³ The article will describe how the TMCA addresses OTPs in greater detail.

II. TYPES OF PRODUCTS AND HEALTH RISKS

Because of the wide variety of tobacco products available,²⁴ examining how every tobacco product is regulated would be an unmanageable task. The task can be made more manageable, however, by examining five varied products that have developed a significant domestic market presence or have strong potential to do so. This article examines the following products: dissolvable tobacco products, electronic cigarettes, little cigars, snus, and water pipes. A brief description of each product type follows.

This section will also briefly describe health concerns associated with each of these products. Ultimately, the magnitude of risk associated with the use of these OTPs may not be at the same level as that of cigarettes.²⁵ This does not mean, however, that the use of these products is risk-free.

It should also be emphasized that the health effects of OTPs are not as well understood as the health effects of more established combustible tobacco products, such as cigarettes.²⁶ In a sense, this relative lack of understanding makes the presence of these nontraditional products in the market all the more troubling. In the event these poorly understood products are in fact more dangerous than it is currently assumed, decisive

23. 2010 Minn. Laws ch. 305-1, available at <https://www.revisor.mn.gov/data/revisor/law/2010/0/2010-305.pdf>.

24. See, e.g., TOBACCO PRODUCTS, <http://www.tobaccoproducts.org> (last visited Aug. 2, 2011) (a website which attempts to catalogue various tobacco products).

25. See, e.g., Brad Rodu, *The Scientific Foundation for Tobacco Harm Reduction, 2006-2011*, HARM REDUCTION J. (July 29, 2011) <http://www.harmreductionjournal.com/content/8/1/19>; contra Mark Parascandola, *Tobacco Harm Reduction and the Evolution of Nicotine Dependence*, 101(4) AM. J. PUB. HEALTH 632, 632-41 (2011) (arguing that "current discussions of harm reduction should look beyond simply assessing exposure reduction and should include assessment of the product's abuse liability, particularly its potential for promoting addiction.").

26. Sokol, *supra* note 6, at 114-115.

regulatory action is that much more critical. Although only a limited amount of research has been conducted on OTPs, a few health concerns are known and warrant description in this article.

A. Dissolvable Tobacco Products

The FDA has described dissolvable tobacco products as “flavored, smokeless tobacco products that resemble candy products and dissolve in the mouth of the user.”²⁷ Unlike “traditional” smokeless tobacco, the use of dissolvable tobacco products does not involve spitting.²⁸

These products are potentially lucrative. R.J. Reynolds recently began the second phase of test marketing three types of dissolvable tobacco products under its popular Camel brand.²⁹ Star Scientific, Inc., has been selling two brands of dissolvable tobacco, Ariva and Stonewall, since 2001 and 2003, respectively.³⁰ In January 2011, Star Scientific sought approval to sell a new line of dissolvable tobacco products under these brand names³¹ as “modified risk tobacco products.”³² The new products are named Ariva-BDL and Stonewall-BDL.³³ In a puzzling decision a few months later, the FDA concluded that the products were not subject to regulation as tobacco products.³⁴ The rationale for this conclusion is unknown. In a letter obtained through a Freedom of Information Act request, the explanation of this decision was redacted.³⁵ As a result of this decision, these products are

27. Letter from Dr. Lawrence R. Deyton M.D., Dir., Ctr. for Tobacco Prods., to Daniel M. Delan, Chairman, President, & Chief Officer, R.J. Reynolds Tobacco Co. (Feb. 2, 2010) [hereinafter Letter from Deyton to Delan], available at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm199712.htm>; See also Sokol, *supra* note 6, at 112.

28. *Frequently Asked Questions*, DISSOLVABLETOBACCO.COM, <http://www.dissolvabletobacco.com/main-w.html> (last visited Aug. 2, 2011).

29. Richard Craver, *Dissolvable Tobacco Products to Be Tested*, WINSTON-SALEM J., Feb. 24, 2011, <http://www2.journalnow.com/news/2011/feb/24/wsbiz01-dissolvabletobacco-products-to-be-tested-ar-808087/>.

30. DISSOLVABLETOBACCO.COM, *supra* note 28 (follow “What is it?” hyperlink; then follow “more. . .” hyperlink; then follow “Is dissolvable tobacco a new product?” hyperlink).

31. *Virginia Tobacco Maker Seeks New FDA Designation*, YAHOO NEWS (Feb. 2, 2011, 10:04 AM), <http://finance.yahoo.com/news/Virginia-tobacco-maker-seeks-apf-3197703398.html?x=0&.v=2>.

32. 21 U.S.C.A § 387k (West 2009).

33. “BDL” in this context is an abbreviation for “below detectable levels,” an implication by Star Scientific that the products have minimal levels of certain carcinogens. *Consumers debate benefits of e-cigs*, CHARLESTON GAZETTE, Mar. 26, 2011.

34. 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>.

35. See Letters from Dr. Lawrence R. Deyton M.D., Dir., Ctr. for Tobacco Products, to Paul Perito, Star Scientific, Inc. (March 17, 2011) [hereinafter Letters from Deyton to Perito] (on file with author).

not subject to any federal regulation.

Dissolvable tobacco products pose a few known health risks. First, recent studies have shown that dissolvable tobacco products can lead to tobacco initiation, particularly by children.³⁶ Second, dissolvables contain addictive nicotine and can lead to continued use of other forms of tobacco.³⁷ Indeed, the marketing of dissolvable tobacco products directly anticipates dual use with other tobacco products.³⁸ The use of dissolvable tobacco products also carries the risk that a child may be poisoned by ingesting them.³⁹ Finally, the products are carcinogenic.⁴⁰

B. Electronic Cigarettes

Electronic cigarettes, or “e-cigarettes,” often referred to as “electronic nicotine delivery systems” (ENDS) in scientific literature, deliver nicotine or other substances to a user in the form of a vapor.⁴¹ They often physically resemble a cigarette, but are typically composed of a rechargeable, battery-operated heating element, a replaceable cartridge that may contain nicotine or other chemicals, and an atomizer that, when heated, converts the contents of the cartridge into a vapor.⁴²

Although the FDA’s stance on the regulation of e-cigarettes has shifted because of litigation, it is clear that the agency views the products as unhealthy. The FDA took enforcement action against manufacturers of e-cigarettes, claiming that they violate the Federal Food, Drug, and Cosmetic Act.⁴³ Specifically, the FDA alleged “violations of good manufacturing practices, making unsubstantiated drug claims, and using the devices as delivery mechanisms for active pharmaceutical ingredients like rimonabant

36. John Reid Blackwell, *Many Teens Mistook Smokeless Tobacco Products for Candy*, RICHMOND TIMES DISPATCH, (May 7, 2010), available at http://www2.timesdispatch.com/business/2010/may/07/b-toba07_20100506-210802-ar-158201/.

37. See Sokol, *supra* note 6, at 114-115.

38. *Id.* at 111 (“[T]he contemplated ‘smoker’ market for smokeless products includes not only, or even primarily, smokers who want to stop smoking, but rather . . . smokers desiring a ‘bridge’ source of nicotine in the office, on airplanes, and other places where smoking is now prohibited. . .”).

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

40. See STANFILL ET AL., CAMEL ORBS: NICOTINE, PH, TOBACCO-SPECIFIC NITROSAMINES, AND SELECT FLAVOR ANALYSIS 8 (2009); see also Sokol, *supra* note 6, at 115.

41. *E-Cigarettes: Questions and Answers*, FOOD AND DRUG ADMIN. (2010), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225210.htm> (last visited Aug. 2, 2011).

42. *Id.*

43. *Sottera v. Food & Drug Admin.*, 627 F.3d 891, 893 (D.C. Cir. 2010); see also 21 U.S.C.A. § 321(g)(1) (West 2009).

and tadalafil.”⁴⁴ E-cigarette manufacturers sued the FDA, claiming that their products should be regulated as tobacco products, not as drugs.⁴⁵ The Court of Appeals for the District of Columbia recently ruled in favor of the manufacturers on the issue.⁴⁶ The FDA chose not to appeal this ruling announcing that it would henceforth regulate e-cigarettes as tobacco products “unless they are marketed for therapeutic purposes, in which case they are regulated as drugs and/or devices.”⁴⁷

C. Little Cigars

The term “little cigar” does not have a consistent definition. To a large extent, the term is a misnomer used by tobacco companies to exploit loopholes that will be discussed in more detail later in this article.⁴⁸ In many instances, the products are indistinguishable from cigarettes and do not deserve a separate appellation. However, some statutes define the term, typically for purposes of taxation.⁴⁹ Typically, statutes define a “little cigar” or a “small cigar” as a roll for smoking wrapped in a leaf of tobacco or a substance containing tobacco and weighing three⁵⁰ or four⁵¹ pounds per thousand. The State of Washington defines a little cigar as a cigar with a cigarette-like filter.⁵² Many states do not define the term at all.⁵³

Between 1997 and 2007, the sale of little cigars increased by 240%.⁵⁴ This sales increase is troubling from a public health standpoint as little cigars share many of the same adverse health effects as other combustible tobacco products, such as increased risk of tobacco initiation, tobacco

44. Letter from Janet Woodcock M.D., Dep’t Director, Food & Drug Admin., to Matt Salmon, Electronic Cigarette Ass’n (Sept. 8, 2010), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM225263.pdf>.

45. *Sottera*, 627 F.3d at 893.

46. *Id.*, at 899.

47. Letter from Lawrence Deyton, Dep’t Director, Food & Drug Admin., to Stakeholders (Apr. 25, 2011) [hereinafter Letter from Deyton to Stakeholders], <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm>.

48. *See, e.g.*, Christine D. Delnevo & Mary Hrywna, “A Whole ‘Nother Smoke” or a Cigarette in Disguise: How RJ Reynolds Reframed the Image of Little Cigars, 97AM. J. PUBLIC HEALTH 1368, 1368 (2007) (“RJ Reynolds engaged in a calculated effort to blur the line between cigarettes and little cigars with Winchester, a little cigar designed for cigarette smokers that was as close to cigarettes as legally possible.”).

49. *See, e.g.*, 72 PA. CONS. STAT. § 8206.1 (2009); VT. STAT. ANN. tit. 32, § 7771 (2011).

50. ARIZ. REV. STAT. ANN. § 42-3052(8) (2011); CAL. HEALTH & SAFETY CODE § 14950(b)(2) (West 2007); GA. CODE ANN. § 48-11-2(a)(1) (West 2011); IOWA CODE § 453A.42(5)(c) (2011); MASS. GEN. LAWS ch. 64C, § 1 (2008); R.I. GEN. LAWS § 11-9-13.4(14) (2010); VT. STAT. ANN. tit. 32, § 7702(6) (2011).

51. HAW. REV. STAT. § 245-1 (2011); 72 PA. CONS. STAT. § 202-A (2011).

52. WASH. REV. CODE § 82.26.010(10) (2011).

53. *See, e.g.*, MINN. STAT. § 297F.01 (2010).

54. AM. LEGACY FOUND., CIGARS, CIGARILLOS & LITTLE CIGARS 2 (2009), http://www.legacyforhealth.org/PDFPublications/CIGARILLOS_0609_temp.pdf.

continuation, cancer, and other lung and heart diseases.⁵⁵

D. Snus

Snus is a spit-free form of moist snuff that comes in small pouches resembling tea bags, and is intended to be placed between one's gum and upper lip.⁵⁶ The product originated in Sweden; "snus," which rhymes with "moose," is the Swedish word for "snuff."⁵⁷ In the U.S., snus is being sold under the popular Camel and Marlboro brand names.⁵⁸

Snus presumably presents similar risks to the products already discussed, with the exception of lung disease. The products are carcinogenic and contain addictive nicotine, potentially representing a gateway to smoking.⁵⁹ Studies have found a potential correlation between snus use and increased preterm birth⁶⁰ and colon cancer.⁶¹

E. Water Pipes

Water pipes, also known as "hookahs" or "sheishas,"⁶² are used to smoke tobacco or other substances.⁶³ A water pipe typically consists of a head, body, water bowl, and hose.⁶⁴ The bowl contains water through which smoke passes prior to being inhaled by the smoker.⁶⁵ The practice of smoking using water pipes originated in the Middle East and is growing in popularity in U.S. college towns⁶⁶ and is in use among immigrant

55. See Frank Baker et al., *Health Risks Associated with Cigar Smoking*, 284(6) J. AM. MED. ASS'N. 735, 737-738 (2000).

56. Sokol, *supra* note 6, at 110; Lindsey C. Dastrup & Jacqueline M. McNamara, *Tobacco Control and Snus: Time to Take a Stand*, 11 J. HEALTH CARE L. & POL'Y 127, 127 (2008).

