HARVARD SCHOOL OF PUBLIC HEALTH

Trends in Smoke Nicotine Yield and Relationship to Design Characteristics Among Popular U.S. Cigarette Brands

1997-2005

A Report of the
Tobacco Research Program
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ABSTRACT

Objective: We sought to determine whether smoke nicotine yields of cigarettes would show an overall increase over time or an increasing trend limited to any particular market category (e.g. full flavor vs. light, medium (mild), or ultralight; mentholated vs non-mentholated), manufacturer, or brand family or brand style, and smoke nicotine yields would be associated with measurable trends in cigarette design.

Methods: Machine-based measures of smoke nicotine yield as well as measures of cigarette design features related to nicotine delivery (ventilation, nicotine content in the tobacco rod, and number of puffs), and market category descriptors were obtained from annual reports filed with the Massachusetts Department of Public by tobacco manufacturers for the years 1997-2005. Trends in smoke nicotine yield and relationship with design features and market parameters were analyzed with multilevel mixed effects regression modeling procedures.

Results: A statistically significant trend was confirmed in increased smoke nicotine yield of 0.019 mg per cigarette (1.1%) per year over the period 1997-2005 or 0.029 mg per cigarette (1.6%) per year over the period 1998-2005. The increasing trend was observed within all major market categories (mentholated vs. non-mentholated and full flavor vs. light, medium (mild), or ultralight). Increasing smoke nicotine yield was associated with increasing nicotine concentration in the tobacco and number of puffs per cigarette, and decreasing percent filter ventilation of the cigarette.

Conclusions: This study confirms increased machine-measured levels of nicotine, the addictive agent in cigarettes, as a result of increased nicotine in the tobacco rod and by other design modifications.

INTRODUCTION

The 1981 U.S. Surgeon General report "The Health Consequences of Smoking: The Changing Cigarette" highlighted the need to "continue to monitor the changing cigarette to ensure that when new cigarette products appear they do not bring with them new hazards to health."[1] Nicotine, as the agent primarily responsible for addiction, has been identified as a parameter of unique importance in assessment of the changing cigarette. [2] Recent findings by the United States District Court for the District of Columbia underscore the need for continued surveillance of the delivery of nicotine. [3] In the District Court's 2006 ruling, Judge Kessler concluded that tobacco companies "can and do control the level of nicotine delivered in order to create and sustain addiction" and further, that the "goal to ensure that their products deliver sufficient nicotine to create and sustain addiction influences their selection and combination of design parameters."[3]

The U.S. Federal Trade Commission (FTC) began publishing standardized machine-generated measures of smoke nicotine yield for U.S. cigarettes beginning in 1967. [4] Machine-generated measures remain the most widely available methods for comparison of smoke generation across brand families and brand styles without regard to individual smoking behavior. However, smokers compensate to increase smoke yield. [5,6] It is well established that smokers tend to take larger puffs or otherwise increase smoke intake when they switch to a lower yield cigarette, and that these shifts in behavior compensate for nicotine exposure.[7-11]

Measures of machine smoke nicotine yield may be instructive to the extent that they reflect the ease with which a smoker can extract nicotine and achieve or sustain a given level of nicotine exposure. [12] This can be enhanced through an increased availability of nicotine in the unburned rod, reduced cigarette burn rate (resulting in more puffs taken per cigarette), or a higher rate of conversion of nicotine from the tobacco rod to the smoke.

Beginning in 1997, Massachusetts regulations require an annual report to be filed with the Massachusetts Department of Public Health (MDPH) by all manufacturers of cigarettes sold in Massachusetts.[13] The reported data include machine-based measures of nicotine yield as well as measures of cigarette design related to nicotine delivery (ventilation, nicotine content in the tobacco rod, and number of puffs). The Tobacco Research Program at Harvard School of Public Health obtained from MDPH a complete set of the available Massachusetts brand-specific data from 1997-2005. Objectives of the present study were to examine trends in smoke nicotine yield and to evaluate these trends with respect to data available pertaining to market category and cigarette design. We sought to determine whether a) machine-generated data reflecting increase over time in smoke nicotine yield; b) an increase in smoke nicotine yield would be limited to any particular market category (e.g. full flavor vs. light, medium (mild), or ultralight; mentholated vs non-mentholated), manufacturer, or brand family or brand style; and c) an increase in smoke nicotine yield would be associated with measurable trends in cigarette design.

METHODS

Description of data. Data were received from MDPH for years 1997-2005. For the majority of brands in each year**,** Massachusetts regulations require manufacturers to report the most recent available Federal Trade Commission (FTC) or International Standards Organization (ISO) machine-generated smoke yield of nicotine. The FTC/ISO methods were developed to facilitate comparison between cigarette brand families and brand styles under a uniform set of smoking conditions, specified as 35 mL puff volume, 60 second interval between puffs, 2 second puff duration, and cigarette smoked to 23 mm butt length.[13] Brand-specific market categories are also reported for each cigarette.

