

September 17, 2010

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: FDA's Request for Comments on the Impact of Dissolvable Tobacco Use on Public Health, Docket No. FDA-2010-N-0123

The Tobacco Control Legal Consortium is pleased to provide comments to the Food and Drug Administration for agency consideration in evaluating the public health impact of dissolvable tobacco products.

These comments focus primarily on weaknesses in the regulation of dissolvable tobacco products at the state and federal level. These weaknesses increase the likelihood that dissolvable products, such as Ariva, Stonewall, or Camel Orbs, will be used by youth and that tobacco users will continue to use tobacco. This consumer use clearly will have an adverse impact on public health. Further, the FDA has the authority to deny a new product application under Section 910(c)(4) of the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") if it leads to these types of tobacco use.¹

The tobacco control laws in Minnesota will be highlighted in these comments. Minnesota offers a unique perspective on the regulation of dissolvable tobacco products. Although Camel brand dissolvable products are not sold by Minnesota retailers, products such as Ariva and Stonewall have been marketed here for several years. Further, in 2010, the Minnesota Legislature updated the state's tobacco laws by enacting the Tobacco Modernization and Compliance Act of 2010,² a law that specifically addresses dissolvables in ways that will be described in greater detail.

¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ031.111.pdf.

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

These comments conclude with recommendations on how dissolvable tobacco products might be effectively regulated.

Tobacco Control Legal Consortium / Public Health Law Center

The Tobacco Control Legal Consortium, www.tclconline.org, America's legal network for tobacco control, has been identified by the CDC as one of the national organizations critical to effective local tobacco control. Since 2003, the Consortium has been America's leading source of legal technical assistance on tobacco control. The Consortium serves as a consultant to CDC's Office of Smoking and Health on issues related to the Family Smoking Prevention and Tobacco Control Act, and is the primary source of legal technical assistance to grantees under the new Communities Putting Prevention to Work Program with regard to their tobacco-related activities. The Consortium received the CDC's 2004 National/Regional Collaboration Award for its collaborative approach to legal technical assistance. The Consortium has prepared a wide range of materials and information relevant to the regulation of tobacco products, including materials about the Family Smoking Prevention and Tobacco Control Act and its implications, as well as publications about the legal issues related to "light" and "low tar" cigarettes, so-called "fire safe" cigarettes, flavored cigarettes, Internet tobacco sales, and many other topics. We have prepared legal briefs as amicus curiae in key cases before the Supreme Court of the United States, federal appellate courts and many state supreme courts.

The Consortium makes its home at the Public Health Law Center, www.publichealthlawcenter.org, a non-profit public interest legal center at the William Mitchell College of Law in Saint Paul, Minnesota. We serve as the National Coordinating Center of the Public Health Law Network, a new national initiative of the Robert Wood Johnson Foundation to provide legal expertise to the nation's public health agencies and practitioners, www.publichealthlawnetwork.org.

A think tank grounded in research and scholarship, but focused on real-world results, the Public Health Law Center helps community leaders around the world use the power of law to advance public health by developing, enacting, implementing and defending legislation, regulations and policies that improve public health. We provide legal technical assistance on tobacco control issues ranging from smoke-free policymaking to tobacco marketing, taxation and product regulation. As the principal source of legal technical assistance to tobacco control advocates in Minnesota, we have helped write almost every tobacco-related law in Minnesota for the last decade, and have helped community leaders with more than a thousand requests for technical assistance on tobacco-related issues. Our Center was recently awarded a two-year

research grant to study the regulation of other tobacco products (OTPs) in Minnesota by ClearWay Minnesota, an independent, nonprofit organization that improves the health of all Minnesotans by reducing tobacco use and exposure to secondhand smoke through research, action and collaboration.

Health Concerns

The health effects of dissolvable tobacco products are not as well understood as the health effects of more established combustible tobacco products, such as cigarettes. This relative lack of understanding makes the presence of these nontraditional products in the market troubling and underscores the need for decisive agency action. Although only a limited amount of research has been conducted on dissolvable tobacco products, a few health concerns are known and deserve to be described in this comment.

