

Tobacco industry response to a ban on lights descriptors on cigarette packaging and population outcomes

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ABSTRACT

Objective The WHO Framework Convention on Tobacco Control and its Guidelines recommend nations ban the use of misleading terms, such as 'light' and 'mild' on tobacco product advertising, packaging and labelling. Many nations, including the USA, have implemented such bans and some have introduced or passed legislation requiring plain packaging on tobacco products. We previously reported that manufacturers in the USA responded by replacing lights terms with colour terms and related colour-coding of packages. This study examines population outcomes and public health impact of the US ban.

Methods We examined available data regarding a) per cent filter ventilation strata used to designate lights subbrand categories; b) market share per tar yield; c) initiation and use of cigarettes by lights categories and d) overall cigarette consumption to identify changes from before to after the ban. We used interrupted time series multivariable logistic regression and joinpoint regression models to test for changes in rates and temporal trends associated with the ban.

Results The per cent filter ventilation strata used to designate lights subbrand categories were maintained in the colour named subbrands. No change was observed following the ban in lights market share, relative prevalence of lights versus non-lights smoking or relative smoking initiation on lights versus non-lights among all ages or among youth in particular. The rate of decline in per capita cigarette consumption slowed by 37% from the period 2007-2010 to 2010-2014.

Conclusions This study strongly suggests that manufacturers' circumvention prevented the lights descriptor ban from succeeding as intended, most likely perpetuating the misleading consumer perceptions about relative risks, while failing to increase smoking cessation and reduce initiation. Laws requiring generic (plain) and elimination of subbrand descriptors should prevent evasion of legislation banning the use of specific terms through marketing, regulatory and legal challenges.

INTRODUCTION

Following the US Surgeon General 1964 report that found smoking causes lung cancer and is associated with other diseases, tobacco manufacturers introduced and marketed lights varieties of cigarettes as 'safer' than conventional cigarettes.^{1,2} Manufacturers designed the new subbrands with cigarette filter ventilation holes to reduce the smoke and machine-measured tar and nicotine (T/N) emissions as established by the Federal Trade Commission (FTC) in the 1950s. Research

has shown that the machine test only reflects the toxin yields under the test conditions, whereas the amounts of smoke, tar and nicotine that smokers obtain are much different.² The difference is due to the fact that many smokers compensate by knowingly or unknowingly, partially or fully blocking the ventilation holes, enabling them to inhale all of the smoke and its constituents, and by smoking more cigarettes per day, puffing more frequently or inhaling more deeply.³ The National Cancer Institute's (NCI) Monograph 13 (2001) confirmed that smoking lights cigarettes was no less harmful than smoking other types of cigarettes², but as a result of cigarette companies marketing lights sub-brands, many smokers switched from higher to lower yield cigarettes under the mistaken impression that it would reduce the harms caused by smoking, and many did so instead of quitting or cutting back.^{2,4,5}

The WHO Framework Convention on Tobacco Control, Article 11 and its Guidelines recommend nations ban the use of misleading terms, such as 'light' and 'mild' on tobacco product advertising, packaging and labelling. A total of 114 nations have done so while five have either introduced or passed legislation requiring plain packaging on tobacco products.⁶⁻⁸ Uruguay has a regulation, which was recently upheld in an international trade dispute, which limits brands to a single named variant.⁹ France has banned certain brand names because they are inherently misleading.¹⁰ Other countries have considered disbranding cigarettes entirely.¹¹

In the USA, the June, 2009 Family Smoking Prevention and Tobacco Control Act (TCA) banned the use of misleading and deceptive 'light', 'mild', 'low' (hereafter 'lights') or similar descriptors under Section 911(b)(2)(ii), effective 22 June 2010,¹⁰ citing NCI Monograph 13 and the 2006 US District of Columbia District Court ruling that found cigarette manufacturers liable under the Racketeer-Influenced and Corrupt Organization Act for longstanding and continuing fraudulent efforts to deceive the American public in their marketing of cigarettes with lights descriptors.¹² The TCA further prohibited false or misleading tobacco product packaging, labelling or advertising, and forbid tobacco product packaging, labelling or advertising from making any explicit or implicit reduced-risk or relative-risk claims without a prior permissive order from the Food and Drug Administration (FDA).¹³