57. Dastrup, *supra* note 56, at 127.

58. Sokol, *supra* note 6, at 110.

59. *Id.* at 115-16.

60. A-K Wikström, et al., *Effect of Swedish Snuff (Snus) on Preterm Birth*, 117 INT'L J. OF OBSTETRICS & GYNECOLOGY 1005, 1010 (2010).

61. Caroline Nordenvall et al., *Smoking, Snus Use and Risk of Right- and Left-Sided Colon, Rectal, and Anal Cancer: a 37-Year Follow-Up Study*, 128 INT'L J. OF CANCER 157, 163 (2011).

62. In this article, the term "water pipe" will generally be used as a catch-all term. It should be acknowledged that the term is somewhat inexact and there is a wide range of products available, each of which may pose unique health risks. Kamal Chaouachi, *More Rigor Needed in Systematic Reviews on "Waterpipe" (Hookah, Narghile, Shisha) Smoking*, 139(5) CHEST 1250, 1250 (2011).

63. *State v. Badr*, 2 A.3d 436, 438-439, (N.J. Super. Ct. App. Div. 2010).

64. WORLD HEALTH ORG., WATERPIPE TOBACCO SMOKING: HEALTH EFFECTS, RESEARCH NEEDS AND RECOMMENDED ACTIONS BY REGULATORS 2 (2005), available at http://www.who.int/tobacco/global_interaction/tobreg/Waterpipe%20recommendation_Final.pdf.

65. *Id.*

66. *Badr*, 2 A.3d 439.

communities.⁶⁷ Many different products can be smoked in water pipes, not all of which contain tobacco.⁶⁸

Because many different products can be smoked in water pipes throughout the world, it is difficult to make general statements about the health effects of smoking products in water pipes.⁶⁹ To the extent the products are unknown, however, there is a need for strong regulation until the health effects can be more conclusively determined.⁷⁰

Further, several health risks have been documented as associated with water pipe smoking. Hookah smoke contains significant amounts of nicotine, tar, heavy metals, and carcinogens.⁷¹ Due to the longer, more sustained period of inhalation, hookah use may actually increase exposure to the carcinogens in tobacco.⁷² In addition, shared mouthpieces and heated, moist smoke may enhance the opportunity for infections and diseases such as herpes, hepatitis, and tuberculosis to spread.⁷³ For these reasons, the World Health Organization issued an advisory on hookah smoking in 2005 which recommended, among other things, regulating water pipes and shisha in the same way as cigarettes and other tobacco products, and prohibiting water pipe use in public places in the same manner as cigarette and other tobacco smoking.⁷⁴

The serious health risks of all of these OTPs are troubling, particularly since many of them are available on the market without first being subject to procedures created by the TCA and required for new tobacco products⁷⁵ or modified risk tobacco products.⁷⁶ Additional regulatory gaps may lead to greater access to the products. Those gaps, and the ways state and local

67. See Mary P. Martinasek et al., *Waterpipe (Hookah) Tobacco Smoking Among Youth*, 41 CURRENT PROBS. IN PEDIATRIC & ADOLESCENT HEALTH CARE 34, 34 (2011).

68. See, e.g., *Tobacco regulation in the West a boom for shisha*, TOBACCO J. INT'L (2011) ("... Soex herbal hookah molasses is 100 per cent tobacco- and nicotine-free.").

69. See, e.g., Chaouachi, *supra* note 62, at 1250.

70. See Martinasek, *supra* note 67, at 34.

71. AM. LUNG ASS'N, AN EMERGING DEADLY TREND: WATERPIPE TOBACCO USE 2 (2007); WORLD HEALTH ORG., *supra* note 64, at 3.

72. AM. LUNG ASS'N, *supra* note 71; AM. CANCER SOC'Y, WATERPIPE (HOOKAH) FACTSHEET (2005), available at <http://www.health.athens.oh.us/he/Hookah%20ACS%20Factsheet.pdf>.

73. AM. LUNG ASS'N, *supra* note 71; CTRS. FOR DISEASE CONTROL & PREVENTION, HOOKAHS FACT SHEET (2007), available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs/.

74. WORLD HEALTH ORG., *supra* note 64, at 7.

75. 21 U.S.C. § 387j (2009).

76. 21 U.S.C. § 387k. It should be acknowledged that Star Scientific, Inc., did attempt to go through this process for its new line of Ariva-BDL and Stonewall-BDL products. *Virginia Tobacco Maker Seeks New FDA Designations*, YAHOO! FINANCE, <http://finance.yahoo.com/news/Virginia-tobacco-maker-seeks-apf-3197703398.html?x=0&.v=2> (last visited Feb. 2, 2011).

governments can address them, will be examined next.

III. WEAKNESSES IN REGULATION

Regulation of OTPs is inadequate in at least five areas: pricing, characterizing flavors, youth access, use restrictions, and health warnings. As a result, these gaps in regulation could increase the likelihood of tobacco access by minors, as well as the initiation and continuation of tobacco use – all of which will have a clear adverse impact on public health. State and local governments can play a key role in addressing these regulatory gaps.

A. The Price of OTPs

Regulatory gaps impact the price of OTPs in at least four areas: taxation; free samples; price reductions such as coupons, discounts, and rebates; and minimum pack size. These gaps potentially render OTPs cheaper than cigarettes and other more traditional tobacco products. Studies have shown that lowering the cost of tobacco products can result in greater access to those products by minors.⁷⁷ The public health risk of a low price for OTPs is therefore apparent. The TCA explicitly preserves the ability of state and local governments to restrict the sale and distribution of tobacco products,⁷⁸ so this is an area that is ripe for state and local regulation.

1. Tax Laws

Tobacco tax laws arguably have the strongest effect on the price of tobacco products.⁷⁹ Unfortunately, many state tax laws define tobacco in a way that potentially excludes some OTPs. This can occur for one of two reasons: either the definition is limited to products that can be smoked or chewed,⁸⁰ or the OTP may not contain tobacco.

77. See, e.g., MIURA, *supra* note 22; FRANK J. CHALOUKKA & PATRICIA A. DAVIDSON, TOBACCO CONTROL LEGAL CONSORTIUM, APPLYING TOBACCO CONTROL LESSONS TO OBESITY: TAXES AND OTHER PRICING STRATEGIES TO REDUCE CONSUMPTION (2010), available at <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-syn-obesity-2010.pdf>; ANN BOONN, CAMPAIGN FOR TOBACCO-FREE KIDS, RAISING CIGARETTE TAXES REDUCES SMOKING, ESPECIALLY AMONG KIDS (2009), available at <http://tobaccofreekids.org/research/factsheets/pdf/0146.pdf>.

78. 21 U.S.C. § 387p(a)(1) (2009).

79. See, e.g., MIURA, *supra* note 22, at 2.

80. See, e.g., COLO. REV. STAT. § 39-28.5-101(5) (2011); CONN. GEN. STAT. § 12-330(a)(2) (2011); FLA. STAT. § 210.25(11) (2011); GA. CODE ANN. § 48-11-1(15) (2011); 35 ILL. COMP. STAT. 143/10-5 (2001); IND. CODE § 6-7-2-5 (2011); IOWA CODE § 453A.42(15) (2011); KAN. STAT. ANN. § 79-3301(w) (2010); KY. REV. STAT. ANN. § 138.130(16)(c) (WEST 2011); ME. REV. STAT. tit. 36 § 4401(9) (2011); MD. CODE TAX-GEN § 12-191(c)(2) (2011); MASS. GEN. LAWS Ch. 64C § 1 (2008); NEB. REV. STAT. § 77-4007 (2010); N.Y. TAX LAWS § 470(2) (2010); OHIO REV. CODE ANN. § 5743.01(J) (LEXISNEXIS 2011); OR. REV. STAT. § 323.500(14) (2009); S.C. CODE ANN. § 12-21-800 (2010); WASH. REV. CODE § 82.26.010(21)

First, many of these products are neither chewed nor smoked. For example, it is questionable whether these laws would apply to dissolvable tobacco products, because the products dissolve in one's mouth. These products are not smoked and, at least arguably, are not chewed. Indeed, the directions on the back of a pack of Camel Orbs state: "Don't chew or swallow one whole."⁸¹ Likewise, the website for Ariva brand dissolvable tobacco advises, "do not chew or swallow the product."⁸² It may be no coincidence that the three states in which R.J. Reynolds initially test marketed dissolvable tobacco products under the popular Camel brand – Indiana, Ohio, and Oregon⁸³ – have tax definitions that are limited by this wording.⁸⁴

Similarly, because of the absence of chewing or smoking, most of these tax laws do not apply to snus or electronic cigarettes. Snus use involves placing a tobacco pouch between a user's lip and gum.⁸⁵ Electronic cigarette use involves the oral expulsion of a heated water vapor, a process sometimes referred to as "vaping", rather than smoking.

Minnesota's tax laws present an interesting case study on how to address this issue. Until August 1, 2010, the tax for OTPs in Minnesota applied only to certain listed products and other products that are "prepared in such manner as to be suitable for chewing or smoking in a pipe or otherwise, or both for chewing and smoking."⁸⁶ Because many of these OTPs are neither chewed nor smoked, it was debated whether or not they were taxable as tobacco products in Minnesota. If not, only the state sales tax of 6.875 percent and any local sales taxes would apply to these OTPs. In contrast, the state charges \$1.23 in fees and excise taxes per pack of cigarettes, in addition to the state sales tax.⁸⁷

To address this potential gap in regulation, in 2010, the Minnesota legislature clarified the definition of "tobacco products" in the tax code.

(2011); WIS. STAT. § 139.75(12) (2011).

81. MIKE FREIBERG, COMMENT SUBMITTED TO FOOD AND DRUG ADMINISTRATION ON THE IMPACT OF DISSOLVABLE TOBACCO USE PUBLIC HEALTH, DOCKET NO. FDA-2010-N-0123 (2010), available at <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-regcommentfda-dissolvables-2010.pdf>.

82. See generally, DISSOLVABLETOBACCO.COM, <http://www.dissolvabletobacco.com/main-w.html> (last visited Aug. 2, 2011).

83. Joe Wambach, *R.J. Reynolds Pulls Smokeless Tobacco Line From Test Markets*, WIBC.COM (Dec. 17, 2010), <http://www.wibc.com/news/Story.aspx?id=1330575>.

84. IND. CODE § 6-7-2-5 (2011); OHIO REV. CODE § 5743.01 (2011); OR. REV. STAT. § 323.500(14) (2009).

85. Karyn K. Heavner et al., *Retailers' Knowledge of Tobacco Harm Reduction Following the Introduction of a New Brand of Smokeless Tobacco*, 7 HARM REDUCTION J. 18, at 2 (2010), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2920862>.

86. MINN. STAT. § 297F.01, subdiv. 19 (2010).

87. *Cigarette and Tobacco Tax*, MINN. HOUSE OF REPRESENTATIVES, <http://www.house.leg.state.mn.us/hrd/databook/cigtobtax.html> (last visited Aug. 2, 2011).

”Tobacco products” are now defined as any tobacco product that is “intended for human consumption, whether chewed, smoked, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means.”⁸⁸ It is now clear that these OTPs will be taxed as tobacco products in Minnesota. Unfortunately, no other state has taken this step.

Some OTPs may not fall within the ambit of state tax laws for a reason beyond the method used to absorb the product into the body: they may not be tobacco products at all. For example, the FDA has concluded that some dissolvable tobacco products do not meet the statutory definition of tobacco products and are therefore exempt from federal regulation.⁸⁹ In the case of e-cigarettes, the FDA recently responded to an unfavorable court ruling⁹⁰ by announcing that it would regulate electronic cigarettes as tobacco products.⁹¹ However, it is still not clear whether every product marketed as an electronic cigarette contains tobacco or even nicotine derived from tobacco.⁹² Similarly, some materials smoked in water pipes may not be taxable as tobacco products because they are not made from tobacco.⁹³

Consequently, with the exception of little cigars, there is a risk that all of the types of OTPs highlighted in this article may not be considered tobacco products under many tax laws, either because they do not contain tobacco, or because they are not absorbed into the body through the means required in the statutory definition. If a tax official were to determine that any of these types of OTPs do not meet the definition of a tobacco product, no tobacco tax would be applied to the product; only the state sales tax would apply. This would result in the product being severely under-taxed, potentially increasing the use of the products among youth.

