

The Pennsylvania State University  
Graduate School  
College of Health and Human Development

**STUDIES IN TOBACCO HARM REDUCTION: THE ROLE OF CONTEXT IN  
SUBJECTIVE EFFECTS AND BEHAVIORAL RESPONSES TO A REDUCED  
EXPOSURE TOBACCO PRODUCT**

A Thesis in  
Biobehavioral Health

by  
Beth Q. Edwards

©2007 Beth Q. Edwards

Submitted in Partial Fulfillment  
of the Requirements  
for the Degree of

Doctor of Philosophy

December 2007

The thesis of Beth Q. Edwards was reviewed and approved \* by the following:

Lynn T. Kozlowski  
Professor of Biobehavioral Health  
Thesis Advisor  
Co-Chair of Committee

Laura Cousino Klein  
Associate Professor of Biobehavioral Health  
Co-Chair of Committee

Frank M. Ahern  
Senior Research Associate

William T. Ross Jr.  
Professor of Marketing

Collins O. Airhihenbuwa  
Professor and Head  
Department of Biobehavioral Health

\*Signatures are in file in the Graduate School.

### **Abstract**

Cigarette smoking remains one of the most important and preventable causes of morbidity and mortality. Tobacco harm reduction has been recognized as one component of a comprehensive tobacco control effort. Potential reduced exposure tobacco products (PREPs), particularly low-nitrosamine smokeless tobacco products, have attracted attention as promising harm reduction products. However, there is little research to date to support a viable role for these products within tobacco harm reduction efforts.

The current study included two trials of smokers' evaluations and use of a low nitrosamine smokeless tobacco product. Both trials employed a between-subjects design and all participants were screened to ensure eligibility. In the first trial, participants were randomly assigned to evaluate information emphasizing harm reduction (n=20) or convenience factors (n=20) and to evaluate the tobacco product. In the second trial, all participants evaluated the product during 3 lab sessions. Participants were randomly assigned to an experimental (n=21) or control (n=19) condition at the end of the 1<sup>st</sup> session. Participants in the experimental group tried the tobacco product daily for 5 days until the 2<sup>nd</sup> lab session; those in the control group had no additional use of the tobacco until the 2<sup>nd</sup> lab session. Between lab sessions 2 and 3, all participants were free to use the tobacco product if they chose, but use was not required. Participants recorded all their tobacco use between lab sessions.

Findings from trial one revealed no statistically significant differences in evaluations of information emphasizing harm reduction potential versus convenience factors of a non-smoked tobacco. Further, results from the 2<sup>nd</sup> trial demonstrated a statistically significant improvement in overall evaluations of the product by itself and compared to cigarettes regardless of experimental condition. However, participants in the control condition demonstrated a small but significant decrease in smoking when they were free to use the trial tobacco outside the lab. The majority of participants stated they would try the tobacco product again, primarily when smoking was not permitted and to cut down on smoking. The contribution of this dissertation research is presented, followed by a discussion of the findings and suggestions for future research.

## TABLE OF CONTENTS

|   |       |
|---|-------|
| List of Tables . . . . .  | xii   |
| List of Figures. . . . .  | xiii  |
| List of Abbreviations . . . . .   | xv    |
| Acknowledgements. . . . .   | xvi   |
| <br>CHAPTER 1: INTRODUCTION . . . . .                                       | <br>1 |
| Tobacco Harm . . . . .  | 1     |
| Overview of tobacco related morbidity and mortality. . . . .                | 1     |
| Lung Cancer. . . . .  | 1     |
| Cardiovascular Disease. . . . .   | 2     |
| Respiratory Illness. . . . .  | 2     |
| Other Health Harms. . . . .   | 3     |
| Environmental Tobacco Smoke: ETS . . . . .                                  | 3     |
| Smoking prevalence & incidence . . . . .                                    | 4     |
| Summary and Relevance . . . . .   | 5     |
| Overview of Tobacco Harm Reduction . . . . .                                | 6     |
| The role of tobacco harm reduction within tobacco control efforts . . . . . | 6     |
| Potential Reduced Exposure Products . . . . .                               | 8     |
| Mechanisms of Toxin Exposure Reduction. . . . .                             | 9     |
| Public Knowledge of Relative Tobacco Product Risks . . . . .                | 10    |
| Studies of Smokers' Knowledge, Attitudes and Experiences with PREPs. . .    | 11    |
| Areas for Further Research . . . . .  | 13    |
| Pre-Clinical Evaluation & Clinical Trials. . . . .                          | 13    |
| Methods of Assessment . . . . .   | 14    |