Brand families (e.g. Marlboro, Camel) with significant market share (defined as greater than 5% in 1997, and as greater than 3% in all subsequent years) were subject to expanded reporting requirements. The regulations also permit MDPH to select a small number of additional brand styles (between 3 and 15 per manufacturer, based on the manufacturer's overall market share) in each year which were then subject to expanded reporting requirements. The expanded MDPH reporting requirements include smoke nicotine yield generated by a smoking machine according to a more intensive set of parameters commonly referred to as the Massachusetts (MA) method. These parameters are comprised of a 45 mL puff volume, 30 second interval between puffs, 2 second puff duration, 50% blocked ventilation holes, and cigarette smoked to 23 mm butt length on an unfiltered cigarette or overwrap, plus 3 mm on a filtered cigarette. The expanded reporting requirements also include the number of puffs generated per cigarette based on the MA smoking method; nicotine content in the unburned tobacco per cigarette (mg/cig) and nicotine concentration (mg nicotine per gram tobacco) (the latter only available beginning in 1998); percent filter ventilation; FTC/ISO smoke nicotine yield; and a classification of yield (high/medium/low) defined by the Massachusetts regulations. Methods for obtaining these measures are described in the MDPH regulations. [13]

Coding of data. The scope of the analysis was limited to brands sold by major manufacturers: Philip Morris (PM) USA, Reynolds American (categorized separately as RJ Reynolds and Brown & Williamson); and Lorillard Tobacco. The analysis was further limited to brand styles for which expanded data regarding design features and smoke nicotine yield were available. All brand styles were coded according to market categories including full flavor / light/ medium (mild) / ultralight; mentholated / non-mentholated; filtered / non-filtered; length (70 / 72 / 85 (King) / 100 / 120); box (hard pack / soft pack / tin) candy- or exotic flavored (e.g. Crema, Dark Mint) / non-candy-flavored. Brand styles were defined as packagings with unique combinations of these market categories (e.g. Camel King Filter Tin Menthol 85). We calculated tobacco weight for each brand style by dividing nicotine content per cigarette by nicotine concentration per gram of tobacco. Per puff smoke nicotine yield was calculated by dividing MA smoke nicotine yield by number of puffs per cigarette.

Full data were available for all variables except market share classification, nicotine concentration in the tobacco rod, and weight, for which at least 95% of the data were available. Reported data were checked against the original submissions from manufacturers, and outliers were flagged for possible misclassification and corrected.

Statistical analysis. *Trends in smoke nicotine yield.* The trends in smoke nicotine yield over time were tested with regression analysis of smoke nicotine yield per cigarette and of smoke nicotine yield per puff as dependent variables, and year, the independent variable. A multilevel mixed fixed and random effects regression model was used to account for the nested structure of brand styles grouped within brand families, which were in turn grouped within manufacturers. [14-16] Time (or the year of the sample) was treated as the fixed effect in this model.

A regression model of trend in smoke nicotine yield was constructed for the reported data. Since interlaboratory reliability in 1997, the first year of testing, was questionable, and due to the relatively low number of brand styles sampled in 1997 (between one half and one third of the number of styles sampled in subsequent years), coupled with the lack of availability of brand-specific data on nicotine concentration (mg nicotine per gm tobacco) and calculated tobacco weight, the primary analyses were conducted on the data reported from 1998-2005. Descriptive analyses included the 1997 data as well as an additional regression model performed for comparative purposes.

In order to assess changes in smoke nicotine yield, the smoke nicotine yields of brand styles reported in the baseline year, 1998, were compared to the smoke nicotine yields of new brand styles introduced in subsequent years. The hypothesis that the smoke nicotine yields of new cigarette brand families and brand styles entering the market differed from the smoke nicotine yields of brand families and brand styles existing on the market in 1998 was tested with regression analysis including time frame of entry into the market (1998 vs. 1999-2005) as an independent fixed effect variable.

Likelihood ratio tests of models in the presence or absence of random effects were used to determine the statistical significance of those effects. For example, differences in smoke nicotine yields between manufacturers were tested for statistical significance by comparing multilevel models with and without the manufacturer random effect.

Statistically significant differences in the trends in smoke nicotine yields between manufacturers, brand families, and brand styles were tested by comparing models with and without the time included as a variable within the respective level.

A subset analysis of trends in smoke nicotine yield among Marlboro brand cigarettes was performed in order to assess a response by PM USA to a reported trend by MDPH in increased smoke nicotine yield for Marlboro. [17]

Potential determinants of smoke nicotine yield. Potential correlates of smoke nicotine yield consist of market categories (full flavor vs. light, medium (mild), or ultralight; mentholated vs non-mentholated; filtered vs. non-filtered; length ≤ 100mm vs > 100 mm; candy- or exotic flavored (e.g. Crema, Dark Mint) vs. non-candy flavored); and physical measures of cigarette design or smoke yield (number of puffs per cigarette; mg nicotine content in the unburned tobacco per cigarette and nicotine concentration (mg nicotine per gram tobacco); tobacco weight per cigarette; and percent filter ventilation. Smoke nicotine yield is generated by burning tobacco and drawing smoke through the tobacco column according to a consistent set of conditions as specified by the MA method. As a result, a change in smoke nicotine yield should reflect physical design differences in the product, such as the amount of burned tobacco, the amount and concentration of nicotine in the tobacco, the burn rate of the cigarette between puffs, degree of ventilation, or other measures.

Bivariate and multivariate regression analyses were performed to determine the relationships between smoke nicotine yield and each of the market categories and design features. Multilevel modeling was performed first with smoke nicotine yield the dependent variable and a single market category or design feature the independent fixed effect variable. Statistically significant predictor variables from these analyses were then entered as fixed effect independent variables in a stepwise backwards multivariate regression analysis. Brand style, brand family, and manufacturer were treated as random effects in the multilevel models. The market category filtered vs. non-filtered was not included in multivariate analyses since filtered products are the predominant cigarettes on the market and comprised 98% of the sample.