Our previous research found that tobacco manufacturers replaced the lights terms explicitly banned in the law with colour terms and colour-coded packages and kept the subbrands with their



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corresponding filter-ventilation on the market.^{14 15} Sales of lights subbrands also remained unchanged in the first 6 months following the ban, while 92% of the US adult smokers reported that they could easily identify their current brand smoked as a lights and 68% correctly named the package colour associated with their current brand.¹⁴ Manufacturers responded to similar bans also in other nations by using colour substitutes as well as alternative terms.^{16–20} Studies have found that consumers perceive colour descriptors and colour-coded packaging similarly to lights descriptors and the subbrands as less harmful to smoke than others.^{21–24}

The FDA initially interpreted the TCA as stating that any brands or subbrands with changed names are new products and required premarket approval by the FDA based on finding that the newly named product would be ‘appropriate for the protection of the public health’ in order to enter or stay on the market.^{25 26} Tobacco manufacturers brought regulatory and legal challenges against the FDA while selling the renamed lights subbrands as substantially equivalent (SE) to the former lights.^{27 28} SE is a regulatory status that would require a simple showing that the product has the same physical characteristics as the original lights subbrand. They argued that FDA’s Guidance declaring renamed products to be new products²⁷ violated the TCA,²⁶ and they filed litigation against the FDA in the US District of Columbia District Court.²⁸ After lengthy regulatory and legal manoeuvring, the court ruled in favour of the tobacco industry that only changes to physical product characteristics, and not the label could subject a product to premarket approval provisions.²⁹ Nevertheless, the opinion also stated that the FDA clearly has the authority under section 903 (Misbranded Products) of the TCA to require prior approval of statements made on the label of a tobacco product to ensure that they are not false or misleading, and under section 911 to require prior approval for labels placed on ‘modified risk tobacco products’ (MRTPs) sold or distributed for the use to reduce the harm or risk of tobacco-related disease.²⁹

The ban on lights descriptors has now been in effect a sufficient length of time for evidence to accrue that allows for a more comprehensive evaluation of its effectiveness in protecting the public health. This study examines population outcomes of the ban over the 6 years since it came into effect by analysing temporal changes in a) per cent of the filter that is ventilated, the key physical design characteristic that determines a cigarette subbrand’s lights—and now colour—category, to ensure that the same subbrand based is compared before and after the ban, b) lights smoking prevalence and initiation rates relative to conventional full flavour cigarettes; c) market share of lights and d) overall cigarette consumption.

METHODS

The sources of data examined in this study were: (a) annual reports from manufacturers to the Massachusetts Department of Public Health (MDPH) listing the per cent filter ventilation, nicotine content and other parameters of cigarettes by brand and subbrand name, including lights category for the years 1998 through 2013, the most recent year available³⁰; (b) Federal Trade Commission Cigarette Reports providing market shares per year by tar yield³¹; (c) National Survey on Drug Use and Health (NSDUH) nationally representative survey data regarding initiation and use of cigarettes by lights categories³² and (d) tax revenue-based cigarette consumption figures.³³

We analysed temporal changes in per cent filter ventilation. Candidate predictor variables included an indicator variable

for the periods before and after the ban, lights category (full flavour, medium/mild, light or ultralight) and chronological time in years. We performed univariate analyses of the relationships between per cent filter ventilation and candidate predictor variables using contingency tables and the Fisher’s exact test. We included in subsequent multivariate analyses variables that were statistically significantly related to the outcome at $p < 0.05$. We compared the per cent filter ventilation prior to and following the ban using an interrupted time series linear regression model with repeated measures and mixed effects. We retained chronological time in all models to control for any underlying linear temporal trend and tested the interaction between time and the ban variable to assess a change in trend associated with introduction of the ban. We computed and tested the overall and stratum-specific effects of the ban for lights cigarette categories. A composite variable of brand family, subbrand name, rod length (70, 80, 100 or 120 mm); menthol versus non-menthol and pack type (hard vs soft) was specified as a random effect. We used a β parameter estimate and p value-driven backward selection procedure, removing covariates that did not change the predictor’s coefficient by 10% or more and whose log-likelihood ratio p value was ≥ 0.05 in comparison to alternative model. We also tested interactions between the ban variable and predictor variables as well as random effects using likelihood ratio tests.