|   |    |
|---|----|
| Communication and Marketing of Relative Tobacco Product Risk . . . . .  | 15 |
| Communicating Health Risk. . . . .                                      | 15 |
| General Summary . . . . .   | 16 |
| Overview of Experiments . . . . .                                       | 20 |
| CHAPTER 2: EXPERIMENT 1. Smokers' Attitudes and Reactions to a Consumer |    |
| Overview. . . . .   | 22 |
| Hypotheses . . . . .  | 26 |
| Design . . . . .  | 28 |
| Methods. . . . .  | 28 |
| Recruitment . . . . .   | 28 |
| Eligibility. . . . .  | 29 |
| Study Procedures. . . . .   | 29 |
| Informed Consent . . . . .  | 30 |
| Expired Carbon Monoxide (CO) Breath Sample. . . . .                     | 30 |
| Tobacco Product Argument . . . . .                                      | 30 |
| Thought Listing Exercise . . . . .                                      | 31 |
| Argument Evaluation . . . . .   | 32 |
| Product (Ariva) Sample . . . . .  | 32 |
| Product Evaluation . . . . .  | 33 |
| Interview . . . . .   | 34 |
| Follow-up Interview . . . . .   | 35 |
| Results. . . . .  | 35 |
| Statistical Analyses. . . . .   | 35 |

|  |    |
|--|----|
| Descriptive Statistics . . . . .                                 | 36 |
| Argument Evaluation . . . . .                                    | 36 |
| Thought Listing Exercise . . . . .                               | 37 |
| Argument Evaluation Items. . . . .                               | 37 |
| Comprehension Test Items. . . . .                                | 38 |
| Argument Salience Scale . . . . .                                | 38 |
| Product Evaluation . . . . .                                     | 39 |
| Differences in Product Evaluation by Message Condition . . . . . | 40 |
| Favorable Product Evaluation Items . . . . .                     | 40 |
| Unfavorable Product Evaluation Items . . . . .                   | 41 |
| Evaluations of Ariva Compared to Cigarettes . . . . .            | 41 |
| Overall Product Interest Score . . . . .                         | 42 |
| Intentions for Future Use and General Reactions . . . . .        | 43 |
| Follow-up Interview . . . . .                                    | 44 |
| Confirmation of Hypotheses. . . . .                              | 44 |
| Summary and Conclusions: Experiment One . . . . .                | 45 |
| CHAPTER 3: EXPERIMENT 2  |    |
| Overview . . . . .   | 52 |
| Hypotheses . . . . .   | 55 |
| Design. . . . .  | 57 |
| Overview. . . . .  | 57 |
| Experimental Procedure. . . . .                                  | 58 |
| Methods . . . . .  | 59 |

|  |    |
|--|----|
| Participants . . . . .                                       | 59 |
| Eligibility. . . . .   | 60 |
| Study Procedures . . . . .                                   | 61 |
| Informed Consent . . . . .                                   | 61 |
| Self-report measures . . . . .                               | 61 |
| Product Information . . . . .                                | 63 |
| Lab Product Sampling . . . . .                               | 64 |
| Subjective Effects: Product Evaluation Exercises . . . . .   | 64 |
| Behavioral Responses: Semi-structured Interview . . . . .    | 65 |
| Product Use Instructions for Follow-up Period 1 . . . . .    | 66 |
| Daily Tobacco Use Diary . . . . .                            | 67 |
| Tobacco Collections and Compliance Calls . . . . .           | 67 |
| Follow-up Lab Session 1 . . . . .                            | 68 |
| Follow-Up Lab Session 2 . . . . .                            | 68 |
| Data Analytic Strategy . . . . .                             | 69 |
| Results . . . . .  | 70 |
| Descriptive Statistics . . . . .                             | 70 |
| Smoking Characteristics . . . . .                            | 71 |
| Quit Attempts and Intentions . . . . .                       | 71 |
| Smoking Restrictions and Social Climate of Smoking . . . . . | 72 |
| Laboratory Session 1: Baseline . . . . .                     | 73 |
| Participant Characteristics by Condition . . . . .           | 73 |
| Smoking Characteristics by Condition . . . . .               | 73 |