First, recent studies have shown that dissolvable tobacco products can lead to tobacco initiation, particularly by children. The similarity of these products to candy has been well documented, as has their appeal to the young. In a study conducted by the Virginia Foundation for Healthy Youth, for example, 39 percent of minors believed that Camel Orbs were not tobacco products, but mints or gum.³ Twenty eight percent of minors interviewed in this study said that they “would try Camel Orbs based on packaging alone.”⁴ Indeed, the FDA noted in letters to the R.J. Reynolds Tobacco Company and Star Scientific, Inc., that their dissolvable tobacco products “resemble candy products.”⁵

Dissolvables can also lead to the continuation of tobacco use. The products contain nicotine, an addictive substance. Further, the marketing of dissolvable tobacco products directly anticipates dual use with other tobacco products. The website for Ariva and Stonewall brand dissolvable tobacco products states that “it is satisfying to both smokeless tobacco users and heavy smokers (those who smoke more than one

³ 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/

⁴ *Id.*

⁵ FDA, Letter to Industry on Dissolvable Smokeless Tobacco Products (R.J. Reynolds Tobacco Company), Feb. 1, 2010, available at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm199712.htm>; FDA, Letter to Industry on Dissolvable Smokeless Tobacco Products (Star Scientific, Inc. Feb. 1, 2010, available at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm199711.htm>

pack of cigarettes a day).⁶ More subtly, Camel-brand dissolvable tobacco products are advertised as “the modern, convenient way to enjoy tobacco anytime, anywhere.”⁷

These issues are troubling. Indeed, they relate directly to the criteria the FDA must consider when determining whether or not to approve an application for a new tobacco product, which state that the agency must consider “the increased or decreased likelihood that existing users of tobacco products will stop using such products” and “the increased or decreased likelihood that those who do not use tobacco products will start using such products.”⁸

The risk of tobacco initiation and dual tobacco use are not the only potential health risks of dissolvable tobacco products. The use of dissolvable tobacco products carries a risk that a child may be poisoned by ingesting them.⁹ Finally, carcinogens such as N-Nitrosornicotine (NNN), 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), and 4-(methylnitrosamino)-4-(3-pyridyl)-1-butanol (NNAL) have been found in dissolvable tobacco products.¹⁰

All of these potential health effects are troubling, particularly since dissolvable tobacco products are available on the market without having been subject to procedures created by the Tobacco Control Act and required for new tobacco products¹¹ or modified risk tobacco products.¹² However, regulation is inadequate not only at the federal level; regulatory gaps at the state level may also lead to greater access to the products. Those state level regulatory gaps will be examined next.

Weaknesses in Regulation of Dissolvable Tobacco Products

Many states’ tobacco laws address “traditional” tobacco products, such as cigarettes and cigars, while failing to account for dissolvable tobacco products. State regulation of dissolvables is inadequate in at least three areas: pricing, characterizing flavors, and youth access. As a result, these gaps in regulation could increase the likelihood

⁶ See generally <http://www.dissolvabletobacco.com/main-w.html>. Screen captures of materials taken from the web are available upon request.

⁷ See generally <https://sites.tobaccopleasure.com/CAM/article.aspx?i=39>.

⁸ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, §910(c)(4), 123 Stat. 1776, 1810 (2009).

⁹ See, e.g., Connolly et al, *Unintentional Child Poisonings Through Ingestion of Conventional and Novel Tobacco Products*, PEDIATRICS 5, 896 (May 2010).

¹⁰ See Stanfill et al., CAMEL ORBS: NICOTINE, PH, TOBACCO-SPECIFIC NITROSAMINES, AND SELECT FLAVOR ANALYSIS 8 (2009), available at <http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480a722ae&disposition=attachment&contentType=pdf>, p. 8.

¹¹ § 910, 123 Stat. 1776, 1807.

¹² § 911, 123 Stat. 1776, 1812.

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.

