Nicotine & Tobacco Research, 2015, 344–349 doi:10.1093/ntr/ntu167 Advance Access publication August 30, 2014 Original investigation

Original investigation

Tobacco Products Sold by Internet Vendors Following Restrictions on Flavors and Light Descriptors

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Abstract

Introduction: The 2009 Family Smoking Prevention and Tobacco Control Act bans characterizing flavors (e.g., grape, strawberry) in cigarettes, excluding tobacco and menthol, and prohibits companies from using misleading descriptors (e.g., light, low) that imply reduced health risks without submitting scientific data to support the claim and obtaining a marketing authorization from the U.S. Food and Drug Administration. This observational study examines tobacco products offered by Internet cigarette vendors (ICV) pre- and postimplementation of the ban on characterizing flavors in cigarettes and the restriction on misleading descriptors.

Methods: Cross-sectional samples of the 200 most popular ICVs in 2009, 2010, and 2011 were identified. Data were analyzed in 2012 and 2013.

Results: In 2011 the odds for selling cigarettes with banned flavors or misleading descriptors were 0.40 times that for selling the products in 2009 (95% confidence interval [CI] = 0.18, 0.88). However, 89% of vendors continued to sell the products, including 95.8% of international vendors. Following the ban on characterizing flavors, ICVs began selling potential alternative products. In 2010, the odds for selling flavored little cigars were 1.71 (95% CI = 1.09, 2.69) times that for selling the product in 2009 and, for clove cigars, were 5.50 (95% CI = 2.36, 12.80) times that for selling the product in 2009.

Conclusions: Noncompliance with the ban on characterizing flavors and restriction on misleading descriptors has been high, especially among international vendors. Many vendors appear to be circumventing the intent of the flavors ban by selling unbanned flavored cigars, in some cases in lieu of flavored cigarettes.

Introduction

The 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA)¹ grants the U.S. Food and Drug Administration (FDA) the authority to regulate the manufacturing, distribution, and marketing of tobacco products (Sec. 3 (1)). Among other goals, the FSPTCA

aims to reduce tobacco use among youth and improve the accuracy of information provided to consumers (Sec. 3 (2); Sec. 3 (6)). To these ends, the FSPTCA bans characterizing flavors (e.g., grape, strawberry) in cigarettes, excluding tobacco and menthol (Title 1, Sec. 101, Sec. 907(a) (1) (A)). It also bans companies from using misleading descriptors (i.e., light, low, mild, or similar terms, hereby

referred to as LLM) that imply reduced health risks without submitting scientific data to support the claim and obtaining a marketing authorization from FDA (Title 1, Sec. 101, Sec. 911 (a)).

Although studies have assessed brick-and-mortar retailer compliance with the FSPTCA,²⁻⁴ no studies have investigated compliance among Internet cigarette vendors (ICVs). One reason could be the difficulty involved in tracking online vendors. Licensing and sales tax requirements vary by state, and in states that do require online cigarette vendors to have licenses and to collect sales taxes, vendor compliance with and state enforcement of these policies is likely to be low. ICVs have typically ignored government regulation, circumventing laws prohibiting sales to minors, avoiding payment of taxes, and violating tobacco marketing restrictions.^{5,6} Initial reports suggest the FSPTCA may be no different, and the FDA has already sent warning letters to ICVs that have violated the ban on characterizing flavors.⁷ However, the full extent of ICV noncompliance has not been empirically examined.

The purpose of this paper was to investigate the extent to which, following the FSPTCA, ICVs continued to sell products banned by the law. As tobacco products face increasing regulation in the offline world, the Internet, which remains largely unregulated, may be emerging as a distribution channel for banned products. Since ICVs are based both inside and outside of the United States and are thus subject to multiple jurisdictions,^{8,9} sales practices may differ by site location, with international ICVs being more likely to sell banned products than U.S.-based ICVs. In addition, given that the tobacco industry historically has promoted and marketed cigars as cigarette substitutes in response to policies discouraging cigarette use,¹⁰ we investigate trends for the availability of flavored cigars. We hypothesize that the proportion of vendors selling these potential substitutes for flavored cigarette swill increase after the ban on characterizing flavors.