Certain predictor variables (e.g. nicotine content per cigarette and nicotine concentration in the tobacco rod) might be highly intercorrelated; resulting in the possibility that variance not related to the prediction of the dependent variable would be suppressed by one of the intercorrelated predictor variables. [18, 19] In these cases, the significant regression coefficients of the two variables might not reflect the direction contributions of those variables as predictors. Therefore, several multiple regression models were examined to explore the contributions of the predictor variables. Inclusion of one or both variables in the selected model was determined on the basis of changes in the standard errors, where evidence of the "suppressor variable" effect was observed.

A full model of factors related to smoke nicotine yield was identified using multilevel regression analysis including time as well as the remaining statistically significant predictors among the market category and design features. Multilevel mixed regression models were also used to analyze changes over time among the market categories and design features that were found to be associated with smoke nicotine yield. Market category and design features that were found to be associated with smoke nicotine yield and that also displayed a corresponding time trend were modeled using the same multilevel structure in order to identify any significant predictors of these parameters.

Statistical analyses were performed using Stata Statistical Software, Release 9. [20]

RESULTS

Description of sample. Brand families and brand styles included in the analysis are summarized in Table 1. The number of sampled brand styles from 1998-2005 ranged between 172 and 217 and peaked in the 2000-2002 period. The much lower relative number of brand styles in 1997 (85) reflects the different Massachusetts regulatory requirements in 1997 (greater than 5% rather than 3% market share).

The number of brand families meeting the subsequent 3% market share threshold reduced gradually from 22 to 18 between 1998 and 2005, while the number of brand styles within brand families increased from year to year, possibly reflecting a consolidation of brand families. In each year, brand styles from brand families with less than 3% market share comprised between 15-21% of the overall sample. In 2004-2005, RJ Reynolds brand families and brand styles reflect the acquisition of Brown & Williamson, specifically the addition of Kool, which returned to 3% market share in 2004 only.

Approximately 38% of the overall sample was full flavor cigarettes, and 39% was light cigarettes, while 5% were medium/mild brand styles and the remaining 18% were ultralights. The percent of full flavor brand styles (40% to 35%) and ultralight brand styles (18% to 15%) trended down from 1998-2004, while the percent of lights trended up (37% to 42%) during this period. In 2005, however, this trend was reversed, with 43% full flavor versus 39% light, and only 2% medium/mild. Thirty-eight percent of the overall study sample was mentholated, with no apparent trend and relatively little year to year variation (36%-43%). A similar proportion of brand styles were mentholated within each of the categories full flavor (42%), light (38%), and medium (mild) (45%), while a much lower proportion of the ultralight category (26%) was mentholated. An extremely small percentage (1-3%) of the total year to year sample was non-filter, consistent with the overall U.S. cigarette market.

Trends in smoke nicotine yield. Based on the multilevel model with the fixed effect, time as the only predictor variable, the smoke nicotine yield of cigarettes increased at an overall rate of 0.019 mg per cigarette per year (95% CI 0.016- 0.022) from 1997 to 2005 (or an overall rate of 0.029 mg per cigarette per year (95% CI 0.010- 0.044) from 1998 to 2005) (Table 3). The rate of increase in total nicotine yield differed between manufacturers (Likelihood ratio test $p<0.001$). Time was therefore treated as both a fixed effect and a random effect within the manufacturer level in the above models. The mean fitted smoke nicotine yield in each model was 1.79 mg per cigarette (not shown). The average annual rate of increase observed was thus 1.1 percent from 1997 to 2005, or 1.6 percent per year from 1998 to 2005. The cumulative increase in nicotine yield was thus 8.5% from 1997 to 2005 or 11.3% from 1998 to 2005. The increasing trend in smoke nicotine yield during this period was also observed on a per puff basis (0.0012 mg nicotine per puff per year, 95% CI 0.0009 - 0.0015) (not shown).

The brand styles of all four major manufacturers exhibited increased nicotine yield trends during this period. Rates of increase in nicotine yield from 1998 to 2005 for each of the four manufacturers are shown in Table 3.

No statistically significant difference was observed in smoke nicotine yield trends between brand families (Likelihood ratio test, $p=0.466$) or between brand styles (Likelihood ratio test $p = 0.299$) (analysis restricted to brand styles with three or more observations). Brand styles introduced in 1999-2005 did not exhibit different smoke nicotine yields on the average compared with brand styles reported in 1998 ($p = 0.349$) (not shown).

Relationship of market categories to smoke nicotine yield. Results of bivariate analyses of smoke nicotine yield and market categories and design features are provided in Table 3. Statistically significant associations were observed between smoke nicotine yield and market categories > 100mm length ($p=0.038$), non-candy flavored ($p=0.041$), and full flavor ($p<0.001$) cigarettes; but were not observed with mentholated ($p=0.367$) or filtered ($p=0.160$) categories.

Mean yearly smoke nicotine yields for all brand styles within selected market categories are provided in Table 4. Increases in smoke nicotine yield were apparent from 1998 to 2005 both menthol categories (mentholated and non-mentholated) as well as within full flavor, light, medium (mild), and ultralight categories.

Relationship of product design features to smoke nicotine yield. Bivariate analyses of smoke nicotine yield and design features demonstrated statistically significant associations with nicotine per cigarette, nicotine concentration in the tobacco rod, number of puffs per cigarette, percent filter ventilation, and tobacco weight (for each, $p<0.001$) (Table 3).

