

Mock PM USA Market Surveillance System Report fabricated for planning purposes only.

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PM USA MARKET SURVEILLANCE SYSTEM REPORT

(MOCK REPORT USING HYPOTHETICAL DATA)

Prepared by

Candace R. Adams, PhD

Angela S. Hayden, MS

Product Assessment/Clinical Evaluation

Philip Morris USA, Inc.

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Market Surveillance System Mock Report

June 18, 2004

Report Authors: Candace R. Adams, PhD, Project Leader

Angela S. Hayden, MS, Surveillance Manager

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Philip Morris USA, Inc.
Product Assessment/Clinical Evaluation
615 Maury Street
Richmond, VA 23225

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Market Surveillance

Initiative Leader: Dr. Hans-Juergen Roethig, Director
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Contents were reviewed by the PM USA Market Surveillance Oversight Board:

Dr. Jane Lewis, Vice President
Product Assessment

Mrs. Nancy B. Lund, Sr. Vice President
Marketing

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Research and Technology

Mr. Daniel L. Westra, Vice President
Quality

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Dr. John R. Nelson, Jr. President
Operations and Technology

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Table of Contents

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Executive Summary

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¶

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¶
The PM USA Market surveillance report summarizes annually the results of combined company-wide efforts towards harm reduction.¶

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BACKGROUND AND INTRODUCTION

In 2005, Philip Morris USA initiated a system for market surveillance. The PM USA Market Surveillance System represents structured processes for the systematic collection, analysis, interpretation, and reporting of information about products marketed in the U.S. by PM USA and adults who smoke them as it relates to smoking and health. PM USA agrees with the overwhelming medical and scientific consensus that cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers. Smokers are far more likely to develop serious diseases, like lung cancer, than non-smokers. There is no safe cigarette. [<http://www.pmus.com/health issues/cigarette smoking and disease> (Accessed June 5, 2004).]

Philip Morris USA is committed to developing new methods and technologies having the potential to reduce harm associated with cigarette smoking, responsibly marketing these products for adult smokers, and accurately communicating the health effects of these products. The Company has in place a harm reduction evaluation process requiring incremental approvals informed by sound science as potentially reduced exposure, reduced risk and reduced harm products are developed. PM USA's Reduced Harm Evaluation Process is graphically depicted in Figure 1.

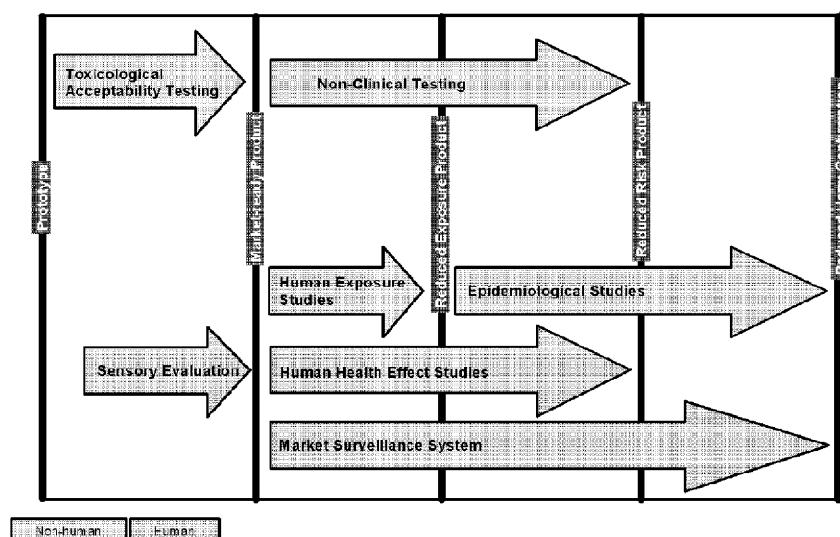


Figure 1: A Consistent Harm Reduction Evaluation Process

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The PM USA framework for reducing exposure, risk and harm as well as its Harm Reduction Evaluation Process is supported by a Market Surveillance System. For PM USA products marketed with claims, Market Surveillance System activities represent an alert system or sensor to detect changes in smoking behavior that may impact exposure and monitor complaints and other developments in the marketplace that may signal product misuse and/or the need to modify communications about the product. For all cigarette products marketed in the US by Philip Morris USA, the Market Surveillance System is designed to monitor changes to cigarette ingredients, smoke constituents, manufacturing processes and consumption that may impact exposure.