Materials and Methods

Web Site Identification Procedures

This study employs data from the ICV study, which was initiated in 1999 to track and analyze the sales and marketing practices of Web sites that sell cigarettes.¹¹ The ICV study includes 10 waves of data collected from calendar years 2000–2011. For each wave of data collection in January 2009, 2010, and 2011, we identified a cross-sectional sample of the 200 most popular ICVs, created offline archival copies of their Web sites using Offline Explorer Pro software (2009),¹² and collected data about their sales and marketing practices.

In each of the study years, vendors were identified in January and February, with archival copies downloaded by April. Thus, we collected the 2009 data prior to the September 2009 ban on characterizing flavors and the 2010 data prior to the June 2010 restriction on products labeled with LLM descriptors. The 2011 data were collected after both provisions were implemented. It is worth noting that the FSPTCA permits companies to use LLM descriptors on products that they demonstrate to reduce harm and risk of disease and that meet the public health standard (Title 1, Sec. 101, Sec. 911 (g)). Before using such descriptors, companies must receive an FDA order. No companies had such an order in place by the end of 2013.

To identify the samples for each wave, we worked with Cyveillance, an online risk monitoring and management firm, to deploy custom algorithms and web spiders that reviewed more than 148 million Web sites, message boards, newsgroups, and spam E-mails to identify likely ICVs. Trained research assistants reviewed all potential ICVs to determine whether they met study inclusion criteria: active English language Web sites selling pre-rolled cigarettes for home delivery. Of the ICV Web sites identified each year (392 in 2009, 464 in 2010, and 413 in 2011), the 200 most popular were selected for content analysis based on Alexa.com visitor traffic rankings. Web site identification procedures are described in further detail elsewhere.^{5,10,13}

Coding Procedures

Two trained raters independently coded each Web site in the study samples using a proprietary online data collection tool with a standardized coding form and detailed codebook. Senior staff reviewed and resolved all interrater discrepancies.

Measures

The coding form included the city, state, zip code, and country location listed for the ICVs and whether the sites had a Native American affiliation. To ensure sufficient power to detect changes in products sold and because there were few differences between the groups, we combined the U.S. (Non-native) and Native American sites into a U.S. category, which included ICVs with indicators (e.g., mailing address) of being based in the United States. The international category served as a dummy variable (0 = United States, 1 = international) and represented ICVs with indicators suggesting location outside the United States.

To determine if a Web site sold a given product, we referred to product descriptions on the Web sites and labels on the product packaging. For example, Web sites that sold cigarettes labeled by the manufacturer or the vendor with the misleading terms noted in the FSPTCA ("light," "mild," "low," and similar terms, such as "low-tar," "lite," and "ultra-light") were counted as selling LLM cigarettes. Web sites selling cigarettes and cigarette products (e.g., rolling papers, roll-your-own tobacco, bidis) with a characterizing flavor other than tobacco or menthol (e.g., clove, strawberry, grape, cinnamon, vanilla, chocolate) were counted as selling flavored cigarettes. For the purposes of this study, we defined "little cigars" as small cigars labeled as "little," "filtered," "mini," "miniature," or "cigarillos"; some vendors and manufacturers use those terms interchangeably.

Statistical Analysis

Data were analyzed in 2012 and 2013. Descriptive statistics were calculated using Stata 12.1. We conducted a chi-squared test to determine whether the proportion of vendors selling product types varied by location of ICV over time. We used logistic regression to calculate odds ratios (OR) for the sale of flavored cigarettes, including clove cigarettes, flavored little cigars, clove cigars, and LLM cigarettes, and to assess trends over time.

Results

In each year, a majority of vendors in the sample were based internationally. There were 165 (82.5%) international vendors in 2009, 135 (67.8%) in 2010, and 145 (72.5%) in 2011.