Manufacturers’ reports to MDPH are commonly sent on 15 December of each year. The dates on which the tests were actually done are not always explicitly noted, and so some ambiguity exists for year 2010 data whether were collected prior to or following the date when the ban came into effect. We therefore treated per cent ventilation data for 2010 by classifying them as following the ban or by excluding them in a sensitivity analysis.

We analysed data from 1998 through 2013, in Statistical table 4 of the Federal Trade Commission Cigarette Report for 2013, which lists manufacturers’ yearly reported market shares of cigarettes by tar yield using the FTC-developed standardised machine testing condition.²⁷ We conducted linear regression analysis of market share using an interrupted time series model, with time measured in years to test for underlying temporal trend; time before or after the ban, to test for an incremental effect of the ban and the interaction between time and the ban to test for an effect of the ban on temporal trend. We classified lights cigarettes as yields of 12 mg tar or less and 15 mg tar or less in a sensitivity analysis.

We examined NSDUH public use data sets from 2005 through 2014 to determine whether the ban resulted in a change in smoking initiation rates with lights (medium, light or ultralight) relative to full flavour cigarettes or in a change in smoking prevalence (past 30 days, or ‘current smoking’) of lights relative to full flavour cigarettes.³² NSDUH is a cross-sectional survey that assesses substance use behaviours in the US civilian, non-institutionalised population aged 12+ years. Each year, approximately 70 000 eligible individuals complete the survey. NSDUH uses a 50-state design with independent, multistage area probability samples for each state and the District of Columbia to provide nationally representative data regarding tobacco use, alcohol use and other illicit drug use. Data are collected using computer-assisted personal interviewing for basic questions and audio computer-assisted self-interviewing to complete questions on substance use to encourage more truthful reporting. Complete information regarding data collection methods can be found online at <http://www.oas.samhsa.gov/nsduh/methods.cfm>.

Smoking initiation with lights was defined as having initiated smoking on a lights versus full flavour category during the year prior to the interview. We used the year and quarter of the

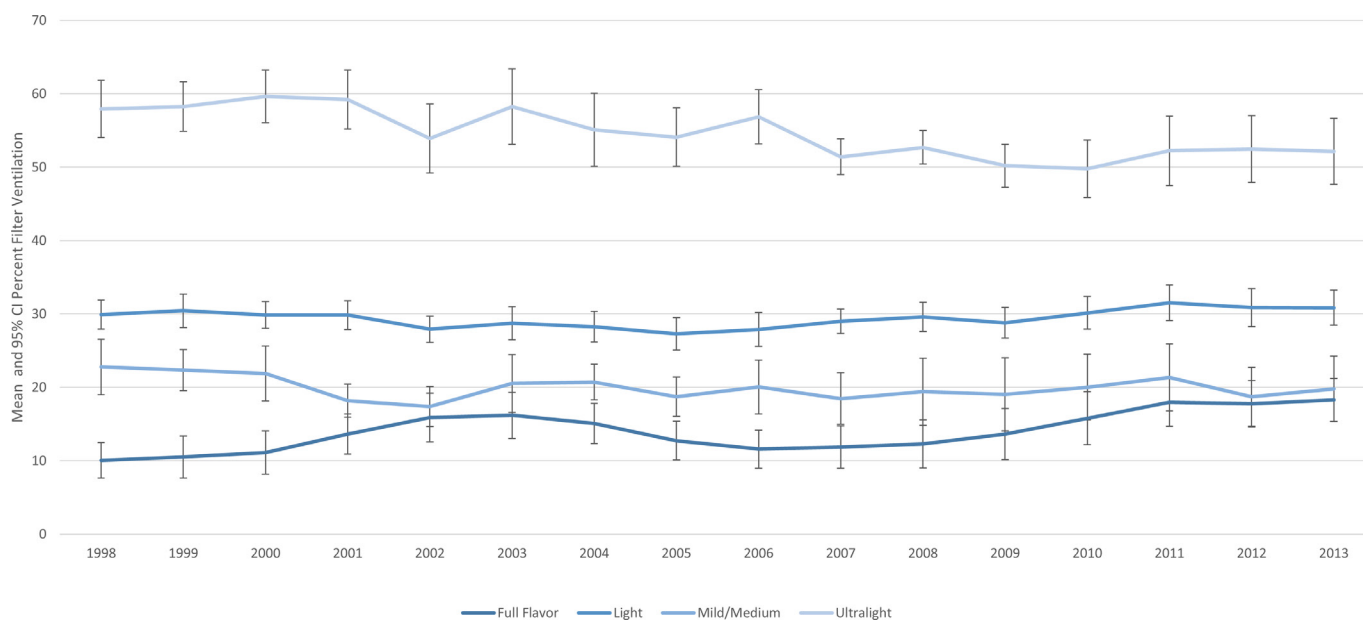


Figure 1 Trends in per cent filter ventilation across 'lights' cigarette, 1998–2013.