The PM USA Market Surveillance System represents a collaborative effort among multiple functions and disciplines across the Company to include PM USA's Quality System/Quality Systems Integration and Control, chemistry, toxicology, clinical studies, behavioral psychology, marketing, and communications.

For guidance in the development of its Market Surveillance System, PM USA engaged external stakeholders (e.g., public health officials, academicians, and other scientists) and presented plans for implementation of its planned market surveillance system at a public conference organized by renowned professionals sharing the common goal of reducing exposure, risk and harm from cigarette smoking. (Reference science website where SRNT poster presentation is posted). Ultimately, PM USA embraced the spirit of principles outlined in the 2001 Institute of Medicine (IOM) Report entitled *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*¹ for development of its Market Surveillance System.

¹Kathleen Stratton et al. (Eds.). (2001). *Clearing the Smoke: assessing the science base for tobacco harm reduction*. Washington, D.C. National Academy Press.

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Deleted: effort is but one aspect of the harm reduction program at PM USA, which also includes the prevention of youth smoking (decreased initiation), clinical and non-clinical exposure and toxicity studies, new potentially reduced exposure product (PREP) development, modifications to existing products that may decrease risks (of all types), and improved communication with our consumers.¶

↑
The objective of the PM USA Market Surveillance System

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Deleted: After seeking guidance from

Deleted: authorities and advocacy groups, PM USA has embraced the elements outlined by the Institute of Medicine in the report "Clearing the Smoke", which identifies the following activities for a surveillance program: monitoring tobacco consumption; monitoring changes to and having information available about tobacco product ingredients and smoke constituents; demonstrating clarity and transparency in marketing and claims concerning PREPs; assessing biomarkers of exposure through clinical (human) studies; assessing personal tobacco product use and smoking behavior; and studying disease outcomes

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METHODS

To implement its Market Surveillance System, PM USA organized cross-functional teams and applied existing processes for market surveillance of existing cigarette products marketed without any claims of reduced exposure or reduced risk and developed additional surveillance processes for market surveillance of potential reduced exposure products (PREPs) marketed by Philip Morris USA with claims of reduced exposure or reduced risk.

The PM USA Market Surveillance System is comprised of six elements:

1. Monitoring national trends in tobacco consumption (e.g., publications of the United States Department of Agriculture: U. S. Tobacco Production, Consumption and Export Trends; Federal Trade Commission: "Tar," Nicotine and Carbon Monoxide of the Smoke of 1294 Varieties of Domestic Cigarettes; Management Science Associates' Year End Shipment Volumes; and American Lung Association: Trends in Tobacco Use);
2. Monitoring changes to and making information available about tobacco product ingredients and smoke constituents from information published on the PM USA website as well as additional information provided by divisions within PM USA (i.e., Product Integrity and the Product Testing Laboratory);
3. Evaluating clarity and transparency in marketing and communications for products marketed with claims from information published on the PM USA website and information provided by PM USA's Marketing Department;
- 4A. Measuring population exposures from human studies (i.e., the Total Exposure Study²) conducted by PM USA's Clinical Evaluation division;

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² The primary objectives of this study are:

1. To estimate the exposure of U.S. adult cigarette smokers to cigarette smoke constituents using selected biomarkers of exposure and biologically effective dose.
2. To investigate the relationship between cigarette smoke exposure of U.S. adult smokers and tar delivery (Federal Trade Commission [FTC] method).