Flavored Cigarette Products and Flavored Little Cigars

Analysis by location in Table 1 reveals a statistically significant decline in the proportion of U.S. ICVs selling flavored cigarettes (p < .05) from 2009 to 2011 (please refer to Supplementary Figure 1 for a

Variable	2009			2010			2011			Within-group across years
	n	No. (%)	₽°	n	No. (%)	₽°	n	No. (%)	₽°	₽°
Flavored cigarettes			.010			.000			.000	
United States	55	28 (50.9)		54	17 (31.5)		35	10 (28.6)		.046
International	127	90 (70.9)		144	90 (62.5)		165	109 (66.1)		.347
Total	182	118 (64.8)		198	107 (54.0)		200	119 (59.5)		.101
Flavored little			.106			.008			.003	
cigars										
United States	53	18 (34.0)		49	26 (53.1)		35	16 (45.7)		.146
International	121	27 (22.3)		133	42 (31.6)		165	35 (21.2)		.090
Total	174	45 (25.9)		182	68 (37.4)		200	51 (25.5)		.018
Clove cigarettes			.001			.068			.023	
United States	64	22 (34.4)		55	9 (16.4)		35	1 (2.9)		.001
International	135	19 (14.1)		145	42 (29.0)		165	30 (18.2)		.006
Total	199	41 (20.6)		200	51 (25.5)		200	31 (15.5)		.047
Clove cigars			.307			.167			.001	
United States	61	1 (1.6)		51	12 (23.5)		35	12 (34.3)		.000
International	130	6 (4.6)		134	20 (14.9)		164	19 (11.6)		.020
Total	191	7 (3.7)		185	32 (17.3)		199	31 (15.6)		.000
Cigarettes labeled as light, low,			.001			.034			.000	
mild, or similar terms										
United States	59	48 (81.4)		55	43 (78.2)		35	15 (42.9)		.000
International	130	125 (96.2)		145	130 (89.7)		165	151 (91.5)		.118
Total	189	173 (91.5)		200	173 (86.5)		200	166 (83.0)		.043

Table 1. Tobacco Products Sold by Internet Cigarette Vendors, 2009-2011^{a,b}

ICV = Internet cigarette vendor.

^aThe ban on cigarettes with characterizing flavors, including clove, was implemented in September 2009, and the ban on products labeled with misleading terms, such as low and light, was implemented in June 2010.

^bWe tracked the percentage of ICVs selling cigarettes, bidis, smokeless tobacco, snus, other novel tobacco products (i.e., Ariva, Quest, and Omni), herbal cigarettes, loose tobacco, cigars, and small cigars but did not include the numbers in the table since they did not reveal compelling trends.

 $^{\circ}p$ values were determined by using the Pearson χ^2 test.

graph of the trend). The proportion of U.S. vendors selling flavored cigarettes dropped from 50.9% in 2009 (prior to the flavors ban) to 31.5% in 2010 to 28.6% in 2011. International sites did not experience a statistically significant trend from 2009 through 2011 and, in fact, comprised a majority (84.1% in 2010 and 91.6% in 2011) of the sites that continued to sell flavored cigarettes to U.S. customers after the ban was implemented. Trends for flavored little cigars were not statistically significant for U.S. or international vendors.

Table 2 shows the ORs and 95% CIs for the probability of selling each product from 2009 through 2011. In 2010, a year after the ban on characterizing flavors, there was a statistically significant drop in the overall proportion of ICVs selling flavored cigarettes (OR = 0.64; 95% CI = 0.42, 0.96). Meanwhile, there was a statistically significant increase in the overall proportion of ICVs selling flavored little cigars (p < .05). Vendors were 1.71 times as likely to sell flavored little cigars in 2010 than in 2009 (95% CI = 1.09, 2.69). By 2011 this effect had dissipated for both products.

Clove Cigarettes and Clove Cigars

The trend in the overall proportion of vendors selling clove cigarettes was erratic but significantly differed over time (p < .05). The proportion of vendors selling the product rose from 20.6% in 2009 to 25.5% in 2010 before decreasing to 15.5% in 2011. Table 1 suggests that international vendors drove the 2009–2010 increase. Following the ban on characterizing flavors, the percentage of international sites selling clove cigarettes increased from 14.1% to 29%.

In 2011, the percentage of international sellers of the product fell to 18.2%. There was a statistically significant and steady decline in U.S. vendors selling the product from 2009 through 2011 (p < .01). In 2011, only 2.9% of U.S. vendors sold clove cigarettes, down from 34.4% in 2009.