Modeled predictors of smoke nicotine yield. Table 3 displays results of the best fitting multivariate regression analysis model. The highly intercorrelated nature of nicotine concentration in the tobacco rod and nicotine content per cigarette and the direct relationship between these two variables and tobacco weight results in the "suppressor variable" effect described above. Inclusion of these variables in the model was therefore determined on the basis of changes in standard errors. The cigarette design features significantly associated with increased smoke nicotine yield were: nicotine concentration, number of puffs per cigarette, and percent filter ventilation. Cigarette market category full flavor vs. light/ ultralight/ and medium (mild)) was associated with increased smoke nicotine yield (0.187 mg / cig) (95% CI = 0.155 – 0.219) although the year to year rate of change between these categories reported was small. No statistically significant difference was observed in smoke nicotine yields comparing the segment of candy- or exotic-flavored products (which grew from one brand style in 1999 to a high of 31 brand styles in 2004) to non-candy flavored products (p=0.198) (not shown).

The overall rate of increase in nicotine yield controlling for significant market category (full flavored vs. light or ultra-light) and the above cigarette design features was 0.009 mg per year (95% CI = 0.006 – 0.011). This suggests that these parameters account for some but not all of the increase in smoke nicotine yield. The results were similar when limiting the analysis to cigarette brand styles with 3% or greater market share (not shown).

Changes over time in cigarette design features and market categories. Mean values and standard errors of smoke nicotine yield; market categories length, full flavor / non-full flavor, mentholated / non-mentholated; and design features total nicotine, nicotine concentration, number of puffs, percent filter ventilation, and tobacco weight for all years in the study are provided in Table 2.

Results of mixed multilevel regression of trends in cigarette design features are shown in Table 3. From 1997-2005, mean nicotine content per cigarette rose 17%, from 11.85 mg/cig to 13.93 mg/cig (p<0.001). Mean concentration of nicotine in the tobacco rod rose 9% from 17.13 mg/gm in 1998 to 18.71 mg/gm in 2005 (p<0.001) (data for 1997 were not available). Mean number of puffs per cigarette rose 10% from 11.3 in 1997 to 12.4 puffs per cigarette in 2005 (p<0.001). The peak mean values for each of these three design features occurred in 2003 (14.53 mg/cig nicotine; 19.73 mg/gm nicotine; 12.5 puffs/cig). The year rate of change of filtered vs. non-filtered brand styles was statistically significant but negligibly small (p= 0.001). Mean filter ventilation fluctuated in a tight range of 26%-29% between 1998-2005, with lower values in 1997 (23%) and 2005 (25%) respectively (p=0.828). The mean tobacco weight remained essentially constant from year to year at 0.7 g (p=0.105) (1998-2005, 1997 not available). Full-flavored brands showed a statistically significant but very small increase, from 1998 to 2005 (p<0.001). No change over time was observed in filter ventilation (p=0.752), length (model includes manufacturer and brand levels only) (p=0.399), mentholated (p=0.113), or candy- or exotic-flavored brands (p=0.865).

Multivariate regression analysis of the number of puffs per cigarette (not shown) demonstrated increases with time (p<0.001), tobacco weight (p<0.001) nicotine concentration in the tobacco rod (p=0.027), percent ventilation (p<0.001), length >85 (p<0.001), full flavor (p<0.001) and non-mentholation (p=0.014).

Comparisons within brand families and brand styles. Since statistically significant differences in smoke nicotine yield trends were not observed between brand families or brand styles, examination of nicotine trends at these levels is exploratory. Among the brand families with 50 or more observations, seven brand families showed a significant increase in smoke nicotine yield (Camel, Doral, GPC, Kool, Marlboro, Newport, Salem), while 2 brand families (Basic, Winston) showed no significant increase (Table 5). Among the brand families with increased smoke nicotine yield, increasing trends in number of puffs, nicotine content per cigarette, nicotine concentration in the tobacco rod were observed in Camel, Doral, and Newport brand family cigarettes. Increasing trends in nicotine content and nicotine concentration, but not in number of puffs, were observed in Kool and Salem brand family cigarettes. Increasing trend in number of puffs, but not nicotine content measures, was observed for GPC. No trends were observed in any of these measures for Marlboro cigarettes (Table 5).

Assessment of smoke nicotine yield changes in Marlboro brand family. A multilevel regression analysis of the smoke nicotine yields of the fifteen Marlboro brand styles reported in each year from 1997 through 2005 as reflected by the MDPH data, shows a statistically significant increasing trend of 0.013 mg per year ($p < 0.001$). Smoke nicotine yield figures reported for Marlboro by PM USA in a recent press release [17] are shown in Figure 1 alongside the smoke nicotine yield figures reflected by the MDPH nicotine disclosures data. Smoke nicotine yields predicted by the model of the full nicotine disclosure data were generated, and these values are graphed on the same chart. The slope of this line (0.019 mg per cigarette per year) ($p<0.001$), or the linear trend in smoke nicotine yield, is similar to the calculated slope of the simple linear averages reported by PM USA (0.014 mg per cigarette per year) ($p=0.034$).

DISCUSSION

The present analysis of the MDPH nicotine data confirms a statistically significant trend in increased smoke nicotine yield of 0.019 mg per cigarette (1.1%) per year from 1997-2005 as measured by a smoking machine under the MA method. The increasing trend was observed within all major market categories including full flavor, light, medium, ultralight), mentholated, and non-mentholated. A similar overall trend (0.029

mg per cigarette (1.6%) per year was observed with exclusion of the more limited brand-specific data available in 1997.