The Price of Dissolvable Tobacco Products

Regulatory gaps impact the price of dissolvable tobacco products in at least four areas: taxation; free samples; coupons, discounts, and rebates; and minimum pack size. These gaps potentially render dissolvables substantially 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.¹³ One criterion which the FDA can use to deny a new tobacco product application is “the increased ... likelihood that those who do not use tobacco products will start using such products.”¹⁴ A tobacco product with a low price increases this likelihood.

Tax Laws

Tobacco tax laws arguably have the strongest effect on the price of tobacco products.¹⁵ Although the Tobacco Control Act defines “smokeless tobacco” to include dissolvable tobacco products,¹⁶ many state tax laws define tobacco in a way that potentially excludes dissolvables. Most frequently, tobacco taxes apply to products that can be smoked or chewed.¹⁷ It is questionable whether these laws would apply to dissolvable tobacco products, because the products dissolve in one’s mouth. They 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.” Likewise, the website for Ariva brand dissolvable tobacco says “do not chew or swallow the product.”¹⁸

¹³ See, e.g., 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>; FRANK J. CHALOUPKA & 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>; ERIC LINDBLOM & 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>.

¹⁴ § 910(c)(4)(B), 132 Stat. 1776, 1810.

¹⁵ See, e.g., MIURA, *supra*.

¹⁶ § 900(18), 132 Stat. 1776, 1810.

¹⁷ See, e.g., COLO. REV. STAT. § 39-28.5-101(5); CONN. GEN. STAT. § 12-330a(2); FLA. STAT. § 210.25(11), GA. CODE § 48-11-1(15); 35 ILL. COMP. STAT. 143/10-5; IND. CODE § 6-7-2-5; IOWA CODE § 453A.42(15); KAN. STAT. § 79-3301(v); KY. REV. STAT. § 138.130(16)(c); ME. REV. STAT. tit. 36, § 4401(9); MD. CODE TAX-GEN. § 12-101(c)(2); MASS. GEN. LAWS Ch. 64C, §1; NEB. REV. STAT. § 77-4007; N.Y. TAX LAW § 470(2); OHIO REV. CODE § 5743.01; OR. REV. STAT. § 323.500(14); S.C. CODE § 12-21-800; WASH. REV. CODE § 82.26.010(1); WIS. STAT. § 139.75(12).

¹⁸ See generally, <http://www.dissolvabletobacco.com/main-w.html>.

If a tax official were to determine that dissolvables do not meet the definition of a tobacco product because they are not chewed, no tobacco tax would be applied to dissolvables; only the state sales tax would apply. This would result in dissolvables being severely under-taxed, potentially allowing greater youth access to the products. It may be no coincidence that the three states in which R.J. Reynolds is test marketing dissolvable tobacco products under its popular Camel brand – Indiana, Ohio, and Oregon – have tax definitions that suffer from this flaw.

Even in states with tobacco tax laws that do contemplate dissolvable tobacco products, the tax *rate* for dissolvable products may be substantially lower than that of more traditional 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.”¹⁹ The tax rates in two states where R.J. Reynolds is test marketing dissolvable tobacco products are also instructive. In Indiana, OTPs are taxed at only 24 percent of the wholesale price of tobacco,²⁰ and a package of 15 Camel Orbs sells for under three dollars. In contrast, a pack of cigarettes costs approximately five dollars in Indiana.²¹ In Ohio, OTPs are taxed at only 17 percent of the wholesale price.²² Although the proper relative level of taxation between cigarettes and dissolvables can be debated, the frequently lower rate for dissolvables may increase access to the products and create a public health hazard.

Minnesota’s tax laws present an interesting case study. The tax for other tobacco products that was on the books in Minnesota until August 1, 2010, 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.”²³ Because dissolvable tobacco products are neither chewed nor smoked, it was debated whether or not Minnesota would tax dissolvables as tobacco products.

If not, only the state sales tax of 6.875 percent and any local sales taxes would apply to dissolvables. In contrast, the state charges \$1.23 in fees and excise taxes per pack of cigarettes, in addition to the state sales tax.²⁴

To address this potential gap in regulation, the Minnesota legislature in 2010 clarified the definition of “tobacco products” in the tax code. “Tobacco products” are now

¹⁹ See generally, <http://www.dissolvabletobacco.com/main-w.html>.