After the ban on characterizing flavors, the overall proportion of sites selling clove cigars spiked from 3.7% to 17.3%. Table 1 suggests that U.S. vendors drove these effects as there was a statistically significant and steady rise in U.S. vendors selling clove cigars following the ban (p < .001) (please refer to Supplementary Figure 2 for a graph of the trend). In 2011, 34.3% of U.S. vendors sold the products, up from 1.6% in 2009. Table 2 indicates sites were 5.50 times as likely to sell the product in 2010 than in 2009 (95% CI = 2.36, 12.80). In addition, vendors were 4.85 times as likely to sell the product in 2009 (95% CI = 2.08, 11.31).

Cigarettes Labeled With Light, Low, Mild, or Similar Descriptors

During the study period, there was a statistically significant downward trend in the overall proportion of vendors selling LLM cigarettes (p < .05). This drop was likely due to U.S. vendors, a large proportion of which stopped selling the products (please refer to Supplementary Figure 3 for a graph of the trend). In 2011, ICVs were 0.45 times as likely to sell such products as in 2009 (95% CI = 0.24, 0.85). Despite this decline, the overwhelming majority

Table 2. Odds Ratios (OR) and 95%	Confidence Intervals (CI) f	for Probability of Selling E	ach Product, 2009–2011
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Flavored		Cigarette	S	Little cigars			
	n	No. (%)	OR (95% CI)	n	No. (%)	OR (95% CI)	
2009 (Ref)	182	118 (64.8)	1.00	174	45 (25.9)	1.00	
2010	198	107 (54.0)	0.64 (0.42-0.96)*	182	68 (37.4)	1.71 (1.09-2.69)*	
2011	200	119 (59.5)	0.80 (0.53-1.21)	200	51 (25.5)	0.98 (0.62-1.56)	
Clove		Cigarette	S	Cigars			
	п	No. (%)	OR (95% CI)	п	No. (%)	OR (95% CI)	
2009 (Ref)	199	41 (20.6)	1.00	191	7 (3.7)	1.00	
2010	200	51 (25.5)	1.32 (0.83-2.11)	185	32 (17.3)	5.50 (2.36-12.80)***	
2011	200	31 (15.5)	0.71 (0.42–1.18)	199	31 (15.6)	4.85 (2.08–11.31)***	
Light		Cigarette	S				
	n	No. (%)	OR (95% CI)				
2009 (Ref)	189	173 (91.5)	1.00				
2010	200	173 (86.5)	0.59 (0.31-1.14)				
2011	200	166 (83.0)	0.45 (0.24-0.85)*				

p* < .05, **p* < .001 for a two-tailed test.

(83%) of the overall sample continued to sell these products after the LLM provision was implemented, including 91.5% of international vendors.

To assess compliance with both provisions, we analyzed the sale of flavored or LLM cigarettes (data not presented). In 2011, a large proportion of vendors (89%) continued to sell one or both of the banned products, including 95.8% of international vendors. There was, however, a significant drop in the likelihood of selling these products. In 2011, vendors were 0.40 times as likely to sell the products as in 2009 (95% CI = 0.18, 0.88).

Discussion

A significant proportion of Internet cigarette vendors continue to sell products banned by the FSPTCA. The vast majority of these vendors are based internationally, which may suggest that vendors based outside of the United States consider themselves exempt from U.S. law or feel they are less likely to be successfully punished. The U.S. vendor response to the provisions has been more promising. The provisions resulted in immediate drops in the proportion of U.S. vendors selling flavored cigarettes and cigarettes with LLM descriptors, and 2 years after the ban on characterizing flavors, the proportion of U.S. vendors selling flavored cigarettes continued to decrease, suggesting the policy has had lasting effects.