An increase in smoke nicotine yield from 1998-2005 was observed within each major manufacturer, though at varying rates. Exploratory analyses conducted on individual brand families observed increasing trends in smoke nicotine yield among Camel, Doral, Kool, Marlboro, Newport, and Salem brand families, six of the top ten selling brand families accounting for 63.6% of the U.S. market share in 2005. [21]

Design features that best defined smoke nicotine yield in this study were concentration of nicotine in the tobacco rod, number of puffs per cigarette, and percent filter ventilation of the cigarette. Significant increases over time were observed in the concentration of (9%) and total nicotine (17%) in the tobacco rod and in the number of puffs per cigarette (10%), whereas percent ventilation demonstrated no significant change (from 23% to 25%) over time. Thus, the increase in smoke nicotine yield is at least partially explained by a higher concentration of nicotine, and a reduced burn rate (which increases the number of puffs generated from a given unit of tobacco). Since the total increase in smoke nicotine yield was greater than that accounted for by these design factors, further influence might also be attributed to additional factors not included in this analysis.

The apparent increase in nicotine concentration within the cigarette appears to reflect manufacturers' trend toward providing greater ease at obtaining nicotine dose in a single puff. This trend is further suggested by the observed increase in per puff smoke nicotine yield. A reduced burn rate may be driving the increase in number of puffs per cigarette, which could also facilitate a greater dose of nicotine from a given cigarette in the absence of behavioral changes.

The sample of brand families and brand styles included in this analysis was defined by MDPH regulations and is not random. However, the year to year composition of the sample from 1998-2005 was consistent across market category full flavor vs. light, medium or ultralight; mentholated vs non-mentholated; and filtered vs. non-filtered; and does reflect the overall composition of the cigarette market. Comparison of brand styles in the initial sample versus brand styles introduced in subsequent years demonstrated no significant trend differences in smoke nicotine yield. Comparison of candy-or exotic-flavored brand styles, which were first introduced in 1999 and peaked in frequency in 2004, likewise showed no significant trend differences. Results when restricting the analyses to cigarette brand families with 3% or greater market share were similar to those in which the full set of available data were included. Together these findings suggest that the trends identified in smoke nicotine yield are neither limited to any particular market category nor driven by significant changes in the composition of the overall sample.

The MDPH issued a report in August 2006 regarding smoke nicotine yield in U.S. cigarettes based on data it received from tobacco manufacturers in compliance with Massachusetts law. [22] That report observed an increase of 9.9% in the average smoke nicotine yield of the 116 cigarette brand styles for which data were available in both 1998 and 2004. [22] PM USA issued a press release in response to the MDPH report observing that the apparent trend in smoke nicotine yield from 1998-2004 was not present when data from 1997 and 2005 (available to MDPH) were included. [17] The PM USA web site also shows simple linear average smoke nicotine yields for eighteen Marlboro cigarette styles reported in all years from 1997 through 2005 claiming no significant trend and concluding that "year-to-year variations in nicotine occur as part of the normal processes of growing tobacco and manufacturing cigarettes."[17] The present analysis of the leading U.S. brand family, Marlboro, demonstrates a significant increase in smoke nicotine yield, contradicting the PM USA claims.

Tobacco manufacturers have extensive understanding of how design parameters affect the composition of smoke delivered to a smoker, and this understanding influences the selection and combination of these parameters as testified by a former PM scientist in the recent U.S. District Court case. [25] The testimony described that ". . . a critical part of cigarette design is first ensuring that enough nicotine is available in the unsmoked rod, and then making sure that the design enables the smoker to get enough of the nicotine out to maintain his or her addiction."[25] Further, evidence was cited that the main component of a cigarette that contributes to nicotine delivery is the tobacco blend "because the amount and types of tobacco determine how much nicotine will be in the unsmoked rod" [25, 26]. The testimony pointed out that year-to-year tobacco crop variation does not determine nicotine content in the cigarette, as "the manufacturers blend not only across types of tobacco, but also across years, in order to compensate for the year-to-year variations…" [25]

All cigarettes are highly addictive and deadly, and relatively minor changes in nicotine yield may not significantly alter the product's addictive properties. Nevertheless, the total nicotine dosing capability, the speed with which nicotine can be delivered and the ease with which nicotine can be extracted are among the determinants of the addiction potential of a cigarette. [12] Higher nicotine content in the tobacco rod increases the potential for smokers to extract more nicotine from the cigarette. Animal and human studies have demonstrated that the development and maintenance of a drug addiction can be facilitated by ease of achieving addictive levels of the drug. [27]

The product changes described in this report may for example represent an effort by tobacco manufacturers to enable persons of lower income to sustain prior levels of nicotine intake, even with a consumption of fewer cigarettes on the assumption that prices would increase due to litigation during this time period.

Interpretation of these findings is limited by the testing methodology for smoke nicotine yield and its application to exposure among smokers. The increase in smoke nicotine yield does not necessarily signify any change in exposure within the population of smokers, particularly as human smoking behavior is compensatory and will adjust for differences in smoke yield. [5] Despite these limitations, the confirmation of a trend in increased smoke nicotine yield underscores the need for ongoing scrutiny of the cigarette market and the way that changes in design and yield may relate to population exposure and behavior.

The Food and Drug Administration previously observed an increasing trend in smoke nicotine yield from 1982 to 1991, with the greatest increases in the lowest-tar cigarettes. [23] This trend strongly suggested that manufacturers had manipulated and controlled the levels of nicotine. [24] More research is warranted with respect to the relationship between tar and nicotine yields during the time period (1997-2005) evaluated in the present study.