interview, the reported month and year of first cigarette use, the reported age of respondent and age when first used cigarettes to determine initiation in the past year. For a small number of cases, the time since first cigarette use could not be determined with precision within a month or alternatively more than a year before the interview, and these were coded as missing.

We performed univariate analyses, including contingency tables with the χ^2 statistic and logit regression, of the relationships of each of the two outcomes (lights smoking prevalence and past-year initiation on lights) with the period prior to versus following the ban, which was identified as the second quarter of year 2010, as well as with other potential covariates: gender (male or female), age group (12–17 vs 18 years and over), race/ethnicity (white vs non-white), annual household income (\leq US\$19 999, US\$20 000–US\$49 999, US\$50 000–US\$74 999 or \geq US\$75 000); and chronological time (using year and quarter of the interview as unit of analysis). We used an interrupted time series multivariable logistic regression modelling approach to test the relationships between the time before versus after the ban and the two outcome variables, controlling for sociodemographic characteristics and chronological time to account for underlying linear temporal trend. We examined the effect of the ban on each of the outcome variables stratified by socioeconomic characteristics by adding the respective interaction terms individually into the model and testing their significance with the adjusted Wald test. We investigated for change in the temporal trends associated with the ban by including the interaction term between date of the ban and the time variable. We used a β -driven (parameter estimates) and p value-driven backward selection procedure, removing the covariates that did not change this main predictor variable's coefficient by 10% or more, and whose log-likelihood ratio test p value was ≥ 0.05 . All data analyses incorporated the survey weighting variables to yield nationally representative estimates.

We analysed trend in per capita cigarette consumption and changes in trend over the years 2000–2014 using joinpoint software.³⁴ The procedure fits the simplest model allowed by the data, beginning with the minimum number of joinpoints, and tests whether more joinpoints are statistically significant and

must be added to the model using a Monte Carlo Permutation method.³⁵

RESULTS

Comparability of the per cent ventilation of lights and renamed colour subbrands

The number of subbrands reported to the MDPH in 1998–2013 ranged from 103 to 216 (median 176) per year. Per cent filter ventilation ranged from 10.0 to 18.3 for full flavour, 17.4 to 22.8 for mild/medium, 27.3 to 31.5 for light and 49.7 to 59.6 for ultralight cigarettes over this time period. Per cent filter ventilation increased overall by 2.4 percentage points (95% CI 1.6 to 3.2) following the ban. The amount of increase varied by lights category, 4.8 percentage points (95% CI 3.7 to 5.9) for full flavour subbrands, 3.8 percentage points (95% CI 1.9 to 5.7) for medium/mild subbrands, 1.4 percentage points (95% CI 0.3 to 2.4) for light subbrands and 0 percentage points (95% CI –2.8 to 0.4) for ultralight subbrands (figure 1). The differential between full flavour and medium/mild cigarette subbrand categories narrowed slightly, while preserving the gradient of categories that has been characteristic of lights categories.⁵ A small, but statistically significant increasing temporal trend of 0.1 per cent filter ventilation per year was observed over all cigarette brands (95% CI 0.1 to 0.2) from 1998 to 2013. No change in temporal trend was observed in association with the ban ($p=0.776$).