The secondary objectives of this study are:

1. To evaluate smoking behavior as it relates to cigarette smoke exposure.
2. To compare selected biomarkers of U.S. adult smokers to adult non-smokers.
3. To investigate the relationship between selected biomarkers of potential harm and cigarette smoke exposure.

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4B. Estimating individual exposures among market surveillance participants from self-reports of brand(s) smoked and consumption levels;

5. Monitoring personal tobacco product use and measuring aspects of smoking behavior (e.g., from information in the public domain (e.g., the Behavioral Risk Factor Surveillance System) and responses to questionnaires administered to (#) adult smokers recruited for participation; and

6. Reviewing the scientific literature on disease outcomes and disease trends.

Adult smokers of products marketed in the US by PM USA were recruited for possible participation in market surveillance by MRSI. A baseline questionnaire was administered and follow-up questionnaires at quarterly intervals by Guardian, LLC. Participants were given the option of supplying responses to the survey on-line, by telephone, or mail. Responses to questionnaires were by de-identified by Guardian prior to receipt by PM USA.

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DISCUSSION

Tobacco Smoking in the United States (Element 1)

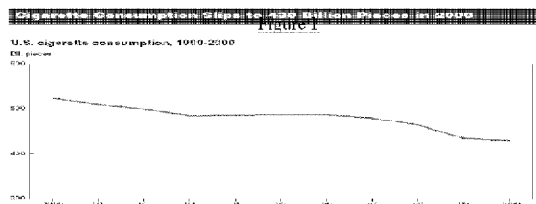
Peaking in 1981 at consumption of approximately 640 billion cigarettes, cigarette consumption has declined nearly every year as shown in Figure 2 (Economic Research Service, 2001. Briefing room. [online] Available: <http://www.econ.ag.gov/briefing/tobacco>).

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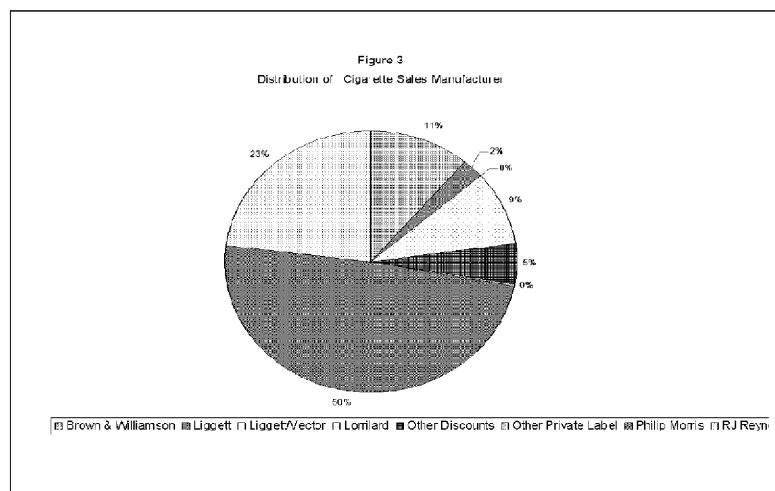
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Philip Morris brands account for approximately 48% of all cigarettes sold in the US (See Figure 3). Ref MSA shipment Data)

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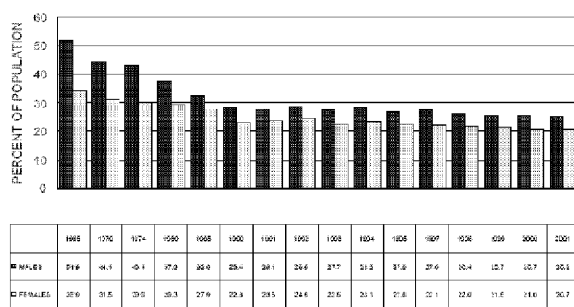
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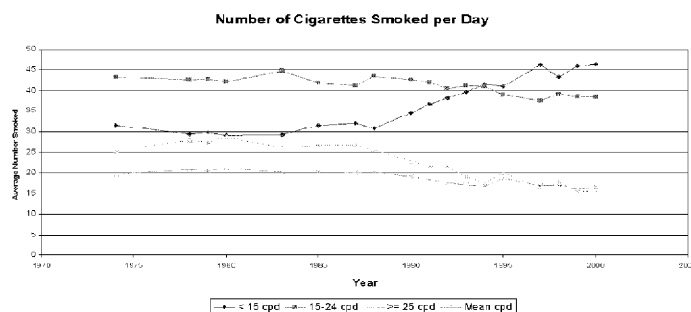
Trends in Tobacco Use