|   |    |
|---|----|
| Information Evaluation at Baseline . . . . .                        | 74 |
| Product Evaluation at Baseline . . . . .                            | 74 |
| Laboratory Session 2: Follow-up One . . . . .                       | 75 |
| Confirmation of Experience Manipulation . . . . .                   | 75 |
| Ariva Use and Cigarette Smoking During Follow-Up Period 1 . . . . . | 75 |
| Laboratory Session 3: Follow-Up Two . . . . .                       | 76 |
| Ariva Use and Smoking . . . . .                                     | 76 |
| Product Evaluations across Lab Sessions . . . . .                   | 77 |
| Product Excellence . . . . .  | 78 |
| Relief of Nicotine Withdrawal . . . . .                             | 78 |
| Relief of Urges to Smoke . . . . .                                  | 78 |
| Did not Need Cigarettes . . . . .                                   | 79 |
| Provides enough Nicotine . . . . .                                  | 79 |
| Still Crave Cigarettes . . . . .                                    | 80 |
| Would Use Product Again . . . . .                                   | 80 |
| Would Tell Friends . . . . .  | 80 |
| Product Excellence Compared to Cigarettes . . . . .                 | 81 |
| Non-significant Evaluation Items . . . . .                          | 81 |
| Visual Analog (VAS) Evaluations across Lab Sessions . . . . .       | 81 |
| Drug Effects of Ariva . . . . .                                     | 82 |
| Drug Effects on Cigarette Craving . . . . .                         | 83 |
| Palatability . . . . .  | 85 |
| Secondary Outcomes of Interest . . . . .                            | 86 |



|   |    |
|---|----|
| Behavioral Intentions Regarding Ariva Use . . . . .                 | 86 |
| Quitting Intentions . . . . .                                       | 87 |
| Tobacco Risk Perception . . . . .                                   | 88 |
| Perceived Personal Risk of Smoking a Cigarette . . . . .            | 88 |
| Perceived Personal Risk of Smoking a Pack of Cigarettes . . . . .   | 89 |
| Perceived Personal Risk of Smoking a Cigar . . . . .                | 89 |
| Perceived Personal Risk of Using Chewing Tobacco or Snuff . . . . . | 90 |
| Confirmation of Hypotheses . . . . .                                | 90 |
| Summary and Conclusions: Experiment Two . . . . .                   | 93 |

#### CHAPTER 4: GENERAL DISCUSSION

|  |     |
|--|-----|
| Overview . . . . .   | 123 |
| Background and Relevance . . . . .   | 123 |
| Review of Experiment One . . . . .   | 125 |
| Impact and Evaluation of Harm Reduction vs. Convenience Aspects of<br>Products Information . . . . . | 125 |
| Acceptability of Ariva Among Smokers . . . . .   | 126 |
| Review of Experiment Two . . . . .   | 127 |
| Subjective Effects . . . . .   | 128 |
| Convenience Factors . . . . .  | 129 |
| Cost . . . . .   | 129 |
| Smoking Restrictions . . . . .   | 130 |
| Ariva Use and Smoking . . . . .  | 131 |
| Limitations and Future Directions . . . . .  | 134 |