Trends in lights cigarette consumption

Lights cigarette market share ranged between 50.4% and 59.5% during the period 1998–2013 based on tar yield 12 mg or less measured using the FTC method as reported by the tobacco companies to FTC (figure 2) and between 75% and 94% based on tar yield 15 mg or less during the same period. The analysis found no underlying temporal trend in lights market share ($p=0.776$) over the study period, no, new trend following introduction of the ban ($p=0.867$) and no effect of the ban on lights market share ($p=0.220$) in analyses adjusted for socioeconomic characteristics and chronological time. These findings were upheld in sensitivity analysis that classified year 2010 as being

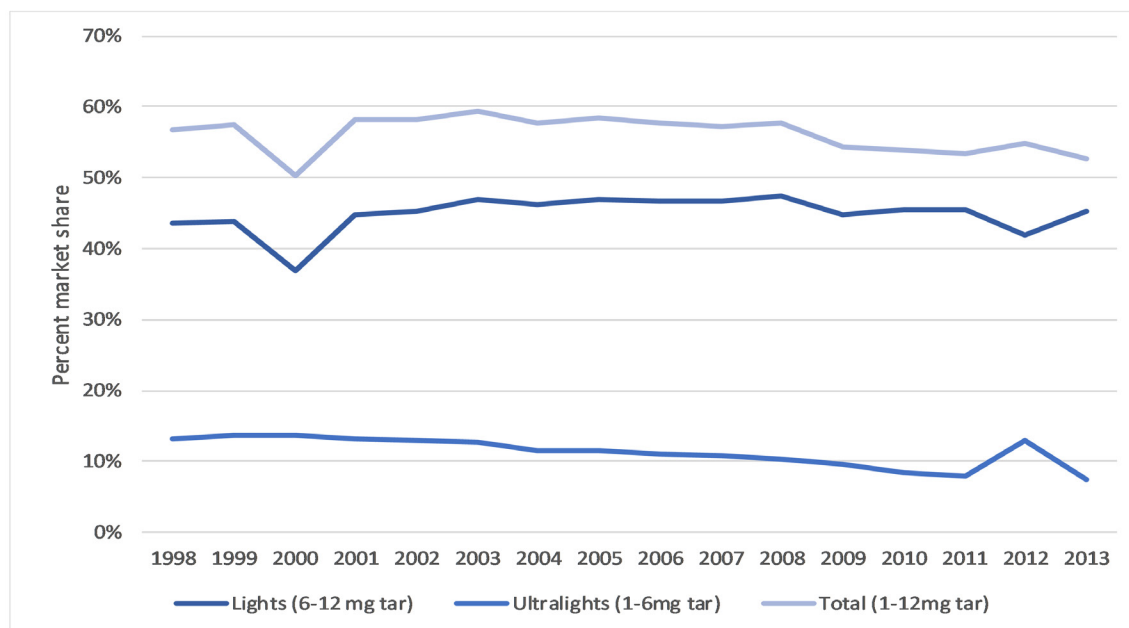


Figure 2 Annual market share of cigarettes by tar yield, 1998–2013.

after introduction of the ban, as well as in analysis based on a threshold tar yield of 15 mg or less.

Trend in lights smoking prevalence and initiation

The annual prevalences of smoking by lights categories among all current smokers aged 12 years and older from 2005 through 2014 are shown in Table 1. The results of univariate and multivariate analyses of lights (medium/mild, light, ultralight) smoking among current smokers are shown in Table 2. The prevalence of smoking lights cigarettes compared with non-lights among all current smokers aged 12 years and older was higher among persons with higher household incomes, females, whites and adults (aged over 17 years). Although the raw prevalence data appear to show declines in lights smoking after the ban (56.4%) compared with (61.6%) before the ban ($p < 0.001$) (table 1), no change in prevalence of lights smoking was observed in association with the ban (OR 0.95, 95% CI 0.98 to 1.04) when controlling for the underlying decreasing trend over the study period and socioeconomic characteristics.

Furthermore, no change was observed in the trend in association with the ban ($p = 0.519$).

The results of univariate and multivariate analyses of lights (medium/mild, light, ultralight) smoking among current smokers are shown in table 2.

The results of univariate and multivariate analyses of past-year smoking initiation on lights cigarettes are shown in table 3.

Smoking initiation on lights cigarettes compared with non-lights among all current smokers aged 12 years and older was higher among persons having higher household incomes, females, whites and adults (aged over 17 years). The proportion decreased by 6% per year over the study period. No change in smoking initiation on lights cigarettes compared with non-lights was observed in association with the ban (OR 1.13, 95% CI 0.73 to 1.76) when controlling for this underlying trend and socioeconomic characteristics. Similarly, no change in smoking initiation on lights cigarettes compared with non-lights among youth, ages 12–17 years was observed in association with the ban (OR 1.26, 95% CI 0.78 to 2.02).