In 2001, an estimated 46.2 million, or 22.8% of adults (age 18+) were current smokers. Smoking prevalence was highest among people aged 18-24 years (26.9) and lowest for those greater than 65 years of age. The percentage of smokers was significantly higher in males (25.5%) than in females (20.7%). Between 1965 and 2001 smoking rates decreased 51.4% among men and 38.9% among women, and 46.2% overall. The trend in cigarette smoking by sex is depicted in Figure 3 (American Lung Association, 2003). Trends in Tobacco Use. [online] Available: <http://www.lungusa.org> Accessed June 2003.

FIGURE 3: CURRENT CIGARETTE SMOKING IN PERSONS AGE 18 YEARS AND OLDER BY SEX, 1965-2001 (1,2)



SOURCE: NATIONAL HEALTH INTERVIEW SURVEY, SELECTED YEARS AND MMWR REPORTS



It is reasonable to conclude that decreases in the prevalence of smoking and levels of consumption will evidence decreases in exposure at the population level over time.

Social and regulatory factors that potentially impact consumption and other aspects of adults' smoking behavior were monitored to include increases in cigarette price and taxes, passage of tobacco control legislation, studies conducted and reports generated externally (e.g., public health entities, academicians, etc.) were reviewed and media coverage monitored to assess their impact on purchase and consumption of brands marketed with claims.

While Philip Morris USA did not conduct consumer research to support this hypothesis, many in the public health area contribute reduced consumption to increased cigarette price and taxes.

Cigarette Ingredients and Smoke Constituents (Element 2)

Tobacco products manufactured and marketed by Philip Morris USA are blended with varying proportions of different grades of flue-cured, burley, Maryland and oriental tobaccos. The Philip Morris USA website (www.philipmorrisusa.com) provides a "Search for Ingredients" link that documents cigarette ingredients by brand and packaging as well as tar and nicotine yields for all PM USA-manufactured cigarettes.

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Deleted: In addition to the prevalence of smoking declining, there appears to be a shift downward in the average number of cigarettes smoked per day. Figure (http://www.cdc.gov/tobacco/research_data/adults_prov/adstat3print.htm) shows the percentage distribution of adult current smokers, by number of cigarettes smoked per day. National Health Interview Survey, selected years 1974-2000.¶

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Deleted: Visitors can also see a list of all the tobacco and non-tobacco ingredients used in all of the PM USA brands. A link from the page makes it easy to travel directly to the "Tar and Nicotine Numbers" pages of philipmorrisusa.com, where consumers can find the

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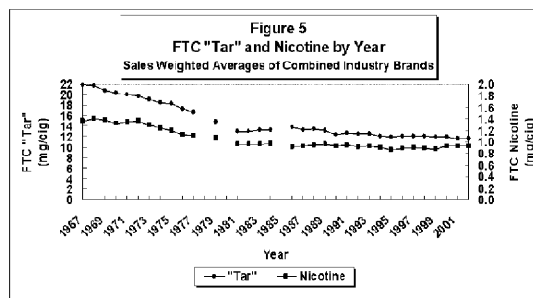
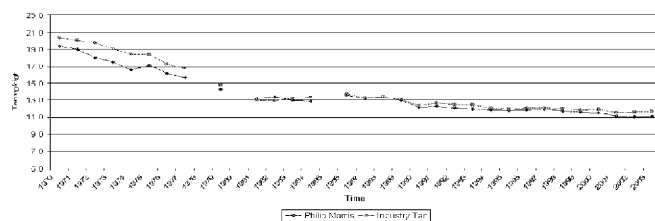
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Over the years, Philip Morris USA has consistently reduced the tar and nicotine levels of cigarettes they manufacture. Decreasing trends for tar are reported in Figures 3 which demonstrates patterns of reduction are similar for PM USA as compared to reductions across the industry in general.