²⁰ IND. CODE §6-7-2-7.

²¹ Shari Rudavsky, *Federal tax on cigarettes increasing 62 cents*, STAR MEDIA, March 12, 2009, available at <http://www.indy.com/posts/federal-tax-on-cigarettes-increasing-62-cents>.

²² OHIO REV. CODE ANN. § 5743.51 (1995).

²³ MINN. STAT. § 297F.01, Subd. 19 (2009).

²⁴ Minnesota House of Representatives, House Research, “Cigarette and Tobacco Tax,” available at <http://www.house.leg.state.mn.us/hrd/databook/cigtobtax.htm>.

defined as any tobacco product that is “intended for human consumption, whether ... dissolved ... or ingested by any other means.”²⁵ It is now clear that dissolvable tobacco products will be taxed as tobacco products in Minnesota. Unfortunately, few other states have taken this step.

One other potential regulatory gap relates to taxation. Several states and the federal government tax smokeless tobacco products according to weight.²⁶ Because of the extremely low weight of dissolvable tobacco products, such a system may severely undertax the products. For example, a tax of \$1.00 per ounce on a pack of 15 Camel Orbs would amount to less than one cent per dose.²⁷ Again, these low tax rates increase the risk that dissolvable tobacco products will be used by minors.

Free Samples

In June, the FDA implemented a rule limiting the ability of tobacco manufacturers to sell and market their products.²⁸ This rule restricts the distribution of free samples of “cigarettes, smokeless tobacco, or other tobacco products.”²⁹ Dissolvable tobacco products likely would fall within the rule’s definition of “smokeless tobacco,” which includes “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.”³⁰ Even if dissolvable tobacco products are not considered “smokeless tobacco,” they certainly would be considered an “other tobacco product.” Indeed, the free sample provision is the only provision in the rule or the recently adopted Tobacco Control Act that specifically addresses “other tobacco products.”³¹

Although the restriction on the distribution of free samples includes dissolvable tobacco products, an exception limits its effectiveness. Under this exception, free samples of smokeless tobacco may be distributed in “qualified adult-only facilities.”³² A “qualified adult-only facility” must meet several specific criteria,³³ but it appears that the definition

²⁵ 2010 MINN. LAWS 305 §2, available at <https://www.revisor.mn.gov/data/revisor/law/2010/0/2010-305.pdf>.

²⁶ See, e.g., 26 U.S.C. § 5701(e); ALA. CODE 1975 § 40-25-2(a)(9)-(11); ARIZ. REV. STAT. §§ 42-3052 (2002), 42-3251 (2002), 42-3251.01 (2002), 42-3371 (2006); 36 ME. REV. STAT. ANN. § 4403(1); N.D. CENT. CODE § 57-36-25(2); TEX. TAX CODE ANN. § 155.0211(b).

²⁷ 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>.

²⁸ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 21 C.F.R. § 1140 (2010).

²⁹ *Id.* at § 1140.16(d)(1).

³⁰ *Id.* at § 1140.3(i).

³¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 102(a)(2)(G), 123 Stat. 1776, 1830 (2009).

³² 21 C.F.R. § 1140.16(d)(2).

³³ *Id.* at § 1140.16(d)(2)(iii).

was written in contemplation of tobacco company sampling tents often seen at rodeos or motor racing events. Although minors are not permitted in such facilities, young adults certainly may enter, as may minors if the provision is not enforced.

Furthermore, the free samples of tobacco distributed in a “qualified adult-only facility” are limited to one package containing 0.53 ounces (15 grams) of smokeless tobacco, or “eight individual portions” of smokeless tobacco, whichever weighs less.³⁴ Because of the incredibly low weight of dissolvable tobacco products, this provision has the potential to turn into a significant loophole. A package of 15 Camel Orbs, for example, weighs only 0.12 ounces,³⁵ well under the 0.53 ounce limit.