However, with 28.6% of U.S. vendors selling flavored cigarettes and 42.9% selling LLM cigarettes in violation of the provisions, and 66.1% of international vendors selling flavored cigarettes and 91.5% selling LLM cigarettes, these products remain widely available to U.S. consumers. It is worth noting that during the study period, FDA compliance and enforcement efforts were in their infancy. The FDA's Center for Tobacco Products was in the early stages of establishing offices and building its infrastructure, and resources to enforce these provisions were minimal. Still, this study suggests that ICVs could be a back door to banned products, and continued monitoring and effective enforcement of the FSPTCA are needed. Means of preventing banned products from being shipped by foreign ICVs to U.S. customers must also be implemented. In 2005 Federal Express, DHL, and United Parcel Service voluntarily agreed not to ship cigarettes to consumers, leaving the U.S. Postal Service (USPS) as the only major shipping option available to ICVs.⁵ The Prevent All Cigarette Trafficking Act (PACT) of 2009¹⁴ closed this gap, banning delivery of cigarettes and smokeless tobacco via the USPS (Sec. 3, §1716E (a) (1)) such that all cigarettes shipped from international vendors via foreign postal services (which are ultimately delivered by the USPS) violate federal law. Enforcement of the act has been on hold due to legal challenges ("Gordon v. Holder," 2013¹⁵; "Red Earth LLC v. US," 2011¹⁶), but once revived, PACT could be a powerful tool in blocking shipments of banned products by international vendors.

Notably, after the ban on characterizing flavors, a higher proportion of ICVs sold potential alternative products, like clove cigars and flavored little cigars, than before the ban. This pattern matches the response to the ban offline, where tobacco manufacturers and brick-and-mortar retailers alike have been promoting these products.17-19 For flavored little cigars, this effect was short-lived and disappeared by 2011, which could suggest that ICVs attempted to market flavored little cigars to their flavored cigarette consumers, but consumer demand was not high enough for vendors to continue stocking the products. For clove cigars, however, the substitution effect was lasting, particularly among U.S. vendors (over a third of which sold clove cigars in 2011), which could indicate consumers found clove cigars to be a suitable substitute for clove cigarettes. Following the flavors ban, the number of clove cigars sold in the United States increased dramatically.¹⁸ Research also suggests that many flavored cigars now on the U.S. market are virtually identical to flavored cigarettes aside from the color of their outer paper.²⁰ One major clove manufacturer only slightly modified its clove cigarette products and rebranded them as clove cigars after the flavors ban was implemented.18

The FSPTCA indicates that if a product "includes tobacco, in any form, that is functional in the product, 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," it is defined as a cigarette under the law (Title 1, Sec. 101, Sec. 900 (3) (B)). The indication that consumers (and vendors) may have found clove cigars to be a comparable substitute for clove cigarettes supports the notion that clove cigars should be considered equivalent to clove cigarettes and could potentially be banned by the FDA under the terms of the FSPTCA. The FDA recently issued a proposed "deeming" rule to extend its "tobacco product" authorities to tobacco product categories that are currently unregulated, including cigars.²¹ The rule requests comment on whether all cigars should be subject to FDA's "tobacco product" authorities or whether there should be an exemption for premium cigars.²¹ Either option would cover the clove and flavored little cigars investigated in this study and in similar research,¹⁸ and we urge the Agency to act quickly to finalize the rule. Finalizing the rule would be the first step in what is likely to be a years-long process to regulate flavors in cigars.

Vendor compliance with the flavors ban and restriction on LLM descriptors could depend on the source of cigarettes. While some U.S. vendors have brick-and-mortar retail operations and purchase their products from U.S. distributors, others buy from warehouse clubs and resell online. Still others use order fulfillment services that may ship cigarettes from U.S. sources or from other countries. Lower access to the banned products might account for the higher rates of compliance among U.S. vendors compared to international vendors or U.S. vendors working with international order fulfillment services, which may have a ready source for banned products in their countries or elsewhere.