Future evaluation of product changes and their effects on exposure should include assessment of a broad combination of relevant physical and chemical design parameters (cigarette length, circumference, and density; filter composition and design; ventilation; blend selection, cigarette paper composition, porosity, and use of additives). Human studies, including measures of smoking topography and biomarkers of exposure, may be necessary to predict consumer and population effects. Future regulatory strategies should therefore consider incorporating human studies as a means to evaluate exposure as well as reporting of additional design features.

Ongoing and expanded, detailed product information disclosure is essential for the systematic monitoring of "the changing cigarette" urged by the 1981 U.S. Surgeon General and others. The tobacco industry is characteristically resistant to being required to disclose information regarding its products. The industry's legal opposition to the MA nicotine disclosure reporting requirements, however, met with defeat [28], one of the factors permitting the present independent examination of nicotine yield trends in relation to product design.

In conclusion, this study confirms that tobacco manufacturers have increased nicotine levels, the addictive agent of cigarettes, in the smoke of their products by increasing the nicotine in the tobacco rod and by other design modifications.

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Table 1

Frequencies of Reported Cigarette Brand Families and Brand Styles

	1997	1998	1999	2000	2001	2002	2003	2004	2005
Manufacturer									
Brown & Williamson	19	45	44	44	28	27	17	NA	NA
Lorillard	13	18	17	21	22	22	22	21	21
Philip Morris	20	49	57	58	59	64	61	63	64
RJ Reynolds	33	79	82	93	108	101	93	113	87
Market Category									
Non-Mentholated	29	72	82	82	80	74	78	85	59
Mentholated	56	119	118	134	137	140	115	112	113
Full Flavor	34	77	74	79	81	81	68	69	74
Light	35	70	73	82	88	87	79	83	67
Medium/Mild	6	10	10	11	9	11	12	16	3
Ultralight	10	34	43	44	39	35	34	29	28
Filtered	83	185	195	211	212	208	188	194	170
Non-filtered	2	6	5	5	5	6	5	3	2
Total									
Brand Families	5	22	23	23	21	18	19	16	18
Brand Styles	85	191	200	216	217	214	193	197	172
≥ 3% market share per Brand Family									
Brand Families	NR	9	9	9	8	7	7	7	6
Brand Styles	NR	162	167	181	180	175	152	163	136

NA = Not applicable after Brown & Williamson's acquisition by RJ Reynolds.
NR = Not reported

Table 2

Machine Smoking Measures and Cigarette Design Features and Selected Market Categories 1997-2005
Mean (Standard Error)

Year	Nicotine Yield (mg/cig)	Total Nicotine (mg/cig)	Nicotine Conc. (mg/gm)	Number Puffs	% Filter Ventilation	Full flavor Brands*
1997	1.70 (0.05)	11.85 (0.20)		11.34 (0.15)	22.81 (1.70)	0.40 (0.05)
1998	1.68 (0.03)	12.56 (0.14)	17.13 (0.14)	11.83 (0.12)	27.39 (1.43)	0.40 (0.04)
1999	1.68 (0.03)	12.54 (0.14)	17.27 (0.13)	11.94 (0.12)	29.01 (1.46)	0.37 (0.03)
2000	1.73 (0.03)	13.22 (0.15)	18.26 (0.15)	11.89 (0.11)	29.09 (1.41)	0.37 (0.03)
2001	1.82 (0.03)	13.67 (0.16)	18.88 (0.18)	12.24 (0.12)	28.18 (1.34)	0.37 (0.03)
2002	1.82 (0.03)	13.56 (0.20)	18.59 (0.20)	12.28 (0.15)	27.51 (1.31)	0.38 (0.03)
2003	1.84 (0.04)	14.53 (0.19)	19.74 (0.16)	12.50 (0.15)	28.67(1.39)	0.35 (0.03)
2004	1.91 (0.04)	14.40 (0.19)	19.62 (0.16)	12.34 (0.14)	26.08 (1.24)	0.35 (0.03)
2005	1.90 (0.04)	13.93 (0.22)	18.71 (0.17)	12.43 (0.16)	25.36 (1.30)	0.43 (0.04)
Total	1.79 (0.01)	13.46 (0.06)	18.52 (0.06)	12.13 (0.05)	27.47 (0.47)	0.38 (0.01)

* Binomial exact computation of standard errors

Table 3

Bivariate and multivariate regression analyses of trend and determinants of nicotine yield (mg/ cig) from 1998 through 2005