Some other laws address free samples of tobacco products. Twenty two states and the District of Columbia restrict the distribution of free samples in some way.³⁶ The scope and effectiveness of these laws varies widely. Some of the laws apply only to products that are smoked or chewed.³⁷ The Smokeless Tobacco Master Settlement Agreement also limits the distribution of free samples of smokeless tobacco.³⁸ However, the settlement has at least three weaknesses: it applies only to products manufactured by manufacturers that participated in the agreement; it exempts adult-only facilities; and it exempts two-for-one offers. The inconsistent or nonexistent treatment of free sampling in state and other laws has potentially increased access to tobacco products, particularly before the federal tobacco marketing regulation took effect this year.

Up until August 2010, a Minnesota law prohibiting the distribution of tobacco products “at no cost or at nominal cost for product promotional purposes”³⁹ applied only to tobacco products that can be smoked, as well as to “chewing tobacco or tobacco snuff.” Although it might arguably have included dissolvable tobacco products, the law was clarified this year to ensure that it does.⁴⁰ The potential failure of the law to apply to dissolvable tobacco products prior to 2010 may have increased access to the products. Further, the law does not and has not defined the term “nominal cost,” which could lead to attempts to circumvent the law or otherwise result in access to deeply discounted tobacco products. Finally, the law 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

³⁴ *Id.* at § 1140.16(d)(2)(iv).

³⁵ Campaign for Tobacco-Free Kids, *supra* note 27.

³⁶ *See, e.g.*, CONN. GEN. STAT. § 12-314a, D.C. CODE ANN. § 7-1731, HAW. REV. STAT. § 328K-22, IDAHO CODE § 39-5707, 720 ILL. COMP. STAT. 675/1, 940 CODE MASS. REG. § 21.04, MINN. STAT. § 325F.77, NEB. REV. STAT. §§ 69-1901 to 69-1904, N.H. REV. STAT. ANN. § 126-K:5, N.Y. PUB. HEALTH LAW § 1399-bb, UTAH CODE ANN. §§ 76-10-111, WASH. REV. CODE § 70.155.050, WIS. STAT. § 134.66.

³⁷ *See, e.g.*, CONN. GEN. STAT. § 12-314a.

³⁸ Smokeless Tobacco Master Settlement Agreement III(g), available at <http://ag.ca.gov/tobacco/pdf/1stmsa.pdf>.

³⁹ MINN. STAT. § 325F.76-77 (2009).

⁴⁰ 2010 Minn. Laws 305 §3, available at <https://www.revisor.mn.gov/data/revisor/law/2010/0/2010-305.pdf>.

“qualified adult-only facilities.” Still, the existence of this exemption prior to 2010 may have also increased access to dissolvable tobacco products. All of these gaps in regulation may have increased access to dissolvables, or are still causing greater access, leading to a public health risk.

Coupons, Discounts, and Rebates

The federal tobacco marketing regulation does not define the term “free samples.” This phrase has been interpreted narrowly, leading to increased access to the products and low prices manifested through sales techniques including coupons, rebates, and two-for-one offers. The interpretation may stem from the Smokeless Tobacco Master Settlement Agreement – which would apply to dissolvable tobacco products sold by manufacturers participating in the settlement. The settlement 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.”⁴¹

Tobacco manufacturers use coupons and other price-related incentives to make their products more attractive to consumers,⁴² particularly young consumers, and to blunt the effects of rising tobacco taxes. In recent years, the tobacco industry has spent staggering sums on price-related strategies such as coupons and valued-added discounts.⁴³ Although some states regulate the use of coupons for tobacco products,⁴⁴ they appear to be a small minority of jurisdictions and the effectiveness of the regulations varies. Approximately half the states also have a minimum price law for cigarettes. However, most of these laws apply only to cigarettes, and many have loopholes that undermine their effectiveness.⁴⁵ The availability of heavily discounted dissolvable tobacco products represents a severe gap in regulation and a public health hazard, particularly among youth.

Minimum Pack Size

⁴¹ Smokeless Tobacco Master Settlement Agreement III(g), available at <http://ag.ca.gov/tobacco/pdf/1stmsa.pdf>.