To be sure, a legitimate argument could be made that non-tobacco products should not be taxed as tobacco products, because they are not tobacco products by definition. However, in light of the potential harmful effects of many of these products, it would be worthwhile for policymakers at least to discuss whether a state’s tobacco tax should apply to these products as well.

It is not just the definitions in tax laws that can lead to an artificially low price for OTPs. Even in states with tobacco tax laws that do contemplate

88. 2010 Minn. Laws ch. 305 § 2, available at <https://www.revisor.mn.gov/data/revisor/law/2010/0/2010-305.pdf>.

89. Peterson, *supra* note 34.

90. *Sottera v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

91. Letter from Deyton to Stakeholders, *supra* note 47.

92. See, e.g., Letter from Michael M. Levy, Jr., Dir., Div. of New Drugs and Labeling Compliance, FDA, to William P. Bartkowski, President, Ruyan Am., Inc. (Sept. 8, 2010), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm225181.htm>.

93. See, e.g., *Tobacco regulation in the West a boom for shisha*, *supra* note 68.

all of these OTPs, the tax *rate* for these products may be substantially lower than that of more traditional tobacco products. While many states apply a fixed excise tax to cigarettes,⁹⁴ OTPs are often taxed on an *ad valorem* or percentage-of-price basis.⁹⁵ While this form of taxation has the advantage of increasing with inflation, many states set the percentage at a level substantially below the excise tax.⁹⁶

The price disparity between cigarettes and OTPs is readily apparent. In the case of dissolvable tobacco products, the web site for Ariva and Stonewall brand dissolvable tobacco products states that the products are “roughly half the cost of premium smokeless products” and that a pack of twenty tablets is “about one dollar less than a pack of premium cigarettes.”⁹⁷ It is also instructive to examine the tax rates in two of the states in which Camel-brand dissolvable tobacco products were test marketed. In Indiana, OTPs were taxed at only twenty-four percent of the wholesale price of tobacco at the time Camel-brand dissolvables were being test marketed,⁹⁸ and a package of fifteen Camel Orbs sold for less than three dollars.⁹⁹ In contrast, a pack of premium brand cigarettes costs approximately five dollars in Indiana.¹⁰⁰ In Ohio, OTPs are taxed at only seventeen percent of the wholesale price.¹⁰¹ Although the proper relative level of taxation between cigarettes and OTPs can be debated, the frequently lower rate for dissolvables may increase the use rates of the products among youth and create a public health hazard.

Little cigars pose a unique problem in many jurisdictions because they are often taxed on an *ad valorem* basis even though they are virtually indistinguishable from cigarettes. The wholesale price of the products is so low that even a reasonably high tax rate leaves them dramatically cheaper than cigarettes. In Minnesota, for example, the price differential is stark, even though the state has a relatively high OTP tax rate of seventy percent.¹⁰² A smoker can purchase a pack of twenty filtered little cigars for

94. See, e.g., MINN. STAT. § 297F.05, subdiv. 1 (2010); see also CAMPAIGN FOR TOBACCO-FREE KIDS, MAP OF STATE CIGARETTE TAX RATES (2011), available at <http://www.tobaccofreekids.org/research/factsheets/pdf/0222.pdf>.

95. See, e.g., MINN. STAT. § 297F.05, subdiv. 3 (2010); see also CAMPAIGN FOR TOBACCO-FREE KIDS, STATE EXCISE TAX RATES FOR NON-CIGARETTE TOBACCO PRODUCTS (2011), available at <http://www.tobaccofreekids.org/research/factsheets/pdf/0169.pdf>.

96. CAMPAIGN FOR TOBACCO-FREE KIDS, THE BEST WAY TO TAX SMOKELESS TOBACCO (2011), available at <http://www.tobaccofreekids.org/research/factsheets/pdf/0282.pdf>.

97. See generally, DISSOLVABLETOBACCO.COM, *supra* note 82.

98. IND. CODE § 6-7-2-7 (2009) (amended in 2011).

99. FREIBERG, *supra* note 81, at 6.

100. Shari Rudavsky, *Federal tax on cigarettes increasing 62 cents*, STAR MEDIA (Mar. 12, 2009), <http://www.indy.com/posts/federal-tax-on-cigarettes-increasing-62-cents>.

101. OHIO REV. CODE ANN. § 5743.51 (1995).

102. MINN. STAT. § 297F.05, subdiv. 3 (2010); MINN. STAT. § 256.9658, subdiv. 3(b)

less than two dollars, while a pack of twenty cigarettes costs over five.¹⁰³ In 2011, legislation was introduced to correct this imbalance.¹⁰⁴

Several states and the federal government tax OTPs not on an *ad valorem* basis, but apply a tax based on the weight of the product.¹⁰⁵ This tax rate has the potential to severely undertax many OTPs because of the extremely low weight of many of these products. To take the most extreme example, a tax of \$1.00 per ounce on a pack of fifteen Camel Orbs would amount to less than \$0.01 per dose.¹⁰⁶ Snus is also a very lightweight product. Marlboro sells snus in pouches weighing one gram (one twenty eighth of an ounce) and one half-gram (one fifty sixth of an ounce),¹⁰⁷ meaning the same dollar-per-ounce tax would yield only \$0.035 and \$0.018 per dose, respectively. An additional problem with weight-based taxes is that they do not increase with inflation as would an *ad valorem* tax.

It is no coincidence that tobacco companies advocate for weight-based taxes in many states.¹⁰⁸ As part of these campaigns, tobacco companies will often advocate for a weight-based tax rate at a level sufficient for a state to see a modest increase in revenue from the outset.¹⁰⁹ In challenging budget times, it is often difficult for legislators to refuse this additional revenue. This is particularly true when the interest group most likely to oppose a tax is in fact proposing it, as weight-based tax proposals are being advocated by UST, the largest U.S. smokeless tobacco manufacturer.¹¹⁰ Indeed, some states have fallen prey to these arguments and adopted weight-based taxes.¹¹¹ However, because the tax value is stagnant, it loses value over time and the products become more affordable, while low-weight products are severely under-taxed from the outset. These low tax rates increase the risk that OTPs will be used by minors.

To better accommodate OTPs, state tax laws should be written

(2010).

103. Editorial, *A Cigarette In All But Its Name*, STAR TRIBUNE, Feb. 22, 2011, available at <http://www.startribune.com/opinion/editorials/116625028.html>.

104. H. R. 473, 87th Sess. (Minn. 2011), <http://wdoc.house.leg.state.mn.us/leg/LS87/HF0743.0.pdf>; S. 473, 87th Sess. (Minn. 2011), <https://www.revisor.mn.gov/bin/showPDF.php>.

105. See, e.g., 26 U.S.C. § 5701(e) (2009); ALA. CODE § 40-25-2(a)(9)-(11) (2011); ARIZ. REV. STAT. §§ 42-3052 (2002), 42-3251 (2002), 42-3251.01 (2002), 42-3371 (2006); 36 ME. REV. STAT. § 4403(1) (2011); N.D. CENT. CODE § 57-36-25(2) (2009); TEX. TAX CODE § 155.0211(b) (2009).

106. CAMPAIGN FOR TOBACCO-FREE KIDS, CLOSING WEIGHT-BASED TAX LOOPHOLES FOR THE NEW GENERATION OF LOW WEIGHT MOIST SNUFF SMOKELESS TOBACCO PRODUCTS (2009), available at <http://www.tobaccofreekids.org/research/factsheets/pdf/0355.pdf>.

107. See *Discover Marlboro Snus*, MARLBORO, <https://www.marlboro.com/marlboro/welcome.action#/snus/varieties/> (last visited Aug. 5, 2011).

108. See CAMPAIGN FOR TOBACCO-FREE KIDS, *supra* note 96.

109. *Id.*

110. *Id.*

111. See, e.g., N.D. CENT. CODE § 57-36-25 (2001).

comprehensively to ensure that all tobacco and related products are covered, not merely those that are chewed or smoked. An *ad valorem* tax is preferable to a weight-based tax, but it should be set at a high level to mirror the excise tax on cigarettes. This system would work for dissolvable tobacco products, snus, and tobacco smoked in water pipes. Little cigars that resemble cigarettes should be taxed at the cigarette rate.¹¹²

Because e-cigarettes are a very different kind of product containing electronic parts, existing tobacco tax laws may not be a good fit for these products. However, a new system should be developed to ensure that a comparable tax can be applied to them, unless the FDA determines conclusively that the products have genuine therapeutic uses, such as smoking cessation.

Tobacco taxes are unquestionably within the bailiwick of state governments.¹¹³ So, unlike some of the other regulatory approaches suggested in this article, there should be no debate about the authority of states to adopt these policies. Indeed, in an era of ever-tightening public budgets, the appeal of increasing tobacco taxes is apparent.¹¹⁴

Some advocates recommend taxing tobacco products according to their toxicity or nicotine level.¹¹⁵ Under this system, products low in tobacco-specific nitrosamines (carcinogens found only in tobacco products) would be taxed at a lower rate than products with a higher rate of these carcinogens in an attempt to steer consumers towards the least harmful or least addictive products. As stated previously, however, the health effects of novel tobacco products are poorly understood, even by international experts and federal regulators. Adopting this sort of system would be well beyond the capabilities of health officials and policymakers working for cash-strapped state and local governments. If and when a comprehensive approach is recommended by high-level officials, state and local governments can reconsider their systems of taxation. Until that point, however, it makes sense to treat all products equally.

112. This could be accomplished by language similar to that in the Federal Cigarette Labeling and Advertising Act, which defines a cigarette as tobacco “which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.” 21 U.S.C. § 387(3)(B) (2009).

113. 21 U.S.C. § 387p(a)(1) (2009).

114. See, e.g., CLEARWAY MINNESOTA, NEW POLL: 72 PERCENT OF MINNESOTANS SUPPORT TOBACCO TAX INCREASE (2009), available at <http://www.clearwaymn.org/vertical/Sites/%7BF1680E9A-EF78-41E7-8793-6913CF57DBAB%7D/uploads/%7B4094E65D-4EFD-4FA5-A977-90791907B970%7D.DOC>.

115. See, e.g., Mitchell Zeller & Dorothy Hatsukami, *The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the United States*, 18(4) TOBACCO CONTROL 324 (2009) (approach “identified for further exploration”).

2. Free Samples

In June 2010, acting under a statutory directive contained in the TCA, the FDA implemented a rule limiting the ability of tobacco manufacturers to sell and market their products.¹¹⁶ This rule restricts the distribution of free samples of “cigarettes, smokeless tobacco, or other tobacco products.”¹¹⁷ Limiting the ability of tobacco manufacturers to distribute free samples of their products is an important objective to advance public health.¹¹⁸

This is the only provision in both the rule and the TCA that specifically addresses “other tobacco products.”¹¹⁹ The definition of “tobacco products” is very broad and includes “any product made or derived from tobacco that is intended for human consumption.”¹²⁰ Clearly, dissolvable tobacco products, little cigars, snus, and tobacco smoked in water pipes would meet this definition, since they all contain tobacco. In light of the FDA’s recent decision to regulate electronic cigarettes as tobacco products,¹²¹ it appears that these products would also meet the definition. Assuming that the products are regulated, the TCA restricts the distribution of free samples of all of these products.

However, some sections of the TCA suggest that the sampling restriction should not be read so broadly. As mentioned previously, the introductory language to the law states that it applies only to “cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.”¹²² The TCA specifies that the FDA rule is “deemed to be issued” according to this authority.¹²³ Under this interpretation, the restriction on free samples would apply only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. It appears that this is the position that the FDA has taken.¹²⁴ Therefore, electronic cigarettes, little cigars, and anything smoked

116. 21 C.F.R. § 1140 (2011).

117. 21 C.F.R. § 1140.16(d)(1).

118. See, e.g., U.S. DEP’T OF HEALTH & HUMAN SERV., PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GEN. 160 (1997), available at http://tobaccodocuments.org/ti/TIMN01388439164.html?pattern=&ocr_position=&rotation=0&zoom=750&start_page=160&end_page=160 (“Free samples do away with cost sensitivity altogether and actually give consumers an opportunity to try something new . . . Promotional devices such as these are more likely than advertising alone to lead consumers to purchase a product more than once – a pattern sought by all manufacturers.”).

119. 21 U.S.C. § 387a-1(a)(2)(G) (2009).

120. 21 U.S.C. § 321(rr)(1) (2009).