Table 1 Prevalence and 95% CI of 'lights' smoking among current smokers 2005–2014

	Full flavour	Medium	Light	Ultralight
2005	36.5% (35.1, 37.9)	5.2% (4.6, 6.0)	44.9% (43.6, 46.2)	13.4% (12.3, 14.6)
2006	38.2% (36.7, 39.7)	6.5% (5.9, 7.2)	44.2% (42.8, 45.6)	11.1% (10.3, 12.0)
2007	38.7% (37.2, 40.2)	5.4% (4.7, 6.2)	44.9% (43.5, 46.3)	11.0% (10.2, 11.9)
2008	38.6% (37.1, 40.1)	6.6% (5.9, 7.3)	43.5% (42.0, 45.0)	11.4% (10.2, 12.7)
2009	39.6% (38.0, 41.2)	7.0% (6.3, 7.7)	44.2% (42.3, 46.1)	9.2% (8.2, 10.3)
2010	39.7% (38.1, 41.4)	7.0% (6.2, 7.7)	42.6% (41.0, 44.2)	10.7% (9.6, 12.0)
2011	43.8% (42.5, 45.2)	7.1% (6.4, 8.0)	39.7% (38.4, 41.1)	9.3% (8.2, 10.5)
2012	44.5% (42.9, 46.1)	8.3% (7.6, 9.1)	38.0% (36.4, 39.6)	9.2% (8.2, 10.3)
2013	43.9% (42.2, 45.5)	9.5% (8.7, 10.5)	38.6% (37.1, 40.1)	8.0% (7.2, 9.0)
2014	43.8% (42.4, 45.3)	9.0% (8.4, 9.7)	39.6% (38.4, 40.8)	7.6% (6.8, 8.4)

Table 2 Factors associated with prevalence of lights vs full flavour smoking among current smokers

	Univariate analyses					Multivariable analysis					Adjusted OR Stratified by covariates		Wald test p Value
	N	% Lights	95% CI	OR	95% CI	p Value	OR	95% CI	OR	95% CI			
Male (referent)	2 711 115	54.2	53.6 to 54.9	-	-	-	-	0.97	0.89 to 1.06	0.97	0.89 to 1.06	0.267	
Female	2 877 886	65.4	64.7 to 66.0	1.59	1.53 to 1.66	<0.001	1.67	1.61 to 1.74	0.92	0.83 to 1.02	0.83 to 1.02	0.046	
Adult (referent)	5 040 051	59.6	59.1 to 60.0	-	-	-	-	0.95	0.87 to 1.03	0.95	0.87 to 1.03	0.007	
Youth	54 950	53.3	52.2 to 54.3	0.77	0.74 to 0.81	<0.001	0.68	0.65 to 0.72	1.01	0.95 to 1.22	0.95 to 1.22	0.007	
Non-white (referent)	1 859 24	49.9	48.9 to 50.8	-	-	-	-	1.03	0.92 to 1.14	1.03	0.92 to 1.14	0.007	
White	3 730 77	63.3	62.7 to 63.8	1.73	1.65 to 1.81	<0.001	1.49	1.42 to 1.57	0.92	0.84 to 1.00	0.84 to 1.00	0.516	
Household income <US\$20 000 (ref)	1 026 33	47.2	46.2 to 48.1	-	-	-	-	0.96	0.86 to 1.04	0.96	0.86 to 1.04	0.516	
Household income US\$20 000–49 999	1 828 49	57.7	56.8 to 58.5	1.53	1.45 to 1.61	<0.001	1.52	1.44 to 1.61	0.93	0.85 to 1.01	0.85 to 1.01	0.516	
Household income US\$50 000–74 999	972 10	65.5	64.4 to 66.5	2.12	2.01 to 2.24	<0.001	2.10	1.97 to 2.23	0.97	0.85 to 1.09	0.85 to 1.09	0.516	
Household income US\$75 000 or more	1 763 09	72.3	71.6 to 73.5	2.96	2.79 to 3.14	<0.001	2.95	2.76 to 3.16	0.98	0.87 to 1.10	0.87 to 1.10	0.519	
Time (years)	5 590 01	-	-	0.96	0.96 to 0.97	<0.001	0.97	0.96 to 0.98	1.00	1.00 to 1.01	1.00 to 1.01	0.519	
Preban	3 007 98	61.6	61.0 to 62.2	-	-	-	-	-	-	-	-	-	
Postban	2 582 03	56.4	55.7 to 57.2	0.81	0.78 to 0.84	<0.001	0.95	0.87 to 1.04	0.95	0.87 to 1.04	0.87 to 1.04	0.519	