⁴² According to a 1994 U.S. Surgeon General's report, the use of coupon promotions 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. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL (1994), available at http://www.cdc.gov/tobacco/data_statistics/sgr/1994/index.htm.

⁴³ April Roseler et al., Tobacco Marketing in California and Implications for the Future, 19 TOBACCO CONTROL i21 (2010) (stating that, in 2006 alone, cigarette companies allocated 93% of all of their advertising and promotional expenditures, amounting to \$11.5 billion, toward price-related strategies like promotional allowances, coupons, retail valued-added programs, and price discounts, while smokeless tobacco companies spent 69% or \$246 million of all their advertising and promotional expenditures on these categories).

⁴⁴ See CAL. HEALTH & SAFETY CODE § 118950; HAW. REV. STAT. § 328J-17(a); MD. CODE CRIM. LAW. § 10-107(a); TEX. HEALTH & SAFETY CODE § 161.087(a).. See also MIURA, *supra*.

⁴⁵ See, e.g., Minn. Stat. § 325D.30 *et seq.* See also MIURA, *supra*.

Another regulatory gap affecting the price of dissolvable tobacco products is the lack of a minimum pack size. The federal tobacco marketing regulation prohibits the sale of cigarettes in packages containing fewer than twenty cigarettes.⁴⁶ Single cigarette sales have been shown to appeal to minors because of their low price, and have the potential to lead to tobacco initiation.⁴⁷

Unfortunately, no comparable restriction exists for dissolvable tobacco products. In Minnesota, for example, Stonewall brand tobacco tablets are sold in packs of five for \$1.49. This price may be considerably more appealing to a young person than the price of a pack of cigarettes – typically at least five dollars. The ability of cash-strapped young people to purchase a small number of dissolvable tobacco products at a lower price than an expensive pack of cigarettes represents another public health risk.

Characterizing Flavors

Price is not the only area where the regulation of dissolvable tobacco products lags behind the regulation of cigarettes. The Tobacco Control Act prohibits tobacco manufacturers from including a “characterizing flavor” in cigarettes, with the exception of menthol and tobacco flavor.⁴⁸ The law does not prohibit these characterizing flavors in dissolvable tobacco products. Indeed, Stonewall brand dissolvable tobacco tablets come in flavors like “Wintergreen” and “Java.” Camel Orbs come in a mint-like flavor called “fresh” and a cinnamon-like flavor called “mellow.”

Star Scientific, Inc., the maker of the dissolvable tobacco products Ariva and Stonewall, acknowledges in its comment on this docket 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.⁴⁹ This self-serving statement should not be taken at face value. Flavored tobacco products – and the marketing accompanying them – have an obvious appeal to youth⁵⁰ and pose a serious risk to the public health.

⁴⁶ 21 C.F.R. §§ 1140.14(d), 1140.16(b).

⁴⁷ See, e.g., Landrine et al., *Minors’ Access to Single Cigarettes in California*, 4 PREVENTATIVE MED. 503 (1998) abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/9672942>.

⁴⁸ 21 U.S.C. § 387g, available at http://www.law.cornell.edu/uscode/html/uscode21/usc_sec_21_00000387---g000-.html.

⁴⁹ 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.regulations.gov/search/Regs/contentStreamer?objectId=0900006480b1fe93&disposition=attachment&contentType=pdf>.

⁵⁰ See, e.g., KATHLEEN DACHILLE, TOBACCO CONTROL LEGAL CONSORTIUM, PICK YOUR POISON: RESPONSES TO THE MARKETING AND SALE OF FLAVORED TOBACCO PRODUCTS (2009) available at <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-syn-flavored-2009.pdf>.