121. Letter from Deyton to Stakeholders, *supra* note 47.

122. 21 U.S.C. § 387a(b).

123. FSPTCA, Pub. L. No. 111-31, § 102(a)(1)(A), 123 Stat. 1776 (2009).

124. See, e.g., FDA, DOCKET NO. FDA-2010-D-0277, DRAFT GUIDANCE FOR INDUSTRY: COMPLIANCE WITH REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS 3 (2011), available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM248241.pdf>. Despite the FDA’s interpretation of the free sampling provision,

in water pipes would not be subject to the restrictions on free sampling in the TCA.

This distinction between the two interpretations of the sampling provision of the TCA is more than academic. It has been reported that tobacco companies have distributed free samples of little cigars at family-friendly events.¹²⁵ When confronted by local public health officials, tobacco industry representatives cite to FDA documents stating that little cigars are exempt from the sampling restrictions.¹²⁶

Even under the FDA's interpretation of the free sampling provision, some of the products examined in this article would still fall within the purview of the restriction on free samples. "Smokeless tobacco" is defined as "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity."¹²⁷ This definition would clearly include snus, which has been defined as "small pouches of moist powdered tobacco."¹²⁸

The case is less clear with some dissolvable tobacco products. Camel-brand dissolvable tobacco products are described as being "made of finely ground tobacco with mint or cinnamon flavoring."¹²⁹ Because they are ground tobacco, Camel-brand dissolvable tobacco products meet the definition of smokeless tobacco and fall within the restriction on free samples. According to documents on file with the Securities and Exchange Commission (SEC), Ariva dissolvable tobacco products are "compressed powdered tobacco."¹³⁰ Yet, as mentioned previously, the FDA does not consider the new line of Ariva and Stonewall products to be tobacco products.¹³¹ Assuming the products are not tobacco products, free samples of these products can be distributed.

standard canons of statutory construction militate against such a narrow reading of it. Under the presumption of meaningful variation, different statutory wording suggests different statutory meaning. *See, e.g., Lopez v. Gonzalez*, 549 U.S. 47, 55 (2006) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion") (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)). The fact that the free sampling provision specifically references "other tobacco products" strongly suggests that the sampling restriction should include them.

125. LESLIE ZELLERS & MIKE FREIBERG, COMMENT ON FDA DOCKET NO. FDA-2010-D-0277 4 (2011), available at <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fdacommments-cigarsinsamplingrestrictions-2011.pdf>.

126. *Id.*

127. 21 C.F.R. § 1140.3(i) (2010).

128. *See, e.g., Swedish Match Eyes Entry To New Snus Market in 2011*, DOW JONES NEWSWIRE (June 22, 2011), <http://online.wsj.com/article/BT-CO-20110622-708094.html>.

129. Duff Wilson, *Flavored Tobacco Pellets Are Denounced as a Lure to Young Users*, N.Y. TIMES, Apr. 19, 2010, <http://www.nytimes.com/2010/04/19/business/19smoke.html>.

130. Star Scientific, Inc., Registration Statement (Form S-3) (Apr. 20, 2011), available at <http://sec.gov/Archives/edgar/data/776008/000095012311037327/w81927sv3.htm>.

131. Peterson, *supra* note 34.

An exception further limits the effectiveness of the restriction on free samples. Under this exception, free samples of smokeless tobacco may be distributed in “qualified adult-only facilities.”¹³² A “qualified adult-only facility” must meet several specific criteria,¹³³ but it appears that the definition was written in contemplation of tobacco company sampling tents often seen at rodeos or motor racing events.¹³⁴ Although minors are not permitted in such facilities, young adults certainly may enter, as may minors if the provision prohibiting the presence of minors is not enforced. Because of the size and billboard-like nature of these tents, they can also serve functionally as advertising for smokeless tobacco companies, thus undermining existing restrictions on advertising that can be noticed by minors.¹³⁵

Furthermore, the free samples of tobacco distributed in a “qualified adult-only facility” are limited to one package containing 0.53 ounces (fifteen grams) of smokeless tobacco, or “eight individual portions” of smokeless tobacco, whichever weighs less.¹³⁶ Because of the incredibly low weight of many OTPs – in particular, dissolvable tobacco products – this provision has the potential to turn into a significant loophole. A package of twenty Stonewall dissolvable tobacco pellets, for example, weighs only 0.335 ounces, while a tin of fifteen pouches of Camel Snus weighs only 0.32 ounces.¹³⁷ Both are well under the 0.53 ounce limit.

Although the FDA’s narrow interpretation of the law and the exemption for qualified adult-only facilities limit the effectiveness of the free sampling provision, state and local governments can, should, and do fill the gap. At least nineteen states and the District of Columbia restrict the distribution of free samples in some way.¹³⁸ Unfortunately, many of the state and local

132. 21 C.F.R. § 1140.16(d)(2) (2010).

133. 21 C.F.R. § 1140.16(d)(2)(iii).

134. CRAIG DODGE ET AL., TOBACCO GIVEAWAYS IN CALIFORNIA 5 (2010), *available at* <http://www.bucktobacco.org/resources/pdf/SamplingReport-June2010.pdf>.

135. *See, e.g.*, SMOKELESS MASTER SETTLEMENT AGREEMENT, at III(d) (preventing certain smokeless tobacco manufacturers from erecting billboards), *available at* <http://ag.ca.gov/tobacco/pdf/1stmsa.pdf> (noting that although the FDA rule prohibits “tobacco product advertising” from being located on the exterior of these facilities, it does allow brand names to be displayed, with no limitation on size. 21 C.F.R. § 1140.16(d)(2)(iii)(F)(2011)).

136. 21 C.F.R. § 1140.16(d)(2)(iv) (2011).

137. CAMPAIGN FOR TOBACCO-FREE KIDS, *supra* note 106.

138. ARK. CODE § 5-27-227(F) (2009); CONN. GEN. STAT. § 12-314a (2011); D.C. CODE § 7-1731(2011); DEL. CODE ANN. tit. 11, §§ 1118, 1121, 1122 & 1123 (2011); IDAHO CODE § 39-5707 (2011); 720 ILL. COMP. STAT. 675/1 (2010); KY REV. STAT. § 438.313 (2011); ME. REV. STAT. tit. 22, § 1552 (2011); 940 CODE MASS. REG. § 21.04 (2011); MINN. STAT. § 325F.77 (2010); NEB. REV. STAT. §§ 69-1901 - 69-1904 (2010); N.H. REV. STAT. § 126-K:5 (2011); N.M. STAT. ANN. §§ 30-49-8 - 30-49-12 (2011); N.Y. PUB. HEALTH LAW § 1399-BB (2003); OR. REV. STAT. § 180.486(D) (2009); R.I. GEN LAWS § 11-9-13.10 (2001); TEX. HEALTH & SAFETY CODE § 161.087 (2011); UTAH CODE §§ 76-10-111 (2011); WASH. REV.

laws in place are flawed. One of the most notable flaws is the inconsistency of both the scope and effectiveness of these laws. For example, some of the laws apply only to products that are smoked or chewed,¹³⁹ or are even more limited.¹⁴⁰ Many laws also have exemptions that limit their effectiveness.¹⁴¹ The Smokeless Tobacco Master Settlement Agreement, which settled lawsuits between the major smokeless tobacco manufacturer and forty-five state attorneys general, also limits the distribution of free samples of smokeless tobacco.¹⁴² However, the settlement has at least three weaknesses: it applies only to products produced by manufacturers that participated in the agreement, it exempts adult-only facilities, and it exempts two-for-one offers.¹⁴³

Minnesota's free sample law is particularly instructive. Until August 2010, a law prohibiting the distribution of tobacco products "at no cost or at nominal cost for product promotional purposes"¹⁴⁴ applied only to tobacco products that can be smoked, as well as to "chewing tobacco or tobacco snuff." Although this latter term arguably included dissolvable tobacco products, the law was clarified in 2010 to ensure the product's inclusion.¹⁴⁵ Unfortunately, this change did not address all of the flaws with Minnesota's law. For example, the law still does not define the term "nominal cost," which could lead to attempts to circumvent the law or otherwise result in access to deeply discounted tobacco products. The law also contains an exemption for the distribution of "single serving samples of tobacco . . . in tobacco stores," but this exemption is likely superseded by the new federal regulation, except in tobacco stores that qualify as "qualified adult-only facilities."

To diminish the likelihood of tobacco usage initiation and continuation, state and local governments should prohibit the distribution of all free samples of OTPs and unapproved products delivering nicotine. This would have the effect of eliminating the exemption in the federal law for "qualified adult-only facilities." It is well within the authority of states to

CODE § 70.155.050 (2011); WIS. STAT. § 134.66 (2011).

139. See, e.g., CONN. GEN. STAT. § 12-314a.

140. See, e.g., NEB. REV. STAT. §§ 69-1901 - 69-1904 (smokeless tobacco only).

141. See, e.g., D.C. CODE § 7-1731 (tobacco stores, conventions, and conferences catering to adults); HAW. REV. STAT. § 328J-17 (private commercial establishments); 720 ILL. COMP. STAT. 675/1, WIS. STAT. § 134.66 (2007) (adult-only facilities); MINN. STAT. § 325F.77, subdiv. 4 (2010) (tobacco stores); N.H. REV. STAT. ANN. § 126-K:5 (adult-only facilities, licensed facilities, factory sites); N.Y. PUB. HEALTH LAW § 1399-bb (2003) (conventions, bars, and factories).

142. SMOKELESS MASTER SETTLEMENT AGREEMENT, *supra* note 135, at III(g).

143. *Id.*

144. MINN. STAT. § 325F.76-77 (2009).

145. 2010 Minn. Laws ch. 305 § 3, available at <https://www.revisor.mn.gov/data/revisor/law/2010/0/2010-305.pdf>.

adopt such a regulation. The TCA explicitly protects the ability of state and local governments to regulate “the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age.”¹⁴⁶

Furthermore, the authority of state and local governments to adopt regulations pertaining to OTPs may be even more unquestionable than their ability to regulate cigarettes. The Federal Cigarette Labeling and Advertising Act (FCLAA) prohibits state and local governments from adopting any “requirement or prohibition based on smoking and health . . . with respect to the advertising or promotion of any” properly labeled cigarettes.¹⁴⁷ Although the TCA relaxed this preemption to allow state and local governments to adopt “specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes,”¹⁴⁸ this provision still acts as a check on the ability of state and local governments to adopt regulations relating to the marketing of cigarettes. The ability of state and local governments to regulate non-cigarette tobacco products has no comparable limitation. Regulations on OTPs are limited only by the First Amendment and other constitutional provisions.¹⁴⁹

3. Coupons, Discounts, and Rebates

The federal tobacco marketing regulation does not define the term “free samples.” This phrase has been interpreted narrowly,¹⁵⁰ leading to increased access to the products and low prices manifested through sales techniques including coupons, rebates, and two-for-one offers. The only restriction on coupons in the regulation is a prohibition on the mail-order redemption of coupons.¹⁵¹

Tobacco manufacturers use coupons and other price-related incentives to make their products more attractive to consumers,¹⁵² particularly young

146. 21 U.S.C. § 387p(a)(1) (2009).

147. 15 U.S.C. § 1334(b) (2009).

148. *Id.* § 1334(c).

149. It should be acknowledged that this can represent a high barrier to regulation. *See, e.g.,* *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (striking down Massachusetts regulations on the marketing of non-cigarette tobacco products as violative of the First Amendment). The price restrictions discussed in this section of this article would presumably not raise the specter of First Amendment invalidation to the same extent as the marketing restrictions in *Lorillard*.

150. This interpretation may stem from the Smokeless Tobacco Master Settlement Agreement, which prohibits free samples of tobacco products, but explicitly exempts “a free offer in connection with the purchase of Tobacco Products, such as a ‘two-for-one’ offer.” SMOKELESS MASTER SETTLEMENT AGREEMENT, *supra* note 135, at III(g).

151. 21 C.F.R. § 1140.16(c)(2)(i) (2011).