Figure 4
FTC "Tar" Levels by Year:
Sales-weighted averages of Philip Morris USA Brands
and Other Tobacco Industry Brands



"Data on the health impact of low-yield products are conflicting, part due to a lack of systematic and comprehensive study early in the production of these products. Most . . . data suggest, however that low-yield products are associated with far less health benefit than predicted based on FTC-assay-generated tar, CO, and nicotine levels."³ It is generally believed that smokers switching to a cigarette lower in tar "compensate" or change their smoking behavior to extract

³Kathleen Stratton et al. (Eds.), (2001).

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PM USA Science Website¶

Philip Morris USA has created a new Internet website that brings together scientific information related to the Company's processes, products and technologies. In order to share that information with and invite peer-review from scientists and the public health community.

The content of the new website is technical in nature and is not intended for use by the general public or by consumers. The website features scientific information on PM USA's cigarette harm reduction efforts; a listing of scientific and technical articles authored or co-authored by Philip Morris USA and Philip Morris USA affiliate scientists; and scientific information on toxicological assessments of cigarette ingredients.¶

Smoke Constituents¶

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the same levels of nicotine as their previous brand. Baseline and follow-up surveys were administered to market surveillance participants by a 3rd to collect information on changes in smoking behavior following introduction of cigarette product marketed with claims. Responses were de-identified when reported to PM USA (See Element 5 for a discussion).

Philip Morris USA conducted a study to obtain baseline measures of exposure among a sample (insert correct terminology) (See Element 4 for a discussion).

PM USA's market surveillance practices include evaluating non-tobacco ingredients potentially impacting exposure and harm. In June 2004, one hundred eleven (111) Philip Morris brands shipped to the state of New York for sale were designed with "banded" (i.e., lower ignition propensity) paper. Cigarettes with this lower ignition propensity paper markedly reduce the susceptibility to ignite certain fabrics when left burning. Tests conducted by (insert references) demonstrate a (insert acceptance criteria). Market surveillance to evaluate the products' performance in the marketplace is not feasible as complaints or personal claims related to the incidences of fabric ignition may not be made.

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¶ Youth Smoking Prevention¶
Since 1999, YSP has provided over \$110 million in grants to schools and youth serving organizations to support youth smoking prevention and positive youth development programs, as well as youth smoking cessation programs.¶ These programs minimize kids' exposure to risk factors, like negative peer pressure and access to risky products, and build protective factors into their lives, like positive adult relationships and access to structured activities.¶ In 2003, we provided grants to more than 75 organizations to support life skills education programs, sports and physical fitness activities, mentoring relationships, youth smoking prevention and youth smoking cessation programs, reaching approximately 810,000 kids.¶