|  |     |
|--|-----|
| REFERENCES .....                                       | 137 |
| APPENDICES .....                                       | 145 |
| Appendix A. Consent Form Study 1 .....                 | 146 |
| Appendix B. History Questionnaire Study 1 .....        | 151 |
| Appendix C. Harm Reduction Message Study 1 .....       | 161 |
| Appendix D. Consumer Benefit Message Study 1 .....     | 165 |
| Appendix E. Thought Listing Exercise Study 1 .....     | 170 |
| Appendix F. Argument Evaluation Exercise Study 1 ..... | 174 |
| Appendix G. Product Evaluation Exercise Study 1 .....  | 176 |
| Appendix H. Open Ended Interview Study 1 .....         | 179 |
| Appendix I. Follow- Up Interview Study 1 .....         | 182 |
| Appendix J. Telephone Pre-Screener Study 2 .....       | 185 |
| Appendix K. Consent Form Study 2 .....                 | 193 |
| Appendix L. Product Information Study 2 .....          | 199 |
| Appendix M. Social Climate Survey .....                | 205 |
| Appendix N. MNWS .....                                 | 215 |
| Appendix O. QSU-Brief .....                            | 217 |
| Appendix P. WISDM-68 .....                             | 219 |
| Appendix Q. Product Evaluation – VAS .....             | 223 |
| Appendix R. Interview Study 2 .....                    | 226 |
| Appendix S. Diary Instructions .....                   | 229 |
| Appendix T. Closing Interview Study 2 .....            | 233 |
| Appendix U. Symptom Report .....                       | 236 |

|   |     |
|---|-----|
| Appendix V. Mood Assessment . . . . .                                 | 238 |
| Appendix W. Self Evaluation . . . . .                                 | 239 |
| Appendix X. Risk Assessment . . . . .                                 | 241 |
| Appendix Y. Menstrual Cycle Survey . . . . .                          | 243 |
| Appendix Z. Tobacco History Survey Study 2 . . . . .                  | 245 |
| Appendix AA. Thought Listing Exercise Study 2 . . . . .               | 256 |
| Appendix BB. Information Evaluation Study 2 . . . . .                 | 260 |
| Appendix CC. Diary Collection and Recording Compliance Form . . . . . | 262 |

### **List of Tables**

Table 1: Mean ( $\pm$  SEM) Product Evaluation Scores by High or Low

Argument Salience . . . . . 51

Table 2: Average Daily Ariva Use vs. Average Cigarettes per Day (CPD)

(Mean  $\pm$  SEM) . . . . . 121

Table 3: Intentions to Use Ariva® across study sessions by condition . . . . . 122

### **List of Figures**

|   |     |
|---|-----|
| Figure 1. Study Time Line Experiment 2 .....  | 102 |
| Figure 2. Lab Session Time Line Experiment 2 .....  | 103 |
| Figure 3: Average Daily Number of Cigarettes Smoked ( $\pm$ SEM) at Each Lab Session by Condition. ....   | 104 |
| Figure 4: Mean Agreement ( $\pm$ SEM) with Overall Product Excellence at Each Lab Session by Condition. ....  | 105 |
| Figure 5: Mean Agreement ( $\pm$ SEM) Score with Product Provides Relief of Nicotine Withdrawal at Each Lab Session by Condition.. ....                             | 106 |
| Figure 6: Mean Agreement ( $\pm$ SEM) Score with Product Provides Relief of Urge to Smoke at Each Lab Session by Condition. ....                                    | 107 |
| Figure 7: Mean Agreement ( $\pm$ SEM) Score with Did Not Need Cigarettes While Using Product at Each Lab Session by Condition. ....                                 | 108 |
| Figure 8: Mean Agreement ( $\pm$ SEM) Score with Product Provides Enough Nicotine at Each Lab Session by Condition. ....  | 109 |
| Figure 9: Mean Agreement ( $\pm$ SEM) Score with “I Believe I Would Still Crave Cigarettes if I Used the Product Regularly,” at Each Lab Session by Condition. .... | 110 |
| Figure 10: Mean Agreement ( $\pm$ SEM) Score with “I Would Use the Product Again,” at Each Lab Session by Condition. ....   | 111 |
| Figure 11: Mean Agreement ( $\pm$ SEM) Score with “I Would Tell My Friends Who Smoke to Use the Product,” at Each Lab Session by Condition. ....                    | 112 |
| Figure 12: Mean Agreement ( $\pm$ SEM) Score with “Product is an Excellent Product, Compared to Cigarettes,” at Each Lab Session by Condition. ....                 | 113 |
| Figure 13: Mean Endorsement ( $\pm$ SEM)VAS Score for “Do You Feel Any Drug Effect?” at Each Lab Session by Condition. ....   | 114 |
| Figure 14: Mean Endorsement ( $\pm$ SEM)VAS Score for “Does the Drug Have Any Bad Effects?” at Each Lab Session by Condition. ....                                  | 115 |
| Figure 15: Mean Endorsement ( $\pm$ SEM)VAS Score for “Do You Dislike the Drug Effect?” at Each Lab Session by Condition. ....                                      | 116 |