152. According to a 1994 U.S. Surgeon General’s report, the use of coupon promotions

consumers, and to dull the effects of rising tobacco taxes. In recent years, the tobacco industry has spent staggering sums on price-related strategies such as coupons and value-added discounts.¹⁵³ In 2006 alone, smokeless tobacco companies spent sixty-nine percent, or \$246 million, of their advertising and promotional expenditures on price-related strategies such as promotional allowances, coupons, retail valued-added programs, and price discounts.¹⁵⁴

Although some states regulate the use of coupons for tobacco products,¹⁵⁵ they appear to be a small minority of jurisdictions and the effectiveness of the regulations varies. Approximately half the states also have minimum price laws.¹⁵⁶ However, most of these laws apply only to cigarettes, and many have loopholes that undermine their effectiveness.¹⁵⁷ Minnesota, for example, has a law in place prohibiting the sale of cigarettes below their wholesale cost.¹⁵⁸ However, the law applies only to cigarettes, and it contains exceptions for “isolated” transactions, “bona fide clearance” sales, and damaged goods.¹⁵⁹ The availability of heavily discounted OTPs represents a severe gap in regulation and a public health hazard, particularly among youth.

Restricting or prohibiting the redemption of coupons for OTPs is an effective policy approach for state and local government to consider.¹⁶⁰ While increasing tobacco taxes may be the most effective price control strategy to reduce tobacco use, local governments frequently do not have

makes cigarettes appear more affordable to smokers with limited economic resources, including children. Evidence suggests that coupons also encourage new smokers to smoke more often, thereby entrenching their habit. See U.S. DEP'T OF HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL (1994), available at <http://profiles.nlm.nih.gov/ps/access/NNBCLQ.pdf>; Frank J. Chaloupka, *The Impact of Retail Marketing Practices on Youth Smoking Update*, 161 ARCHIVES OF PEDIATRICS & ADOLESCENT MED. 440 (2007).

153. April Roeseler et al., *Tobacco Marketing in California and Implications for the Future*, 19 TOBACCO CONTROL i21, i22 (2010).

154. *Id.*

155. See CAL. HEALTH & SAFETY CODE § 118950 (West 2011); HAW. REV. STAT. § 328J-17(a) (2009); MD. CODE ANN. CRIM. LAW. § 10-107(a) (West 2011); TEX. HEALTH & SAFETY CODE ANN. § 161.087(a) (West 2011); see also MIURA, *supra* note 22, at 3.

156. CTRS. FOR DISEASE CONTROL & PREVENTION, STATE CIGARETTE MINIMUM PRICE LAWS – UNITED STATES, 2009, 59(13) MORBIDITY & MORTALITY WEEKLY REPORT 389, 389 (2010), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5913.pdf>.

157. MIURA, *supra* note 22, at 4.

158. MINN. STAT. § 325D.33 (2010).

159. MINN. STAT. § 325D.36 (2010).

160. Another policy option would be to prohibit the *distribution* of coupons. If adopted at the state or local level, however, such a regulation may raise issues with the dormant commerce clause. See TOBACCO CONTROL LEGAL CONSORTIUM, TOBACCO COUPON REGULATIONS AND SAMPLING RESTRICTIONS 4 (2011), available at <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-guide-tobcouponregsandsampling-2011.pdf>.

taxation authority and tax increases may be controversial. Coupon restrictions may be a more politically palatable approach that can be adopted by local governments as well as state governments. Further, for the reasons stated in the above discussion of restrictions on the distribution of free samples, FCLAA preemption is not a concern if such a regulation applied only to non-cigarette tobacco products.

4. Minimum Pack Size

Another regulatory gap affecting the price of OTPs is the lack of a minimum pack size. If tobacco products are sold individually, the price of the products is lower than when the products are sold as part of a pack, increasing the possibility of youth tobacco use. For this reason, the federal tobacco marketing regulation prohibits the sale of cigarettes in packages containing fewer than twenty cigarettes.¹⁶¹ Single cigarette sales have been shown to appeal to minors because of their low price, and have the potential to lead to tobacco initiation.¹⁶²

Unfortunately, no comparable restriction exists for non-cigarette tobacco products. In Minnesota, for example, Stonewall brand dissolvable tobacco tablets are sold in packs of five for \$1.49.¹⁶³ This price may be considerably more appealing to a young person than the price of a pack of premium brand cigarettes – typically at least five dollars. The ability of cash-strapped young people to purchase a small number of OTPs at a lower price than an expensive pack of cigarettes represents another public health risk.

To combat price disparities caused by small packs of OTPs, state and local governments should adopt regulations creating a minimum pack size for OTPs sold in discrete units. Such a regulation may not be well suited to non-cigarette tobacco products not sold in discrete or single-dose units, such as moist snuff or water pipe tobacco. However, such a restriction would work well for products like dissolvable tobacco products and snus. It would also work well for little cigars, although policymakers may want to exempt premium cigars, which are often sold singly. A minimum pack size requirement would be one effective option to ensure that many OTPs have a price that is compatible with cigarettes.

161. 21 C.F.R. § 1140.16(b) (2010).

162. See, e.g., Landrine et al., *Minors' Access to Single Cigarettes in California*, 4 PREVENTATIVE MED. 503, 503 (1998), available at <http://www.ncbi.nlm.nih.gov/pubmed/9672942>.

163. FREIBERG, *supra* note 81, at 10.

B. Flavoring

1. Fruit, Candy, and Alcohol Flavors

Price is not the only area where the regulation of OTPs lags behind the regulation of cigarettes. OTPs are still sold in flavors such as fruit, candy, or alcohol. It has been well established that these flavors increase the appeal of tobacco products among youth, which can potentially lead to tobacco initiation. In the context of cigarettes, documents uncovered in tobacco litigation demonstrate that tobacco manufacturers use these flavors “as a way to target youth.”¹⁶⁴

In 2006, thirty-nine states’ attorneys general settled an investigation into potential violations by R.J. Reynolds of the 1998 Master Settlement Agreement between forty-six states and the major cigarette manufacturers.¹⁶⁵ R.J. Reynolds had been targeting youth by selling various candy, fruit, and alcohol flavored cigarettes. As part of the 2006 settlement, R.J. Reynolds agreed not to sell cigarettes containing flavors currently seen in many OTPs. Specifically, R.J. Reynolds agreed not to sell cigarettes containing flavors such as cocoa, cacao, mocha, cinnamon, and mint (excluding menthol).¹⁶⁶

More recently, the TCA prohibited tobacco manufacturers from including a “characterizing flavor” in cigarettes, with the exception of menthol and tobacco flavors.¹⁶⁷ The law does not prohibit these flavors in non-cigarette tobacco products.¹⁶⁸ Indeed, the use of such flavors in each of the studied product types has been well documented. Stonewall brand dissolvable tobacco tablets come in cinnamon, citrus, java, mint, and wintergreen flavors.¹⁶⁹ Electronic cigarettes are sold in flavors like strawberry and chocolate.¹⁷⁰ Many products that can be termed little cigars

164. KATHLEEN DACHILLE, TOBACCO CONTROL LEGAL CONSORTIUM, PICK YOUR POISON: RESPONSES TO THE MARKETING AND SALE OF FLAVORED TOBACCO PRODUCTS 2 (2009), available at <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-syn-flavored-2009.pdf>.

165. Bloomberg News, *RJR Agrees to Stub Flavored Smokes*, NEWSDAY (Oct. 12, 2006), <http://www.newsday.com/business/technology/rjr-agrees-to-stub-flavoredsmokes-1.656018>.

166. R.J. REYNOLDS SETTLEMENT AGREEMENT 3-4 (2006), available at http://www.illinoisattorneygeneral.gov/pressroom/2006_10/flavored_settlement_final.pdf.

167. 21 U.S.C. § 387g(a)(1) (2009).

168. *See id.* § 387g.

169. *Testimony of Curtis Wright Before the Tobacco Products Scientific Advisory Committee*, FDA.GOV 45 (July 21, 2011), <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM270282.pdf>.

170. Nathan K. Cobb et al., *Novel Nicotine Delivery Systems and Public Health: The Rise of the “E-Cigarette”* 100 AM. J. OF PUB. HEALTH 2340, 2341 (2010).

are sold in flavors including wine, sweet, peach, grape, and strawberry.¹⁷¹ Marlboro Snus comes in spearmint, peppermint, and “Rich” flavors.¹⁷² Tobacco smoked in water pipes regularly comes in flavors such as fruit, mint, and vanilla.¹⁷³

Star Scientific, Inc., the maker of the dissolvable tobacco products Ariva and Stonewall, acknowledged in a comment to the FDA that fruit flavors do appeal to children. However, the company states in a conclusory manner that “standard adult flavors [such as] cinnamon, citrus, coffee, peppermint, spearmint, [and] wintergreen” should be allowed.¹⁷⁴ This self-serving statement should not be taken at face value. Flavored tobacco products – and the marketing accompanying them – have an obvious appeal to youth¹⁷⁵ and pose a serious risk to public health. Congress has determined that cigarettes should not contain characterizing flavors with the exception of tobacco and menthol, and it is a logical extension of this policy for state and local governments to prohibit the sale of OTPs containing these same flavors.

Although state and local units of government have the authority to prohibit the sale of flavored OTPs, few governments have attempted to do so. New York City has an ordinance in place which prohibits the sale of tobacco products with a characterizing flavor other than menthol, mint, or wintergreen, except in certain “tobacco bars.”¹⁷⁶ The Southern District of New York recently ruled in favor of New York City, finding that the ordinance was not a tobacco product standard that would be preempted by the TCA.¹⁷⁷ Rather, it was deemed an allowable sales restriction.¹⁷⁸

171. See, e.g., *New Products (Swisher Sweets Cigarillos)*, CONVENIENCE STORE NEWS (Dec. 6, 2010), http://www.csnews.com/article-new_products-1345.html.

172. Dorothy K. Hatsukami et al., *Oral Tobacco Products: Preference and Effects Among Smokers*, 118 DRUG & ALCOHOL DEPENDENCE 230, 231 (2011).

173. See Melissa D. Blank et al., *Acute Effects of Waterpipe Tobacco Smoking: A Double-Blind, Placebo-Control Study*, 116 DRUG & ALCOHOL DEPENDENCE 102, 103 (2010).

174. STAR SCIENTIFIC, INC., COMMENT ON FDA DOCKET NO. FDA-2010-N-0123 – IMPACT OF DISSOLVABLE TOBACCO USE ON PUBLIC HEALTH, REQUEST FOR COMMENTS 44 (2010), available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteeMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM263306.pdf>.

175. See, e.g., DACHILLE, *supra* note 164.

176. N.Y.C. CODE § 17-713, 715 (West 2010).

177. See *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 703 F. Supp. 2d 329 (S.D.N.Y. 2010); Heather May, *Lawmaker Wants to Ban Flavored Tobacco Products*, SALT LAKE TRIB. (Aug. 19, 2010, 7:47 PM), <http://archive.sltrib.com/article.php?id=10715208&ittype=storyID&keyword=Lawmaker+Wants+to+Ban+Flavored+Tobacco+Products&sdate=2010-08-08&edate=2011-10-08&qtype=all>; see also Mark Hamblett, *Judge Turns Aside Challenge to City Ban on Flavored Tobacco*, LAW.COM (Nov. 18, 2011), <http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1202532829501> (reporting that a Southern District of New York judge recently denied the tobacco companies’ motion for summary judgment and also dismissed the complaint).

For this reason, any state or local government contemplating a restriction on flavored OTPs would be well-served to make it a sales restriction rather than a manufacturing restriction. Exempting a limited number of facilities from the sales restriction, as New York City has done with tobacco bars,¹⁷⁹ may further buttress the characterization of the law as a sales restriction rather than a preempted product regulation. Further, the state or local government would be well-served *not* to include cigarettes in this sales restriction, thus regulating only OTPs. Most flavored cigarettes are already prohibited by the TCA.¹⁸⁰ Any flavored cigarette sold in violation of this federal prohibition would be considered an “adulterated” tobacco product under the TCA.¹⁸¹ The TCA gives the federal government sole authority to regulate adulterated tobacco products.¹⁸² It is therefore possible that a state or local restriction on the sale of flavored OTPs and cigarettes would be found to be preempted, so it is advisable that the ordinance regulate only flavored OTPs.

2. Menthol

Menthol is an additive with cooling, analgesic, and irritative properties that is used in many products.¹⁸³ In the tobacco realm, it is used most often in cigarettes.¹⁸⁴ Although menthol is added to most cigarettes in small quantities, in some cigarettes, the quantity is sufficient for menthol to become a “characterizing flavor.”¹⁸⁵ Menthol has been found to have “drug like characteristics that modulate the effects of nicotine on the smoker,” in addition to sensory effects which potentially increase the addictiveness of tobacco.¹⁸⁶ Although manufacturers of menthol cigarettes claim that they do not target low income and African-American communities with these products, evidence indicates otherwise.¹⁸⁷ Indeed,

178. *U.S. Smokeless Tobacco*, 703 F. Supp. 2d at 348; *see generally* 21 U.S.C. § 387p(a)(1) (2009).