	Smoke Nicotine Yield (mg / cig) Bivariate Analyses[1]			**Smoke Nicotine Yield (mg / cig) Multivariate Analysis[2]**			**Market Category and Design Time Trends[3]**		
	β§	**95% CI**	**P-value**	**β§**	**95% CI**	**P-value**	**β§§**	**95% CI**	**P-value**
Time Trend (years):									
All Manufacturers	**0.029**	**0.010, 0.044**	**0.003**	**0.009**	**0.006, 0.011**	**<0.001**			
Brown & Williamson	0.059	0.049, 0.069	<0.001						
Lorillard	0.030	0.187, 0.041	<0.001						
Philip Morris	0.011	0.006, 0.015	<0.001						
RJ Reynolds	0.020	0.016, 0.024	<0.001						
Market category:									
Length (≥100mm)	0.097	0.005, 0.190	0.038	-	-	ns			ns
Mentholated vs. non mentholated	-0.043	-0.137, 0.051	0.367	-	-	ns			ns
Candy-Flavored vs. non-flavored	-0.099	-0.194, -0.004	0.041	-	-	ns			ns
Full flavor vs. non-full flavor	0.348	0.300, 0.395	<0.001	0.187	0.155, 0.219	<0.001	0.006	0.004, 0.009	<0.001
Filtered vs. non-filtered	-0.092	-0.221, 0.036	0.160	-	-	ns	0.002	0.001, 0.003	0.001
Design feature:									
Nicotine concentration (mg /gm)	0.037	0.032, 0.042	<0.001	0.030	0.025, 0.034	<0.001	0.177	0.147, 0.207	<0.001
Nicotine (mg) per cigarette	0.061	0.055, 0.067	<0.001			ns	0.135	0.110, 0.161	<0.001
Puffs per cigarette	0.091	0.079, 0.103	<0.001	0.106	0.098, 0.113	<0.001	0.048	0.035, 0.060	<0.001
Percent filter ventilation	-0.013	-0.014, -0.011	<0.001	-0.014	-0.015, -0.013	<0.001			ns
Weight (gm)	1.563	1.325, 1.801	<0.001			ns			ns

[1]Each individual multilevel regression model consists of nicotine yield the dependent variable and one market category, design feature, or time in years the independent variable. [2]Results are for the multilevel mixed effects multiple regression model including all significant parameters. [3]Each individual multilevel regression model consists of one market category or design feature, the dependent variable, and time the independent variable.

β§ coefficients represents mg increase in smoke nicotine yield per unit change of each parameter per year. β§§ coefficients represent unit change of each parameter per year; ns = not significant

Table 4

Smoke nicotine yield (mean mg/cig and standard deviation) based on MA smoking method for all cigarette brand styles and major market categories 1997-2005

	1997	1998	1999	2000	2001	2002	2003	2004	2005
All Styles									
Non-Mentholated	1.64 (0.37)	1.62 (0.46)	1.65 (0.48)	1.67 (0.51)	1.80 (0.51)	1.83 (0.53)	1.85(0.56)	1.91 (0.62)	1.88 (0.62)
Mentholated	1.84 (0.49)	1.77 (0.44)	1.71 (0.46)	1.83 (0.47)	1.84 (0.45)	1.80 (0.47)	1.84 (0.50)	1.90 (0.47)	1.95 (0.47)
Total	1.70 (0.42)	1.68 (0.45)	1.68 (0.47)	1.73 (0.50)	1.82 (0.49)	1.82 (0.51)	1.84 (0.53)	1.91 (0.56)	1.90 (0.57)
Full Flavor									
Non-Mentholated	1.94 (0.25)	2.02 (0.35)	2.08 (0.38)	2.15 (0.44)	2.28 (0.40)	2.28 (0.53)	2.32 (0.55)	2.42 (0.68)	2.28 (0.65)
Mentholated	2.21 (0.47)	2.08 (0.36)	2.12 (0.33)	2.22 (0.38)	2.19 (0.33)	2.04 (0.50)	2.23 (0.42)	2.31 (0.43)	2.24 (0.42)
Total	2.04 (0.37)	2.04 (0.36)	2.10 (0.36)	2.18 (0.41)	2.24 (0.37)	2.19 (0.53)	2.28 (0.50)	2.37 (0.58)	2.26 (0.57)
Light									
Non-Mentholated	1.51 (0.24)	1.56 (0.25)	1.61 (0.23)	1.64 (0.24)	1.71 (0.27)	1.70 (0.18)	1.73 (0.24)	1.75 (0.19)	1.78 (0.29)
Mentholated	1.60 (0.20)	1.56 (0.27)	1.54 (0.21)	1.58 (0.20)	1.67 (0.24)	1.67 (0.34)	1.68 (0.31)	1.69 (0.31)	1.73 (0.29)
Total	1.54 (0.23)	1.56 (0.25)	1.58 (0.22)	1.62 (0.23)	1.70 (0.26)	1.69 (0.24)	1.71 (0.27)	1.72 (0.24)	1.76 (0.29)
Medium/Mild									
Non-Mentholated	1.68 (0.26)	1.62 (0.33)	1.70 (0.31)	1.73 (0.36)	1.78 (0.28)	2.01 (0.62)	2.22 (0.56)	2.26 (0.66)	3.40 (0.00)
Mentholated	NA	1.62 (0.05)	1.68 (0.09)	1.81 (0.12)	1.93 (0.21)	2.05 (0.31)	1.88 (0.24)	1.96 (0.14)	1.97 (0.34)
Total	1.68 (0.26)	1.62 (0.25)	1.69 (0.23)	1.76 (0.27)	1.83 (0.26)	2.02 (0.51)	2.02 (0.42)	2.05 (0.39)	2.45 (0.86)
Ultralight									
Non-Mentholated	1.13 (0.16)	1.11 (0.30)	1.10 (0.27)	1.11 (0.29)	1.18 (0.31)	1.24 (0.16)	1.20 (0.16)	1.23 (0.14)	1.23 (0.20)
Mentholated	1.11 (0.05)	1.12 (0.17)	1.12 (0.21)	1.20 (0.19)	1.22 (0.27)	1.23 (0.15)	1.21 (0.33)	1.30 (0.13)	1.24 (0.14)
Total	1.12 (0.15)	1.11 (0.28)	1.10 (0.25)	1.13 (0.27)	1.19 (0.29)	1.24 (0.15)	1.21 (0.22)	1.25 (0.14)	1.23 (0.19)