¶ Reduced Risk Products¶

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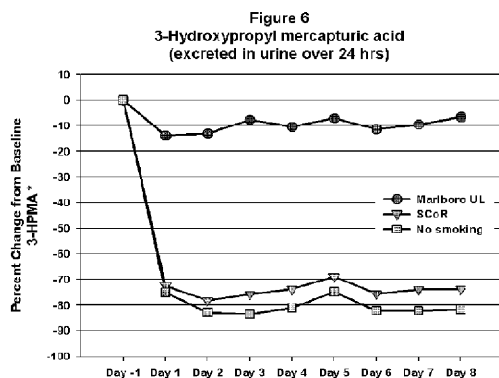
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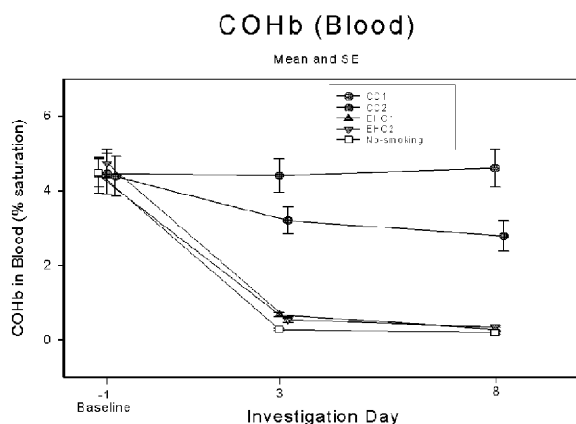
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Clinical studies to determine whether reductions in exposure when smoking a test cigarette designed to reduce exposure to harmful smoke constituents as compared to conventional cigarettes of similar tar delivery were conducted. Figure 6 illustrate a reduction in certain biomarkers of exposure approaching the levels of the "No smoking group."



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Other clinical studies to determine whether there are differences in exposure using the Electrically Heated Cigarette Smoking System (EHCSS) as compared to conventional lit-end cigarettes were conducted. The following graph shows reduced levels of carbon monoxide exposure among adult smokers of the EHCSS.



Monitoring Marketing and Communications for Products Marketed with Claims (Element 3).

The Master Settlement Agreement (200?), entered into by the States' Attorneys Generals and the tobacco industry (insert correct terminology) detail requirements for the responsible marketing of tobacco products (Go to <http://www.pnusa.com> for information on the Master Settlement Agreement). Compliance precludes (insert correct wording). Philip Morris USA remains in compliance terms set forth in the Agreement.

In addition to the Master Settlement Agreement, Philip Morris USA's marketing activities are in compliance with the requirements of the Federal Trade Administration and other regulations

Marketing strategies employed by Philip Morris USA (Insert examples demonstrating responsible marketing practices).

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Reduced Exposure Products¶ Several clinical studies (human smoking) are currently underway to assess US smokers' exposure.¶

Total Exposure Study – The purpose is to estimate exposure of adult US cigarette smokers to cigarette smoke constituents using selected biomarkers of exposure and biologically effective dose. A study sample of 5000 subjects. Preliminary data are expected in August.¶

Potentially reduced exposure products (PREP) Studies – A series of clinical studies examining PREPs are underway to determine whether there are differences in exposure using a special activated carbon filter as compared to conventional fit-on comparable tar delivery cigarettes. The following graphs show preliminary data illustrating a reduction in certain biomarkers of exposure approaching the levels of the No smoking group when these cigarettes are smoked as compared to the control cigarette.¶

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Population Biomarkers of Exposure (Element 4)

Obtaining accurate measures of exposure from smokers is an integral part of smoke exposure and cigarette harm reduction evaluation. From (Insert date) to (Insert date), Philip Morris USA conducted a study to obtain baseline measures of exposure among a (random sample - Insert correct terminology) of 4,000 adult smokers and 1,000 adult non-smokers [i.e., the Total Exposure Study (TES)]. Table 1 lists exposure biomarkers.

Biomarker of Exposure	Smoke Constituent
Carboxyhemoglobin	CO
4-Amenobiphenyl	4-Amenobiphenyl
Cotinine	Nicotine
Nicotine Equivalents	Nicotine
NNAL and NNAL-glucuronides	NNK
3-Hydroxypropylmercapturic acid	Acrolein
1-Hydroxypyrene	PAHs
1,3-Butadiene metabolites	1,3-Butadiene

(Candace to insert summary of anticipated findings re: differences in exposure by gender, across tar categories, and levels of consumption)

Exposure was estimated for Market Surveillance System participants (i.e., Nicotine equivalents, Carboxyhemoglobin, and NNAL) from responses to a survey that captured information on brands smoked, to include tar levels, and levels of consumption. Comparison to population measures obtained from TES among participants who switch to another conventional brand or one marketed with claims evidence a (%) decrease in nicotine equivalents, a (%) decrease in carboxyhemoglobin, and a (%) decrease in NNAL when smoking the product with claims. Participants who switched to a conventional cigarette lower in tar than their previous brand evidenced a (%) decrease in nicotine equivalents, a (%) decrease in carboxyhemoglobin, and a (%) decrease in NNAL.