179. N.Y.C. CODE § 17-715 (West 2010).

180. 21 U.S.C. § 387g(a)(1) (2009).

181. *Id.* § 387b(5).

182. *Id.* § 387p(a)(2)(A).

183. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMM., MENTHOL CIGARETTES AND PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND RECOMMENDATIONS 2 (2011) [hereinafter MENTHOL CIGARETTES REPORT], *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247689.pdf>.

184. *Id.* at 1.

185. *Id.* at 2.

186. *Id.* at 26-28.

187. LISA HENRIKSEN ET AL., NICOTINE & TOBACCO RES., TARGETED ADVERTISING, PROMOTION, AND PRICE FOR MENTHOL CIGARETTES IN CALIFORNIA HIGH SCHOOL NEIGHBORHOODS 1 (June 24, 2011) (on file with the Nicotine & Tobacco Research Journal).

over seventy percent of African-American smokers prefer menthol cigarettes.¹⁸⁸ Menthol cigarettes have also been found to increase the addiction potential of smoking among youth.¹⁸⁹ For these and other reasons, the congressionally authorized committee charged with issuing a recommendation on menthol cigarettes¹⁹⁰ concluded that “[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States.”¹⁹¹ Yet the TCA explicitly exempts menthol from its prohibition on cigarettes containing characterizing flavors, leaving the ultimate decision on menthol to the FDA,¹⁹² or to states and cities.

Although menthol as a characterizing flavor is typically discussed in the context of cigarettes, the flavor also raises issues in the context of non-cigarette tobacco products. First, some brands of little cigars are regularly sold in menthol flavors.¹⁹³ Menthol flavors of snus¹⁹⁴ and water pipe tobacco¹⁹⁵ can also be found online. Second, not only does the TCA exempt menthol from its prohibition on flavored cigarettes, but New York City’s ordinance restricting the sale of flavored OTPs also exempts OTPs with a menthol flavoring (as well as mint and wintergreen).¹⁹⁶

This exemption is both unnecessary and unwise. In light of the serious adverse public health effects of menthol, state and local governments should consider prohibiting the sale of OTPs containing any characterizing flavor, including menthol. Although any such regulation would likely lead to litigation, it is likely that a court would find such a regulation to be an acceptable sales restriction,¹⁹⁷ provided it is drafted in a way that addresses potential preemption concerns.

Since the FDA does not currently regulate the use of menthol as a characterizing flavor in either cigarettes or OTPs, a state or local government could prohibit the sale of all tobacco products containing menthol as a characterizing flavor. Because neither the TCA nor the FDA

188. Philip Gardiner, *The African Americanization of menthol cigarette use in the United States*, 6 NICOTINE & TOBACCO RES. S55, S55 (2004).

189. James C. Hersey et al., *Menthol cigarettes contribute to the appeal and addiction potential of smoking for youth*, 12 NICOTINE & TOBACCO RES. S136, S136 (2010).

190. 21 U.S.C. § 387g(e)(2) (2009).

191. MENTHOL CIGARETTES REPORT, *supra* note 183, at 208.

192. 21 U.S.C. § 387g(a)(1)(A) (2009).

193. See, e.g., *Remington Filter Cigarettes*, GOODTIMESTOBACCO.NET, http://www.goodtimestobacco.net/#!__main-pages/vstc3=remington-filter-cigars (last visited Aug. 5, 2011).

194. See, e.g., *The Northern Citrus and Menthol*, NORTHERNER.COM, [http://www.northerner.com/en/snus/NorthernerPurified_Portion-320/Oomph%20Citrus%20&%20Menthol,%20\(6mg\)-2072/](http://www.northerner.com/en/snus/NorthernerPurified_Portion-320/Oomph%20Citrus%20&%20Menthol,%20(6mg)-2072/) (last visited Aug. 5, 2011).

195. See, e.g., *Hookah Hookah Tobacco*, RYOCIGARETTE.COM, <http://www.ryocigarette.com/i1.html> (last visited Aug. 5, 2011).

196. N.Y.C. CODE § 17-715, 717 (West 2010).

197. 21 U.S.C. § 387p(a)(1) (2009).

prohibits the sale of menthol-flavored cigarettes,¹⁹⁸ menthol cigarettes are not considered an adulterated tobacco product.¹⁹⁹ Since a local regulation restricting the sale of menthol cigarettes would not be a regulation concerning an adulterated tobacco product, it would not be preempted on that basis.²⁰⁰ Therefore, a state or local restriction on the sale of menthol tobacco products could target both cigarettes and OTPs.

If, however, the FDA decides at some point in the future to prohibit the manufacture or sale of menthol-flavored cigarettes,²⁰¹ or otherwise restrict the products, it is possible that state or local regulation of the same products would be preempted. It is therefore advisable for a state or local government to include a “sunset” clause in any such regulation. Under this provision, the state or local regulation of menthol-flavored cigarettes would remain in effect until the FDA chooses to regulate the products and such federal regulation has gone into full force and any potential stay has been lifted. The provision relating to menthol-flavored OTPs could have a separate sunset clause where the regulation would remain in effect until the FDA regulates menthol-flavored OTPs and that federal regulation has gone into full effect. Although this seems like a much more distant possibility, the provision would ensure there is no conflict in the future.

C. Youth Access

Before June 2010, it was unclear as to whether minors could purchase many non-cigarette tobacco products. State and local youth access laws had too often failed to account for many of these products. In at least ten states, youth access laws suffered from the same deficiency as the tax laws in many states: the youth access laws applied only to products that are smoked, chewed, and/or sniffed.²⁰²

On June 22, 2010, however, a nationwide standard for youth access to some tobacco products took effect.²⁰³ This rule made it illegal for retailers to “sell cigarettes or smokeless tobacco to any person younger than eighteen years of age.”²⁰⁴ “Smokeless tobacco” includes “cut, ground, powdered, or

198. *Id.* § 387g(a)(1)(A).

199. *Id.* § 387b(5).

200. 21 U.S.C. § 387p(a)(2)(A) (2009).

201. The Tobacco Control Act discusses menthol exclusively in the context of cigarettes. *Id.* § 387g(e). Therefore, it seems unlikely that the FDA will regulate menthol-flavored OTPs in the near future, although it does have the authority to do so.

202. ARIZ. REV. STAT. ANN. § 13-3622 (West 2010); COLO. REV. STAT. § 24-35-502(6) (2010); FLA. STAT. § 569.002(6) (2011); IND. CODE § 35-46-1-1.7 (2010); IOWA CODE § 453A.1(26) (2010); KAN. STAT. ANN. § 79-3301 (2010); N.D. CENT. CODE § 12.1-31-03 (2007); R.I. GEN. LAWS § 11-9-13 (2010); VT. STAT. ANN. tit. 7, § 1001(3) (2010); WIS. STAT. § 134.66(1)(j) (2010).

203. 21 C.F.R. § 1140 (2010).

204. *Id.* § 1140.14(a).

leaf tobacco . . . that is intended to be placed in the oral or nasal cavity.”²⁰⁵

Unfortunately, this new federal law also potentially excludes most of the products examined in this article. First, although it would seem that dissolvable tobacco products should fall into this definition of “smokeless tobacco,” the FDA’s decision not to regulate Ariva-BDL and Stonewall-BDL²⁰⁶ casts some doubt on this assumption – at least as far as those two products are concerned and at least until the FDA reverses this decision. Second, despite the FDA’s recent announcement that it would regulate electronic cigarettes as tobacco products,²⁰⁷ it seems doubtful that an electronic cigarette would meet either definition. Little cigars and products smoked in water pipes are neither smokeless tobacco nor cigarettes, so they would clearly not be included. The only product mentioned in this article that would likely qualify would be snus, which presumably meets the definition of smokeless tobacco.

Although the FDA has the authority to exercise jurisdiction over other products,²⁰⁸ it has yet to do so. Further, many existing state and local youth access laws are not written comprehensively. It is troubling that minors can potentially purchase these OTPs legally, and state and local governments should, therefore, adopt stronger youth access laws to fill this regulatory gap until the FDA takes action.

Once again, Minnesota’s youth access statutes present an interesting case study. Prior to 2010, it was illegal to sell tobacco to minors only if it was “prepared in such manner as to be suitable for chewing or smoking.”²⁰⁹ As a result, products like dissolvable tobacco products, e-cigarettes, and snus were at least arguably legal for minors to purchase. In 2010, the legislature updated the statute so that it was no longer so narrow,²¹⁰ ensuring that products like dissolvable tobacco products and snus were included.

The same legislation created a new statute making it illegal to sell or provide to a minor any product delivering nicotine or lobelia²¹¹ that is not an FDA-approved cessation product, or for a minor to possess or attempt to purchase any such product.²¹² This statute covers not only e-cigarettes, but new, unapproved nicotine delivery products, such as nicotine balms or

205. *Id.* § 1140.3(i).

206. *See* Letters from Deyton to Perito, *supra* note 35.

207. Letter from Deyton to Stakeholders, *supra* note 47.

208. 21 U.S.C. § 387a(b) (2009).

209. MINN. STAT. § 609.685 (2009), *amended by* 2010 Minn. Laws ch. 305, sec. 11.

210. 2010 Minn. Laws ch. 305, sec. 11.

211. Lobelia is an herbal product similar to nicotine that has been found in some e-cigarettes. *See* Letter from Michael Levy, Division Director of FDA, to William Bartkowski, President, of Ruyan America (Sept. 8, 2010), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm225181.htm>.

212. MINN. STAT. ANN. § 609.6855 (West 2010).

nicotine lollipops.²¹³

Because this provision is in a new statute, it is not contained within Minnesota's existing youth access statutes.²¹⁴ As a result, some provisions of the youth access laws do not apply to electronic cigarettes. This includes the restriction on the self-service of tobacco products,²¹⁵ a policy option recommended by the U.S. Surgeon General.²¹⁶

States and local governments should update their youth access laws to ensure that they encompass a broad range of tobacco products and products containing nicotine, while excluding products authorized by the FDA as pharmaceutical products. It does not appear that they need to create a separate statute for e-cigarettes and other unapproved nicotine delivery devices, as Minnesota did in 2010. Rather, these products should be included within existing youth access statutes.

Another policy option related to youth access available to state and local governments involves the minimum age to purchase tobacco products. Under the TCA, the FDA cannot raise the minimum legal age to purchase tobacco products beyond eighteen.²¹⁷ Because this authority is specifically excluded from federal regulation, there is little risk of preemption if a state or local government were to take this action.²¹⁸ Given the high rates of tobacco use of young adults,²¹⁹ state and local governments may want to consider such a policy, as some states already have.²²⁰

D. Use Restrictions

The type of tobacco regulation that typically generates the most publicity is a restriction on use – most often in the form of a smoke-free law. As its name implies, these laws apply only to products that are smoked.

213. See, e.g., *FDA stops nicotine lollipop, lip balm sales*, CNN.COM (Apr. 10, 2002), http://articles.cnn.com/2002-04-10/health/nicotine.lollipops_1_nicotine-lip-lip-balm-nicotine-lollipops?_s=PM:HEALTH.

214. See, e.g., MINN. STAT. ANN. § 461.12 (West 2010).

215. *Id.* § 461.18.

216. YOUTH & TOBACCO: PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GEN. 162 (1994), available at <http://profiles.nlm.nih.gov/ps/access/NNBCLQ.pdf>.

217. 21 U.S.C. § 387f(d)(3)(A)(ii) (2009).

218. See also *id.* § 387 p(a)(1) (preserving right of state and local governments to adopt regulations relating to access to tobacco products by individuals of any age).

219. See, e.g., MINNESOTA ADULT TOBACCO SURVEY, CIGARETTE SMOKING AND SECONDHAND SMOKE EXPOSURE AMONG ADULT MINNESOTANS CONTINUE TO DECLINE 3 (2010), available at <http://mntobacco.nonprofitoffice.com/vertical/Sites/%7B988CF811-1678-459A-A9CE-34BD4C0D8B40%7D/uploads/%7B7CA6AA41-89A6-4701-BB43-C54E32FA157B%7D.PDF> (“smokeless tobacco users tend to be younger”).