Table 3 Effect of lights descriptor ban on past-year initiation to smoking with lights vs full flavour cigarettes

	Univariate analyses				Multivariable analysis			
	N	% Initiating on lights	95%CI	OR	95%CI	p Value	Adjusted OR	95%CI
Male (referent)	2054	67.1	64.4 to 69.8	-	-	-	-	-
Female	2059	74.4	71.2 to 77.3	1.42	1.15 to 1.76	0.001	1.45	1.17 to 1.79
Adult (referent)		69.7	66.3 to 72.8	-	-	-	-	-
Youth	1795	72.2	69.0 to 74.4	1.13	1.02 to 1.49	0.241	-	p=0.761
Non-white (referent)	1585	68.1	64.3 to 71.6	-	-	-	-	-
White	2528	72.5	70.4 to 74.4	1.23	1.02 to 1.49	0.029	-	p=0.115
Income (referent) <US\$20000	1099	69.0	65.3 to 72.5	-	-	-	-	-
Household income US\$20000–49 999	1234	67.9	64.1 to 71.5	0.95	0.74 to 1.22	0.690	0.95	0.73 to 1.23
Household income US\$50000–74 999	613	72.7	67.3 to 77.5	1.20	0.89 to 1.61	0.239	1.21	0.89 to 1.66
Household income US\$75 000 or more	1166	74.5	71.1 to 77.6	1.31	1.04 to 1.65	0.021	1.33	1.06 to 1.67
Time (years)								
Preban	2706	72.9	70.7 to 75.0	0.94	0.92 to 0.97	<0.001	0.93	0.86 to 1.00
Postban	1407	66.6	63.1 to 70.0	0.74	0.61 to 0.90	0.002	1.13	0.73 to 1.76

Furthermore, no change was observed in the trend in association with the ban ($p=0.294$).

Trends in overall cigarette consumption

The US per capita cigarette consumption ranged from 1551 in 2000 to 845 in 2013. The rate of decline in per capita cigarette consumption slowed from 6.8% per year in years 2007 to 2010 to 4.3% in years 2010 to 2014 ($p=0.006$).

DISCUSSION

This is the first study to our knowledge to examine the effectiveness of a ban on lights descriptors on population outcomes. The level of use, rate of initiation among all ages and youth in particular and market share of lights cigarettes, relative to conventional full flavour cigarettes did not change significantly over the 6 years since the ban on lights and similar descriptors came into effect, while the annual rate of decline of per capita cigarette consumption slowed by 37%. The most apparent reason that the ban was not effective was the ease with which the cigarette companies replaced the banned terms with colour terms and coding that allowed smokers to readily identify the former lights named subbrands.^{2 12} The cumulative evidence now strongly suggests that manufacturers circumvented the lights descriptor ban by substituting colour terms, perpetuating the misleading consumer perceptions as reported by the NCI² that the subbrands offered lower smoking risks.

Lights have long accounted for a large portion of cigarette market share in the USA, over 50% or 87% depending on the tar level threshold used to identify them.²⁹ The failure of the ban represents a major setback for FDA's attempt to regulate the renamed lights subbrands under the SE or new tobacco product review process. Despite the court ruling that the FDA may only consider physical product characteristics, not brand or subbrand name changes, when making SE or new product evaluations, the TCA gave FDA direct authority to take enforcement action against any false or misleading labelling or the use of any similar descriptors with implied reduced-risk claims made without a prior MRTP permissive order.