NA= no observation

Table 5

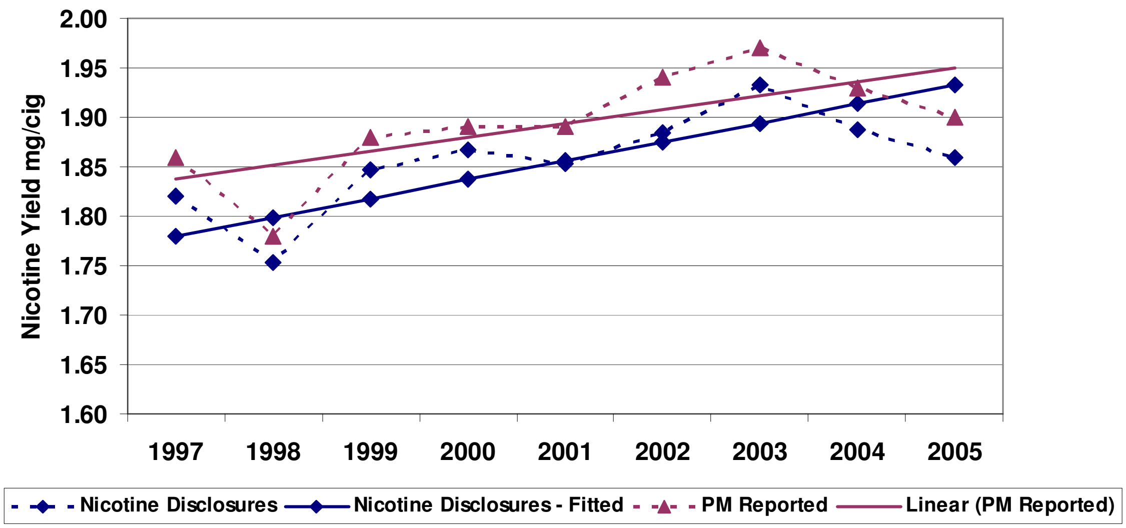
Multilevel Mixed Effects Regression Analyses of Trends Over Time in Smoke Nicotine Yield, Number of Puffs, Nicotine Concentration, and Total Nicotine Among Cigarette Brand Families

			LR Test Brand styles	Smoke Nicotine Yield (mg / cig)		Number of Puffs		Nicotine (mg /gm)		Nicotine (mg / cig)	
	Frequency	Brand styles	P-value	β	P- value	β	P- value	β	P- value	β	P- value
Basic	147	20	nc	0.009	0.102	-0.039	0.036	-0.045	0.195	-0.084	0.007
Benson & Hedges	29	7	0.481	-0.010	0.271	0.043	0.305	0.008	0.904	-0035	0.502
Camel	285	71	0.438	0.010	<0.001	0.074	<0.001	0.158	<0.001	0.180	<0.001
Carlton	18	8	1.000	0.005	0.740	0.052	0.514	1.300	0.038	1.619	<0.001
Doral	168	22	0.270	0.043	<0.001	0.270	<0.001	0.384	<0.001	0.445	<0.001
GPC	127	24	0.413	0.066	<0.001	0.052	0.039	-0.132	0.662	-0.050	0.364
Kool	82	25	nc	0.043	<0.001	0.018	0.591	0.132	<0.001	0.980	<0.001
Marlboro	233	39	0.287	0.015	<0.001	-0.016	0.309	0.006	0.877	-0.037	0.185
Maverick	17	3	0.460	0.047	0.003	0.131	0.007	-0.037	0.782	-0.011	0.931
Merit	25	8	0.461	0.009	0.399	0.144	0.005	0.227	0.028	0.065	0.378
Natural American Spirit	25	9	0.451	0.091	0.022	-0.062	0.770	0.024	0.897	-0.028	0.896
Newport	136	17	0.482	0.024	<0.001	0.054	<0.001	0.141	<0.001	0.134	<0.001
Parliament	19	5	0.466	-0.007	0.539	0.021	0.545	-0.007	0.952	-0.013	0.869
Salem	60	24	0.407	0.038	<0.001	0.055	0.180	0.482	<0.001	0.397	<0.001
Vantage	19	4	nc	0.011	0.438	0.163	<0.001	0.416	<0.001	0.322	<0.001
Virginia Slims	35	10	nc	0.017	0.131	0.032	0.489	-0.015	0.823	-0.031	0.516
Winston	178	31	0.425	0.007	0.144	-0.013	0.506	0.311	<0.001	0.163	<0.001

β coefficients of time (years) as predictor and p-value for each of the outcomes are shown. Likelihood ratios are tests of the significance of the difference between brand styles within each brand family. nc = regression model was nonconvergent; β coefficients are shown where p-values < 0.05.

Figure 1

Trends in Average Nicotine Yields of Marlboro Brand Family Cigarettes as Reflected by Reported Nicotine Disclosures, Philip Morris USA Announcement, and Predicted Values From Modeled Nicotine Disclosures



The average nicotine yields for 18 Marlboro packings as reported on www.philipmorrisusa.com demonstrate a positive linear trend (β = 0.014 mg per cigarette per yer, $p = 0.034$). The predicted values of nicotine yields for the 15 Marlboro brand styles that were marketed in all years between 1997 and 2005, as derived from a model of the full nicotine disclosures data reported to MDPH also demonstrate a positive linear trend (β = 0.019 mg per cigarette per yer, $p < 0.001$).

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