220. See, e.g., ALASKA STAT. ANN. § 11.76.100(a)(2) (West 2010) (minimum age of 19 to purchase tobacco); N.J. STAT. ANN. § 2A:170-51.4 (West 2006) (same); UTAH CODE ANN. § 76-10-104 (LexisNexis 2010) (same).

It is easy to determine whether some of the studied products are encompassed by typical smoke-free laws. Little cigars would clearly be included, since they are tobacco products that are smoked. Dissolvable tobacco products and snus, in contrast, would clearly not be encompassed by smoke-free laws, since neither product is smoked. There may be reasons to include these products in use restrictions, such as providing appropriate role models to youth.²²¹ Indeed, some use restrictions, especially park and school policies, are beginning to take the form of tobacco-free laws, rather than smoke-free laws.²²²

Although it seems like it should be straightforward to determine which products are and should be encompassed by a smoke-free law, it does not always occur. Electronic cigarettes pose one problem. Many smoke-free laws define the act of “smoking” as inhaling or carrying a lighted tobacco or plant product intended for inhalation.²²³ Yet e-cigarettes are not burned; rather, they are “vaped.” Consequently, it is doubtful that most smoke-free laws prohibit the use of e-cigarettes.

However, there are reasons to prohibit the use of e-cigarettes in public. First, the health effects of nicotine-infused water vapor being expelled into the air are poorly understood at best, and may, in fact, be harmful.²²⁴ In addition, the use of e-cigarettes may complicate the enforcement of smoke-free laws. E-cigarettes are constructed to physically resemble actual cigarettes, down to the use of an LED light designed to resemble a lit cigarette. Using e-cigarettes in public may lead people to believe no smoke-free law exists. It is perhaps for this reason that several smoke-free laws now also prohibit the use of e-cigarettes²²⁵ and some advocacy

221. Jean Forster, *Policy Approaches to Reducing Adolescent Tobacco Use*, 1 HEALTHY GENERATIONS 1, 10 (2000), available at http://www.epi.umn.edu/mch/assets/downloads/hg_tobacco.pdf.

222. See, e.g., *Tobacco-Free Outdoor Recreational Area Policies in Minnesota*, TOBACCO FREE PARKS, <http://www.tobaccofreeparks.org/directory.html> (last visited Aug. 5, 2011); *Model Policy for a Tobacco-free Environment in Minnesota's K-12 Schools*, PUB. HEALTH L. CENTER, available at http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-modeltobaccofreek-12policy-qanda-2011_0.pdf.

223. See, e.g., MINN. STAT. § 144.4134(4) (2010) (defining “smoking” as “inhaling or exhaling smoke from any lighted cigar, cigarette, pipe, or any other lighted tobacco or plant product . . . [or] carrying a lighted cigar, cigarette, pipe, or any other lighted tobacco or plant product intended for inhalation”).

224. Advocates for e-cigarette use maintain that the vapor expelled by the products is not harmful. See, e.g., *Electronic Cigarettes Face Smoking Bans*, CONVENIENCE STORE NEWS (June 6, 2011), available at http://www.csnews.com/top-story-electronic_cigarettes_face_smoking_bans-58848.html. However, the distinction between a self-serving statement made by an interest group and a peer-reviewed scientific study should be readily apparent.

225. See, e.g., N.J. STAT. ANN. 26:3D-57 (2010); see also Roger Yu, *Federal regulators to formally ban e-cigarette use on planes*, USA TODAY, Feb. 11, 2011.

organizations recommend that their use be prohibited in public.²²⁶

Water pipes also create three distinct problems. First, if a non-tobacco product is smoked in a water pipe, it is permissible in public under a law that defines “smoking” in terms of tobacco products only.²²⁷ Second, many smoke-free laws prohibit only the direct burning of a tobacco or plant product.²²⁸ Water pipes, however, indirectly heat the tobacco over a flame.²²⁹ Smoking the products may therefore not be prohibited under many smoke-free laws. Finally, many smoke-free laws contain exemptions for establishments that primarily sell tobacco and related products.²³⁰ In states with laws that contain such an exemption, many so-called “hookah bars” have opened, arguing that they fall within the exemption.²³¹ Some jurisdictions even explicitly exempt hookah bars.²³² This is a serious loophole in the law that jeopardizes public health.²³³

To address these health concerns, state and local units of government should adopt smoke-free laws that broadly define smoking as the direct burning or indirect heating of any tobacco and plant product intended for inhalation, as well as the use of e-cigarettes. Governments considering these laws should not exempt tobacco product shops because such an exemption creates the possibility of a serious loophole. Finally, governments should consider prohibiting all tobacco use, not merely the use of combustible tobacco products, particularly in areas frequented by youth.²³⁴ To encourage smoking cessation, any such policy should exempt

226. 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>.

227. See, e.g., FLA. STAT. § 386.203(10) (2010).

228. See, e.g., MINN. STAT. § 144.413(4) (2010).

229. Martinasek, *supra* note 67, at 34.

230. See, e.g., MINN. STAT. § 144.4167(4) (2010).

231. See, e.g., Robert Channick, *Hookah Lounges Thriving, Three Years After Smoking Ban*, CHI. TRIB., Apr. 13, 2011, http://articles.chicagotribune.com/2011-04-13/news/ct-x-n-hookah-lounges-20110413_1_hookah-lounges-friends-cafe-and-lounge-public-places; Melissa Navas, *Hookah Smoking Rises in Popularity Among Oregon Youths, New Study Finds*, THE OREGONIAN, Nov. 9, 2010, http://www.oregonlive.com/health/index.ssf/2010/11/hookah_smoking_rises_in_popula.html.

232. See, e.g., Devon Noonan, *Exemptions for Hookah Bars in Clean Indoor Air Legislation: A Public Health Concern*, 27 PUB. HEALTH NURSING 49 (2010).

233. WORLD HEALTH ORG., *supra* note 64.

234. One setting where a state or local tobacco-free policy might be particularly welcome in the United States is in baseball stadiums. Numerous articles have highlighted the deleterious effects of visible smokeless tobacco use by Major League Baseball players, who serve as role models to many children. See, e.g., Karen Herzog, *Group urges smokeless tobacco ban for teams*, MILWAUKEE J. SENTINEL, March 31, 2011. Yet it does not appear that Major League Baseball is willing to take steps to curb the use of these products. State and local governments can fill this policy vacuum. Because ballplayers typically use spit tobacco, i.e. moist snuff, as opposed to the novel tobacco products highlighted in this article, this policy option is consigned to a footnote.

products that the FDA has approved as cessation aids,²³⁵ unless the use of such products would complicate enforcement.

IV. OPPORTUNITIES FOR REGULATION

In some areas, federal laws limit the authority of state and local governments to regulate cigarettes, but have no comparable limitation on the ability of these governments to regulate OTPs. These areas, which will be discussed next, include point-of-sale warnings, marketing restrictions, and category prohibition.

A. Point-of-Sale Warnings

One area where state and local governments may have an opportunity to regulate OTPs involves the posting of health warnings at the point of sale. New York City recently adopted an ordinance requiring that any tobacco retailer post graphic signs wherever tobacco products are sold to display the health risks of tobacco use.²³⁶ Although the ordinance was phrased in terms of all tobacco products, the New York City Department of Health issued three signs that focused exclusively on the dangers of smoking.²³⁷ These warnings include pictures of diseased lungs, decayed teeth, and human brains damaged by tobacco-induced strokes.²³⁸ These images are not included for shock value; studies reveal that graphic warnings create an emotional response which leads to greater memory of the health risks associated with smoking.²³⁹ Additionally, these graphics are better understood by individuals with poor reading comprehension skills.²⁴⁰

Tobacco manufacturers challenged the New York City ordinance, arguing that it violated their First Amendment protections for commercial speech and that it was preempted by the FCLAA.²⁴¹ At the time the New York City ordinance was adopted, the FCLAA prohibited state governments from adopting any “requirement or prohibition based on smoking and health . . . with respect to the advertising or promotion of any cigarettes” that are properly labeled.²⁴² The District Court judge declined to issue a ruling on the First Amendment question, but held that the ordinance

235. 21 U.S.C. § 387k (2009).

236. N.Y.C. Code § 181.19(a) (2010).

237. 23-34 94th St. Grocery Corp. v. New York City Bd. of Health, 757 F. Supp. 2d 407, 409 (S.D.N.Y. 2010).

238. *Id.*

239. See Hammond et al., *Text & Graphic Warnings on Cigarette Packages: Findings from the Int'l Tobacco Control Four Country Study*, 32 AM. J. PREVENTATIVE MED. 210, 215, 224 (2007).

240. *Id.*

241. 94th St. Grocery Corp., 757 F. Supp. 2d 407 at 410; 15 U.S.C. § 1334(b) (2010).

242. 15 U.S.C. § 1334(b) (2009).

was preempted by FCLAA as “a requirement with respect to promotion of cigarettes.”²⁴³ The litigation has not concluded and is currently on appeal in the Second Circuit Court of Appeals.²⁴⁴

Although this decision was disappointing to tobacco control advocates, it does actually present an opportunity. As its name implies, the FCLAA applies only to warning label requirements and advertising restrictions related to cigarettes. There is no comparable preemptive law relating to OTPs. Therefore, state and local governments can require tobacco retailers to post health warnings at the point of sale wherever non-cigarette tobacco products are sold without any concerns of federal preemption.

Policy arguments would support a state and local regulation requiring the posting of point-of-sale health warnings where OTPs are sold, even if they are not required where only cigarettes are sold. Federal regulations require that cigarette packages sold in the U.S. after September 2012 contain a color image graphically depicting the health effects of smoking.²⁴⁵ These warnings must occupy at least fifty percent of the front and rear panel of each cigarette package, as well as the top twenty percent of each cigarette advertisement.²⁴⁶

In contrast, federally mandated warning labels for OTPs²⁴⁷ are not nearly as effective.²⁴⁸ The warning labels for smokeless tobacco are text-only and required to cover only thirty percent of the two principal display panels.²⁴⁹ Further, as mentioned previously, snus is the only product highlighted in this article that clearly meets the TCA definition of “smokeless tobacco.” Consequently, the TCA requires no warning labels for dissolvable tobacco

243. *94th St. Grocery Corp.*, 757 F. Supp. 2d 407 at 412.

244. See, e.g., Brief of *Amici Curiae* Tobacco Control Legal Consortium, et al., in Support of Appellants, 23-34 94 St. Grocery Corp. v. New York City Bd. of Health, No. 11-0091-CV (2nd Cir. April 15, 2011).

245. Required Warnings for Cigarette Packages and Advertisements, 76 FED. REG. 36,628, 36,676 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141); but see Rob Stein, *Graphic cigarette warnings blocked by judge*, WASH. POST (Nov. 7, 2011), http://www.washingtonpost.com/national/health-science/graphic-cigarette-warning-labels-blocked-by-judge/2011/11/07/gIQAglidvM_story.html; see also Lara Salahi, *FDA Appeals Block on Cigarette Warning Labels*, ABC NEWS (Nov. 30, 2011), <http://abcnews.go.com/Health/Wellness/fda-appeals-block-cigarette-warning-labels/story?id=15059707#.Tt53FtWwXh8> (reporting that a U.S. district judge recently granted several tobacco companies' motion for preliminary injunction, thus blocking the FDA's new labeling mandate; however, litigation remains pending in light of the FDA's recent appeal to the judge's order).

246. *Id.*

247. 21 U.S.C. 387p(a)(2)(A).

248. This fact is used merely as a policy argument supporting state and local regulations requiring the posting of health warnings *at the point of sale*. It should be acknowledged that state and local governments are preempted from adopting regulations related to health warnings *on the labels* of tobacco products.

249. 15 U.S.C. § 4402(a) (2010).

products such as Ariva-BDL, electronic cigarettes, little cigars, and tobacco smoked in water pipes. A state law or local ordinance requiring the posting of health warning signs wherever OTPs are sold would be an effective way to counter the adverse effects that these comparatively weak warning labels have on public health.

To be sure, the First Amendment still poses a potential hurdle to any such law or ordinance; however, this hurdle is not insurmountable. Any such ordinance would need to be carefully drafted and firmly grounded in science. State and local governments would not need to develop their own language if they were to use the language which the TCA requires be posted on smokeless tobacco packaging.²⁵⁰ Although smokeless tobacco warnings are less effective than cigarette warnings by lacking graphics, there is no reason to suspect that the text is inaccurate.