Indeed, in 2006, thirty-nine state attorneys general settled an investigation into potential violations by R.J. Reynolds of the 1998 Master Settlement Agreement between 46 states and the major cigarette manufacturers. R.J. Reynolds had been 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 dissolvable tobacco products. Specifically, R.J. Reynolds agreed not to sell cigarettes flavored like cocoa, cacao, mocha, cinnamon, and mint (excluding menthol).⁵¹

Unfortunately, there is no comparable nationwide prohibition on characterizing flavors in non-cigarette tobacco products. State and local units of government have the authority to prohibit the sale of flavored tobacco products, but to date, few governments have attempted to do so. New York City is the only jurisdiction that has such a regulation in place, and its ordinance has been subjected to a legal challenge.⁵² The ability of tobacco manufacturers to sell flavored dissolvable tobacco products increases the likelihood of tobacco initiation.

Youth Access

On June 22, 2010, a nationwide standard for youth access to tobacco products took effect.⁵³ This rule made it illegal for retailers to “sell cigarettes or smokeless tobacco to any person younger than 18 years of age.”⁵⁴ “Smokeless tobacco” includes “cut, ground, powdered, or leaf tobacco ... that is intended to be placed in the oral or nasal cavity.”⁵⁵ It is therefore illegal for a retailer to sell dissolvable tobacco products to a minor in the United States.

Before June 2010, the status of a retailer selling dissolvable tobacco products was not always clear. Youth access laws had too often failed to account for dissolvable tobacco products. In at least ten states, dissolvables are at least arguably not covered by youth access laws which apply only to products that are smoked, chewed, and/or sniffed.⁵⁶

⁵¹ R.J. REYNOLDS SETTLEMENT AGREEMENT (2006), *available at*

http://www.illinoisattorneygeneral.gov/pressroom/2006_10/flavored_settlement_final.pdf.

⁵² Heather May, *Lawmaker Wants to Ban Flavored Tobacco Products*, SALT LAKE TRIB., Aug. 19, 2010, *available at* <http://www.sltrib.com/sltrib/home/50133959-76/tobacco-products-flavored-ray.html.csp>.

⁵³ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 21 C.F.R. § 1140

⁵⁴ *Id.*, at § 1140.14(a)

⁵⁵ *Id.*, at § 1140.3(i)

⁵⁶ *See* ARIZ. STAT. § 13-3622; COLO. REV. STAT. § 24-35-502(6); FLA. STAT. § 569.002(6); IND. CODE § 35-46-1-1.7; IOWA CODE § 453A.1(26); KAN. STAT. § 79-3301; N.D. CENT. CODE § 12.1-31-03; R.I. GEN. LAWS § 11-9-13; VT. STAT. tit. 7, § 1001(3); WIS. STAT. § 134.66(1)(j).

In the absence of well crafted youth access laws at the local level that clearly include dissolvables and have strong enforcement mechanisms, there is a greater likelihood that minors will acquire these products. Because these weak laws were on the books, minors may have initiated tobacco use before the federal regulation was implemented.

Recommendations

Since gaps in regulation may increase access to unhealthy products, the FDA should remove dissolvable tobacco products from the marketplace until they undergo a full premarket review process. The products have serious health ramifications and are inadequately regulated, leading to an increased possibility that minors will be able to access them. This possibility directly implicates the criteria that the FDA uses to determine whether or not to approve a new tobacco product. The regulatory gaps decrease the “likelihood that existing users of tobacco products will stop using such products,”⁵⁷ and increase the “likelihood that those who do not use tobacco products will start using such products.”⁵⁸

Moreover, dissolvables should go through a review process because they are not similar to any previously existing tobacco product. The FDA has the authority to require premarket review for products that are not “substantially equivalent” to those marketed prior to February 15, 2007.⁵⁹ New tobacco products that have different characteristics than products marketed before 2007 are not considered “substantially equivalent.”⁶⁰ “Characteristics” are defined broadly to include “the materials, ingredients, design, composition, heating source, or other features of a tobacco product.”⁶¹ Therefore, if any one of these characteristics is different in a new tobacco product, it should go through the premarket review process. This suggests that the burden should be on tobacco manufacturers to prove that a new tobacco product is “substantially equivalent” to a previously existing product.

In the case of dissolvable tobacco products, tobacco manufacturers have failed to meet this burden. R.J. Reynolds began test marketing its Camel-brand line of dissolvables only in 2009.⁶² This fact alone should be a sufficient basis for determining that Camel-brand dissolvables are not “substantially equivalent” to previously existing dissolvables.