In order to receive an MRTP order manufacturers must provide scientific evidence meeting standards of research and study designs developed by FDA in consultation with the Institute of Medicine (IOM), including studies of risk perception, risk communication and the use of terms. The IOM recommended in its 2012 report '...if the industry decides to use imagery, colour-coding, or any other visual (but non-verbal) means of conveying information about the MRTP ...then they should also test the influence of this type of messaging on consumer perceptions in premarket studies...'³⁶ Scientific evidence has demonstrated that certain colours on packages communicate brand strength and risk messages to consumers regardless of whether actual colour hues are used.³⁷⁻⁴⁵ Lighter colours, such as blue and gold are perceived as synonymous with lightness, while darker colours, such as red, denote stronger subbrands.⁴⁶⁻⁴⁹ Furthermore, manufacturers' own research highlights the importance companies ascribe to brand name development for influencing consumer perceptions of risk and increasing sales.⁵⁰⁻⁵³ The FDA could also regulate filter ventilation, the physical characteristic that determines consumer perceptions of lightness, smoothness or diminished harshness, which strong evidence indicates are linked to perceptions of risk, as the FDA has reported with regard to menthol.⁵³

The WHO Framework Convention on Tobacco Control treaty also forbids marketing or advertising that directly or

What this paper adds

- ▶ The WHO Framework Convention on Tobacco Control (FCTC) recommends that nations ban the use of misleading terms including 'light' and 'mild' on advertising, packaging and labelling of tobacco products. The US Family Smoking Prevention and Tobacco Control Act bans the use of lights or similar descriptors, prohibits false or misleading packaging or labelling and forbids explicit or implicit reduced risk claims in product packaging or labelling without a prior permissive order from the Food and Drug Administration. Manufacturers replaced lights descriptors in the USA and in other nations with colour terms, while maintaining filter ventilation, the physical characteristic differentiating lights subbrands. Consumers easily recognised the renamed subbrands as the former lights subbrands.
- ▶ This study found that the level of use, rate of initiation among youth and market share of lights cigarettes relative to full flavour cigarettes did not change as a result of the ban in the USA. This experience provides additional evidence that existing cigarette subbrands and their labelling are violating the Act by making implicit inaccurate reduced-risk claims, and that lights descriptor bans are not sufficient to stop the marketing and misleading consumers with these subbrands, and increasing overall smoking levels and harms.

indirectly creates the false impression that a tobacco product is less harmful than other tobacco products.⁷ A review of industry practices following similar bans in other countries concluded that nations should ban lights descriptors and misleading numbers, the use of colours, imagery, brand extensions and other devices that contribute to deception.⁵⁴ Studies from jurisdictions where regulations on misleading descriptors have been implemented have shown that many smokers continue to perceive cigarette brands with package design features, including names of colours yet to be prohibited, as less harmful than others.^{20 21 55-57} Those findings along with the present, population outcomes findings provide strong evidence of the need for more stringent descriptor bans that include other text and messaging that could be used to distinguish subbrands. They also support the WHO guidelines for the implementation of FCTC, which recommend that Parties consider adopting plain-packaging requirements to address industry package design techniques that may suggest that some products are less harmful than others.^{46 58} Strengths of this study include use of postmarket surveillance methods examining industry-reported tobacco product physical design and the total US market share data and the large sample size, nationally representative self-reports of current smoking behaviour among the US adults and youth before and after the ban to assess effects on population health.

These findings should be interpreted within the context of some limitations. Since 2011, manufacturers have only been required to submit to FTC market share of cigarettes by tar yield that are in their possession or control. However, any contrast with unavailable market share data is likely to be non-differential and not bias the results. NSDUH might have some under-reporting, but the validity of self-reporting in similar contexts has been established. The cross-sectional survey design provides prevalence of tobacco use at a consecutive points in time rather than changes in use over time for

Research paper

individuals. A small proportion (slightly <2%) outside the targeted non-institutionalised civilian population of the USA is excluded. NSDUH interview dates are specified to the quarter year, limiting the precision of past-year initiation estimates by 2–3 months in some cases. However, the results remained the same in sensitivity analysis.

This study provides insight into the challenges of regulating a resourceful and powerful tobacco industry that circumvents the intent of laws that ban lights and similar descriptors by substituting implicitly like terms and relentlessly pursues litigation to thwart corrective regulation. The study shows that the US ban on lights descriptors has not realised the public health benefit that the TCA intended. Nations that do not want to repeat this experience may consider requiring plain packaging and eliminating subbrand descriptors.

Contributors HRA and GNC planned the study, HRA conducted the analyses and interpreted the findings of the study, and prepared and submitted the manuscript. GNC interpreted the findings of the study and contributed to the writing of the manuscript. DC contributed to the writing of the manuscript.

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