Information on Smoking Behavior (Element 5)

Philip Morris USA conducted a study of smoking behavior as it relates to exposure during the Total Exposure Study. More than 4,000 adult smokers who participated in the study were administered a survey to test a model of adult smoking. Behaviors believed to operationalize a model of adult smoking formed the basis for questions comprising the Adult Smoker Survey. The model, developed from theories of adult smoking and prior research, will be tested to determine whether a pre-defined pattern of relationships exists. Model testing refers to the process of conducting statistical analyses to determine whether the operational definitions and their interrelationships reflect the pattern of responses for data collected from respondents.

The current model advances theory and research conducted by M. A. H. Russell et al. (1974) and is based on the theory that adult smoking is a multi-dimensional, multi-faceted, highly

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interactive phenomenon involving demographic, smoking history, psychosocial, sensory, and pharmacological factors. These factors and their constructs are:

- Demographics
 - ☐ Age
 - ☐ Gender
 - ☐ Ethnicity
 - ☐ Race
 - ☐ Education
 - ☐ Income
 - ☐ Living status
 - ☐ Urban status
- Smoking History (Questions 2.1-2.55)
 - ☐ Brand name and brand descriptors of regular and alternate cigarette smoked
 - ☐ Number of years regular brand smoked
 - ☐ Reason for alternate brand choice
 - ☐ Number of years of regular smoking
 - ☐ Average number of cigarettes smoked per day
 - ☐ Smoking history over past 3 years
 - ☐ Smoking history over the past 3 months
 - ☐ Place /Occasion of smoking
 - ☐ Important characteristics for smoking
 - ☐ Average number of cigarettes smoked per day over the past 3 months
- Psychosocial
 - ☐ Affect
 - ☐ Cognition
 - ☐ Social factors
- Sensory
 - ☐ Chemoreceptors
 - ☐ Sensorimotor
 - ☐ Hedonics
- Pharmacological
 - ☐ Euphoria
 - ☐ Sedation
 - ☐ Stimulation
 - ☐ Withdrawal relief

Statistical tests were completed to examine relationships between nicotine equivalents and model variables as well as carboxyhemoglobin and 3-HPMA and model variables. From their responses, smokers were classified by "typology" or dynamic groupings biomarkers of exposure.

[Candace to insert hypothetical interpretation of data.]

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The survey developed to test a model of adult smoking contained the Fagerström Test for Nicotine Dependence (FTND). TES study participants' responses were scored.

[Insert hypothetical interpretation of Fagerström data.]

A baseline and follow-up questionnaires developed by Philip Morris USA were administered to market surveillance participants. The questionnaire contains a reduced set of questions from the Total Exposure Study questionnaire to measure smoking behavior as well as questionnaire items from national surveys (e.g., The Behavioral Risk Factor Surveillance System (BRFSS)).

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Disease Trends (Element 6)

Smoking is proven to be a critical risk factor for cancer, chronic obstructive pulmonary disease (COPD), cardiovascular disease, and reproductive health. In the past year PM USA scientists have written (#) manuscripts published in refereed journals and (#) presentations to external stakeholders for each of the above-listed disease areas.

Research conducted by Philip Morris USA has resulted in the development and validation of (#) assays used in clinical studies. [Insert hypothetical implications.]