⁵⁷ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 910(c)(4)(A), 123 Stat. 1776, 1810 (2009).

⁵⁸ *Id.*, at § 910(c)(4)(B).

⁵⁹ *Id.*, at § 910(a)(2)(A)(I).

⁶⁰ *Id.*, at § 910(a)(3)(A)(i).

⁶¹ *Id.*, § 910(a)(3)(B) (emphasis added).

⁶² See Duff Wilson, *Flavored Tobacco Pellets Are Denounced as a Lure to Young Users*, N.Y. TIMES, April 19, 2010, available at <http://www.nytimes.com/2010/04/19/business/19smoke.html>.

In addition, the design of Camel Strips and Camel Sticks is unlike anything previously available in the market. Although Camel Orbs may have a superficial resemblance to products such as Ariva and Stonewall, evidence suggests that the two types of products have different compositions. For example, one study concluded that “levels of total nicotine per tablet in Camel Orbs were significantly lower than found in Ariva and Stonewall.”⁶³ Even though the dissolvable brands Ariva and Stonewall have been on the market since before 2007, evidence suggests that the products have changed substantially. The manufacturer of the products stated in its own comment that it began “a program to update the Ariva and Stonewall products” in 2008.⁶⁴

Since the burden should be on the tobacco manufacturer to demonstrate that a new product is “substantially equivalent” to a previously existing product, these facts should be sufficient to require all dissolvable products to be removed from the market until an application for a new tobacco product has been approved. Because of the public health risks associated with these products, manufacturers of these products should not be allowed to circumvent a premarket evaluation and approval process.

If the FDA is unwilling to remove dissolvables from the market, the agency should take other actions. These steps could include: a prohibition on deep discounts, rebates, and two-for-one offers; elimination of the exemption for “qualified adult-only facilities” to the prohibition on free sample distribution; a minimum pack size requirement for dissolvable tobacco products; and a prohibition on characterizing flavors in OTPs. These steps would be well within the agency’s authority to regulate tobacco products when “appropriate for the protection of the public health”⁶⁵ and to modify existing regulations pertaining to tobacco marketing.⁶⁶

Any such measure should preserve to the maximum extent possible the authority of state and local governments to adopt more stringent measures to protect public health. The Tobacco Control Act permits state and local governments to regulate “the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products.”⁶⁷ Further, administration policy disfavors preemption and requires

⁶³ See Stanfill et al, CAMEL ORBS: NICOTINE, PH, TOBACCO-SPECIFIC NITROSAMINES, AND SELECT FLAVOR ANALYSIS 1 (2009) available at

<http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480a722ae&disposition=attachment&contentType=pdf>, p. 1.

⁶⁴ STAR SCIENTIFIC, INC., COMMENT ON FDA DOCKET NO. FDA-2010-N-0123 – IMPACT OF DISSOLVABLE TOBACCO USE ON PUBLIC HEALTH, REQUEST FOR COMMENTS 33 (2010), available at

<http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480b1fe93&disposition=attachment&contentType=pdf>.

⁶⁵ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 906(d)(1), 123 Stat. 1776, 1810 (2009).

⁶⁶ *Id.*, § 102(a)(3)-(4).

⁶⁷ § 916(a)(1).

the FDA, in formulating its policies, to give full consideration to the potentially harmful effects of any preemption of state and local authority.⁶⁸

Conclusion

Thank you for the opportunity to comment on the impact of dissolvable tobacco use on public health and the need for further regulation of these products. The Tobacco Control Legal Consortium and the Public Health Law Center welcome the opportunity to support the FDA in its efforts to protect the public health. Should you have any questions about these comments, please contact Mike Freiberg via e-mail at michael.freiberg@wmitchell.edu or by calling (651) 290-7517.

Sincerely,

Mike Freiberg
Staff Attorney
Public Health Law Center

⁶⁸ WHITE HOUSE OFFICE OF THE PRESS SECRETARY, MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES (2009) available at http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/.