This study is the first to assess ICV compliance with the ban on characterizing flavors and restriction on LLM descriptors. By summarizing trends over time, pre- and postimplementation of both provisions, the results add to the growing body of research on the impact of the FSPTCA. Nevertheless, several limitations should be noted. First, the samples included the 200 most popular ICV sites for each year (representing roughly half of the population of vendors identified and the sites that receive the overwhelming majority of the traffic). Therefore, there was some but not total overlap in sites across the years, and some of the patterns observed may have been due to the changing sample as opposed to implementation of the provisions. To address this limitation, a subanalysis was conducted with the 39 ICVs from which data were collected in all 3 years. The patterns matched those that were found for the overall sample, with one difference. For U.S. vendors, the trend for the sale of flavored cigarettes did not continue downward in 2011. After the ban on characterizing flavors, the proportion of U.S. vendors (that were in the sample in all 3 years, n = 7) selling flavored cigarettes declined from 28.6% to 0% and then rose to 14.3% in 2011, which could indicate that compliance has not been as promising as data from the full sample suggest. This exploratory analysis implies that these U.S. vendors stopped selling flavored cigarettes after the ban, possibly due to lack of availability or concerns over enforcement. Then, perhaps due to high demand or increased availability from international sources, some started selling them again by 2011.

Another potential limitation is that, even without an FDA order in place, retailers were permitted to sell products with LLM descriptors that were manufactured prior to June 22, 2010 and put into domestic commerce prior to July 22, 2010 (Title 1, Sec. 101, Sec. 911 (b) (3)). Thus, it was possible for vendors to sell products with LLM descriptors in 2011 without violating the FSPTCA,

although the products would have been at least 10 months old and presumably stale.

Lastly, classifying the true location of ICV Web sites is challenging and simplifying it to two categories may not adequately capture the nuanced nature of ICV location. These categories were created based on the site's stated physical address and other information found on the Web site, but sites may have order processing, Web site management/hosting, and order fulfillment locations in different countries. ICVs headquartered in the United States are known to set up locations outside of the country to evade U.S. regulations,⁵ while ICVs physically located in the United States could be foreign-controlled sites with a U.S. presence. In addition, some banned products, despite being listed for sale by an ICV, may not actually be available to U.S. consumers in all locations. For example, vendors may block the sale of flavored products to jurisdictions that have flavor restrictions in place (e.g., New York City and Providence, Rhode Island). Further research is needed to guide issues of jurisdiction and enforcement as applied to sales of tobacco products online, especially with businesses with both U.S. and international presences.

ICVs are notoriously difficult to target for enforcement and study due to the dynamic nature of the Internet and online business management. Sites can be shut down, only to reappear under another URL,⁵ and ICVs that have gone out of business may still have an online storefront. By highlighting potential FSPTCA violations and ways ICVs may be responding to the FSPTCA, this study may help guide FDA enforcement efforts as well as regulatory development on remote sales of tobacco products and the equivalency of flavored little cigars to flavored cigarettes. Further research should investigate the extent to which U.S. consumers purchase products from international vendors. Moreover, the results suggest that although most U.S. vendors may no longer be selling clove cigarettes, they are selling other types of flavored cigarettes (e.g., fruit flavored). Investigating these other types and determining whether specific brands are consistently being sold could inform enforcement activities.

On one hand, the results of this study are somewhat encouraging. Many U.S. vendors appear to be complying with the provisions. Nevertheless, there are still plenty who are violating the provisions by selling flavored (28.6%) and LLM (42.9%) cigarettes. Continued surveillance of U.S. vendors is critical to assessing ongoing trends in the marketing and availability of flavored and LLM cigarettes and industry response to the restrictions with substitute products, such as clove cigars and flavored little cigars. Widespread noncompliance by international vendors also suggests a need for further monitoring and enforcement by federal officials to block illegally imported products. Lastly, the rise in vendors selling flavored cigars underscores the importance and urgency of FDA issuing a final rule on deeming that would extend the agency's authority over cigars. As long as these other products remain unregulated and as long as international vendors evade FDA enforcement, the public health impact of the ban on characterizing flavors and restriction on LLM descriptors will be undermined.

Supplementary Material

Supplementary Figures 1–3 can be found online at http://www.ntr. oxfordjournals.org.

Funding

This work was supported (in part) by the National Cancer Institute at the National Institutes of Health (grant numbers CA154254, 5R01CA169189-02) and the Robert Wood Johnson Foundation Substance Abuse Policy Research Program (grant number 64747).

Declaration of Interests

None declared.

Acknowledgment

We would like to acknowledge the Robert Wood Johnson Foundation Substance Abuse Policy Research Program and the National Cancer Institute for supporting this work.

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