Finally, Philip Morris USA reviewed the scientific literature to monitor trends or changes in health outcomes not covered by the disease areas listed above. Preliminary evidence suggests (fill in the blank) may prove worthy of further study to assess the potential impact

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Discussion

| SUMMARY

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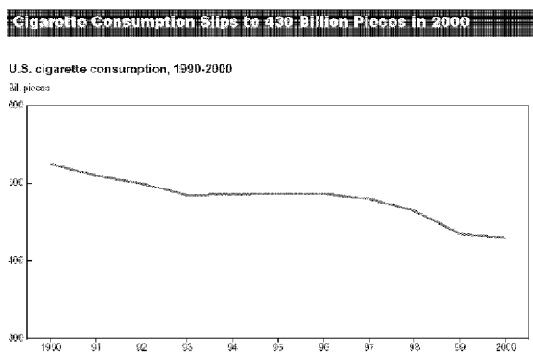
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Cigarette consumption has declined nearly every year since its peak in 1981 at 640 billion cigarettes. Markedly higher prices in 1999 resulted in a 6.5-percent decline, but during each of the previous 10 years, consumption fell between 0 and 3.1 percent. Cigarette consumption continues to decline as shown in Figure 1 (ERS (Economic Research Service). 2001. Briefing room. [online] Available: <http://www.econ.ag.gov/briefing/tobacco>)



Philip Morris brands account for approximately 48% of all cigarettes sold in the US. (Figure 2) (Ref MSA shipment Data)

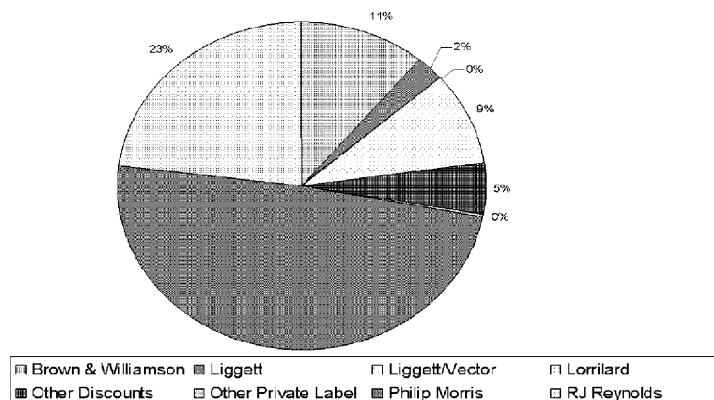
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Market Share Data - All Tobacco Companies

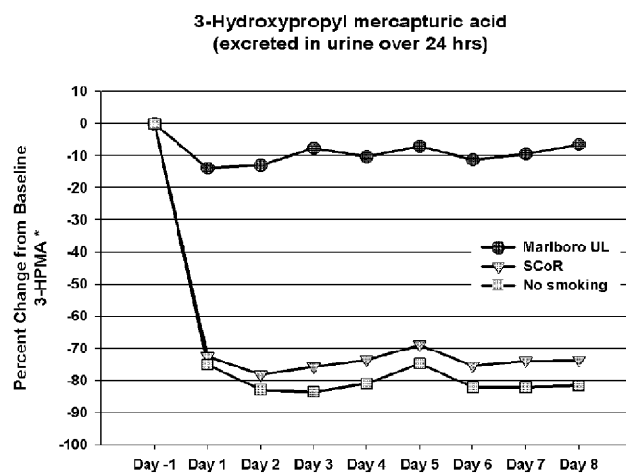


Reduced Exposure Products

Several clinical studies (human smoking) are currently underway to assess US smokers' exposure.

Total Exposure Study – The purpose is to estimate exposure of adult US cigarette smokers to cigarette smoke constituents using selected biomarkers of exposure and biologically effective dose. A study sample of 5000 subjects Preliminary data are expected in August.

Potentially reduced exposure products (PREP) Studies – A series of clinical studies examining PREPs are underway to determine whether there are differences in exposure using a special activated carbon filter as compared to conventional lit-en comparable tar delivery cigarettes. The following graphs shows preliminary data illustrating a reduction in certain biomarkers of exposure approaching the levels of the No smoking group when these cigarettes are smoked as compared to the control cigarette.



Another series of

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