The warnings would also stand a greater chance of being upheld if it is clear that the warnings are issued by a government entity. According to the U.S. Supreme Court, the Free Speech Clause of the First Amendment does not regulate government speech.²⁵¹ Thus, for example, a required warning sign stating that “The Blackacre Health Department has concluded that this product can cause mouth cancer,” combined with a picture of the effects of smokeless tobacco use, would have a greater likelihood of being upheld than a warning sign that merely states “This product can cause mouth cancer.”²⁵²

B. Marketing Restrictions

In the area of tobacco marketing, state and local governments may also have a greater opportunity to regulate OTPs than to regulate cigarettes. The U.S. Supreme Court considered several such regulations in the 2001 case *Lorillard Tobacco Co. v. Reilly*.²⁵³ In a 5-4 decision, the Court struck down several regulations promulgated by the Massachusetts Attorney General to reduce the influence of tobacco marketing.²⁵⁴ These regulations would have prohibited outdoor tobacco advertising within 1,000 feet of schools and parks, prohibited indoor tobacco advertising placed lower than five feet

250. *Id.* § 4402(a)(1) (the warnings include “This product can cause mouth cancer” and “This product can cause gum disease and tooth loss”).

251. *Pleasant Grove City v. Summum*, 555 U.S. 460, 467 (2009).

252. Even an ordinance requiring the latter warning sign would stand a good chance of being upheld under the test for compelled factual speech. *See Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 651 (1985) (“[B]ecause disclosure requirements trench much more narrowly on an advertiser’s interests than do flat prohibitions on speech, ‘warning[s] or disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception.’”).

253. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 525 (2001).

254. *Id.* at 571.

from the floor in any retail establishment located within 1,000 feet of a school or park, and restricted the sampling and self-service of tobacco products.²⁵⁵

In the first part of the *Lorillard* decision, the Court struck down the regulations pertaining to cigarettes as being preempted by the FCLAA.²⁵⁶ In passing the 2009 TCA, however, Congress relaxed the preemptive provisions of FCLAA that were fatal to the cigarette marketing restrictions at issue in *Lorillard*.²⁵⁷ Consequently, this portion of the *Lorillard* holding may not have the salience today that it did in 2001. However, the TCA did not give state and local governments an unfettered ability to regulate cigarette marketing. Under the FCLAA as amended by the TCA, for state or local regulations on cigarette marketing to be valid, they must relate to “the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.”²⁵⁸

No comparable limitation exists on the authority of state and local governments to adopt regulations relating to the marketing of OTPs. This authority is constrained only by the First Amendment, which is undoubtedly a serious hurdle. The First Amendment limitations on the regulation of OTP marketing are evidenced by the second part of the *Lorillard* decision, discussed *infra*, as well as in subsequent First Amendment jurisprudence.²⁵⁹

Because the FCLAA does not apply to OTPs, the *Lorillard* Court applied a First Amendment test to the Massachusetts regulations as they related to smokeless tobacco and cigars, and struck most of them down.²⁶⁰ In determining whether the marketing restrictions at issue in *Lorillard* survived First Amendment scrutiny, the Court applied the test set out in *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York*.²⁶¹ Under this test, a valid restriction on truthful commercial speech will survive scrutiny if it directly advances a substantial governmental interest and is no more extensive than is necessary to serve that interest.²⁶² At issue in *Lorillard* was whether the Massachusetts regulations directly advanced the government’s interest in health, and whether they were no more extensive than necessary.²⁶³ For the first part of

255. *Lorillard*, 533 U.S. at 534-35.

256. *Id.* at 551; 15 U.S.C. § 1334 (2009).

257. *See* 15 U.S.C. § 1334(c) (2009).

258. *Id.*

259. *See, e.g.*, *Citizens United v. Fed. Election Comm’n*, 130 S.Ct. 876 (2010); *Sorrell v. IMS Health Inc.*, 131 S.Ct. 2653 (2011).

260. *Lorillard*, 533 U.S. at 553.

261. 447 U.S. 557 (1980).

262. *Lorillard*, 533 U.S. at 554 (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 566 (1980)).

263. *Id.* at 555-56.

this analysis, the Court sided with Massachusetts. The Court reviewed data on youth use of smokeless tobacco and cigars and found that the regulations directly addressed a real problem.²⁶⁴

In the second part of the analysis, however, the Court sided with the tobacco companies and held that most of the regulations were more extensive than necessary to advance the government's interest in protecting health.²⁶⁵ The Court held that the restriction on outdoor advertising within 1,000 feet of schools "would constitute nearly a complete ban on the communication of truthful information," particularly in major metropolitan areas.²⁶⁶ The Court held that the prohibition on indoor advertising below five feet from the ground within 1,000 feet of schools neither directly advanced the government's interest, nor was it sufficiently narrowly tailored.²⁶⁷ In comments that seem almost specious, the Court noted that children might look up or be over five feet tall.²⁶⁸ The Court did conclude that the self-service restrictions survived scrutiny.²⁶⁹

As daunting as these conclusions may seem, the Court's analysis left some opportunities for regulating OTP marketing. First, the distance requirement in a prohibition on outdoor advertising could vary based on the population density of an area. The Court found it compelling that the effect of the outdoor advertising restrictions "will vary based on whether a locale is rural, suburban, or urban."²⁷⁰ For example, restricting outdoor OTP advertising that is within 500 feet of schools and playgrounds in urban areas, 1,000 feet in suburban areas, and 1,500 feet in rural areas might meet the Court's test.²⁷¹

Second, creating an exception for adult-only facilities to any restriction on indoor OTP marketing would blunt any argument that the restriction "would constitute nearly a complete ban on the communication of truthful information."²⁷² Such an exception would also help address the Court's conclusion that "adults have [an] interest in receiving truthful information about tobacco products."²⁷³ A similar restriction would require that products be kept out of sight to blunt the powerful appeal of "power walls"

264. *Id.* at 556-61.

265. *Id.* at 566.

266. *Id.* at 562.

267. *Id.* at 567.

268. *Lorillard*, 533 U.S. at 566.

269. *Id.* at 570.

270. *Id.* at 563.

271. It should be acknowledged that the Tobacco Control Act required the FDA to consider a regulation on outdoor tobacco advertising that would meet the test set out in *Lorillard*. FSPTCA, *supra* note 123, § 102(a)(2)(E).

272. *Lorillard*, 533 U.S. at 562.

273. *Id.* at 564.

of tobacco products,²⁷⁴ although such a regulation would almost certainly invite litigation. To convey information to consumers, the ordinance could permit customers to request to view a menu of products that are available.²⁷⁵

Finally, basing any such ordinance on the latest scientific studies (*i.e.*, by reference in the ordinance's findings of fact) might improve the chances that the ordinance would withstand a legal challenge. Numerous scientific studies have been published since the *Lorillard* decision demonstrating the deleterious effects of tobacco marketing on public health, as well as the efficacy of marketing restrictions such as those at issue in *Lorillard*.²⁷⁶ The *Lorillard* decision left open the possibility that speech can be restricted if it is scientifically demonstrable that the targeted speech has pernicious effects.²⁷⁷

A simpler – but potentially more controversial – approach to limiting the impact of tobacco marketing is to limit where tobacco products can be sold. For example, a state or local government could restrict the sale of tobacco products to facilities that cannot be entered by minors. This seems clearly permitted under the authority of state and local governments to regulate the sale of tobacco products.²⁷⁸

C. Category Prohibition

A more dramatic regulatory option available to state and local governments would be to prohibit the sale of an entire class of products. For example, a state or local government could prohibit the sale of all dissolvable tobacco products, e-cigarettes, little cigars, snus, or water pipe tobacco.²⁷⁹ In light of the poorly understood health effects of these products

274. Lynn Greaves, *Canada: Demolishing the Power Walls*, 12 TOBACCO CONTROL 7 (2003); *see generally* CENTER FOR PUBLIC HEALTH AND TOBACCO POLICY, TOBACCO PRODUCT DISPLAY BANS, *available at* <http://publichealthlawcenter.org/sites/default/files/resources/nycenter-syn-tobproductdisplaybans-2010.pdf>.

275. CHRISTOPHER BANTHIN, TOBACCO CONTROL LEGAL CONSORTIUM, REGULATING TOBACCO RETAILERS: OPTIONS FOR STATE AND LOCAL GOVERNMENTS 6 (2010), *available at* http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-retailers-2010_0.pdf.

276. CAMPAIGN FOR TOBACCO-FREE KIDS, TOBACCO COMPANY MARKETING TO KIDS (2009), *available at* <http://www.tobaccofreekids.org/research/factsheets/pdf/0008.pdf> (containing a survey of studies on tobacco marketing to children and adolescents); *see also* NATIONAL CANCER INSTITUTE, SMOKING AND TOBACCO CONTROL: CHANGING ADOLESCENT SMOKING PREVALENCE, (2001), *available at* <http://cancercontrol.cancer.gov/tcrb/Mono%20graphs/14/m14.pdf>; BANTHIN, *supra* note 275, at 6.

277. *Lorillard*, 533 U.S. at 563 (“To the extent that studies have identified particular advertising and promotion practices that appeal to youth, tailoring would involve targeting those practices while permitting others.”)

278. 21 U.S.C. § 387p(a)(1) (2010).

279. *See, e.g.*, 2007 Me. Laws 467, *available at* http://www.mainelegislature.org/legis/bills/bills_123rd/chappdfs/PUBLIC467.pdf

and the minimal federal regulation of these products,²⁸⁰ there are policy reasons that would support such action. The addictive nature of these products provides further support that such a policy may be warranted.

Regulatory action along these lines would be politically controversial and would almost certainly invite a legal challenge. Such regulation would likely be within the authority of states, however. Several states have already prohibited certain classes of tobacco products, such as bidis, a type of cigarette wrapped in a tendu leaf which originated in south Asia.²⁸¹

Further, the FDA is prohibited from banning certain categories of products, including all little cigars and all pipe tobacco.²⁸² The removal of these actions from the FDA's authority suggests that there would be no conflict with state or local regulation in the same area. The chances for such an ordinance or law to withstand a legal challenge could be further strengthened through careful drafting. First, the law should be a sales restriction rather than a manufacturing prohibition in order to avoid the TCA's preemptive provisions.²⁸³ As in the case of state and local restrictions on the sale of flavored OTPs discussed above, it might be advisable to exempt a limited number of adult-only facilities from the restriction to further buttress the argument that the law is a sales restriction rather than a preempted product regulation. These steps would help ensure that such a regulation would withstand a legal challenge.

V. CONCLUSION

State and local units of government can and should take steps to regulate OTPs more effectively. These measures could include the following: price restrictions such as strengthened tax laws; restrictions on free samples and coupon redemption; a minimum pack size for OTPs sold in discrete units; a prohibition on the sale of OTPs with characterizing flavors, including menthol; strengthened youth access laws; strengthened use restrictions; a requirement that health warnings be posted at the point of sale; marketing restrictions; and even outright prohibition of the sale of certain categories of products.

(prohibiting sale of "hard snuff" including dissolvable tobacco, since repealed); *see also* Steve Gravelle, *Linn supervisors vote down tobacco restrictions*, THE GAZETTE, Aug. 22, 2011 (county supervisors rejected ordinance prohibiting sale of dissolvable tobacco).

280. *See, e.g.*, 21 U.S.C. § 387g(a)(1)(A) (2010) (flavor prohibition applies only to cigarettes), 21 C.F.R. § 1140.2 (2010) (marketing restrictions do not apply to e-cigarettes, little cigars, or pipe tobacco); Peterson, *supra* note 34 (some dissolvable tobacco products completely unregulated).

281. *See, e.g.*, ARIZ. REV. STAT. ANN. § 36-798.01 (2010); 720 ILL. COMP. STAT. 685/4(a)(5) (2010); N.D. CENT. CODE § 12.1-31-10 (2010); VT. STAT. ANN. tit. 7, § 1003(e) (2010).

282. 21 U.S.C. § 387g (d)(3).

283. 21 U.S.C. § 387p(a)(2).

These efforts would be well within the authority of state and local governments to protect public health and are consistent with the goals outlined in the TCA. The TCA broadly permits state and local governments to regulate “the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products.”²⁸⁴

Tobacco control laws at every level too often fail to account for the full range of tobacco products on the market. Federal regulators have not yet taken decisive action to address this issue, which presents significant opportunities for comprehensive state and local regulation. Now, more than ever, it is important for state and local governments to serve as policy laboratories that can lead to more effective federal regulation.

284. 21 U.S.C. § 387p(a)(2).