Figure 16: Mean Level of Perceived Personal Risk ( $\pm$  SEM) of Smoking a Cigarette measured at Each Lab Session by Condition. ....117

Figure 17: Mean Level of Perceived Personal Risk ( $\pm$  SEM) of Smoking a Pack of Cigarettes measured at Each Lab Session by Condition. .... 118

Figure 18: Mean Level of Perceived Personal Risk ( $\pm$  SEM) of Smoking a Cigar measured at Each Lab Session by Condition. ....119

Figure 19: Mean Level of Perceived Personal Risk ( $\pm$  SEM) of Using Snuff or Chewing Tobacco measured at Each Lab Session by Condition. .... 120

### **Abbreviations**

ANOVA = Analysis of Variance

BP = Blood Pressure

CHD = Coronary Heart Disease

CO = Carbon Monoxide

CVD = Cardiovascular Disease

ETS = Environmental tobacco smoke

FDA = Food and Drug Administration

MNWS = Minnesota Nicotine Withdrawal Scale

NRT = Nicotine replacement therapy

PREP = Potential reduced exposure product

QSU-Brief = Questionnaire of Smoking Urges Brief

TSNA = Tobacco Specific Nitrosamine

VAS = Visual Analog Scale

### **Acknowledgements**

I would like to express my deepest gratitude to the many people who have made this work possible. Each of you has been unexpectedly generous in your assistance and direction and essential to the completion of this dissertation.

I would like to thank my advisor, Dr. Lynn Kozlowski, whose bold scholarship has been an intellectual inspiration. I am especially grateful and indebted to my mentor, Dr. Laura Klein, for her immeasurable support, wisdom, patience, and expert guidance in all aspects of scientific inquiry and method. I have also benefited tremendously from the example she has set as a woman of science, demonstrating the highest standard of scholarship while nurturing students and family on a daily basis. I would also like to thank my committee members, Dr. Frank Ahern and Dr. William Ross, for generously sharing their time and expertise, providing ongoing encouragement and offering thoughtful insight into all aspects of this study.

I am extremely thankful for the kindness, friendship and daily (and often minute to minute) support of my graduate student colleagues, Courtney Whetzel and Jeanette Bennett. It would easily require another volume to describe all of your acts of kindness and the tremendous amount of work each of you contributed to this project, which has also been much improved by your intellectual contributions.

I would also like to thank the research assistants of the Biobehavioral Health Studies Lab, especially Alli Endicot, Julie Leslie, Suzanne Williams, and Erin Ruah for working tirelessly and without complaint to assemble materials, recruit and schedule participants, transport samples, enter and clean data, create codebooks, and cheerfully and professionally handle any other task required.

I would also like to thank my parents, Louis and Margaret Quinio for teaching me to value education and supporting me with love and encouragement in all my endeavors.

I am greatly thankful to my daughter, Audrey Anna, who has been a source of inspiration throughout my training and this project, including many hours spent patiently working and playing by my side to see this work completed. Finally, my most profound gratitude is reserved for my husband, Harold, who has been my greatest champion in this effort and in life. I am blessed by your unconditional love, sincere friendship, intellectual companionship, and vast support. Your infinite patience and great personal sacrifice have afforded me this opportunity. I thank you.



## CHAPTER 1: INTRODUCTION

### **Tobacco Harm**

**Overview of tobacco related morbidity and mortality.** Smoking continues to be a leading cause of premature death and disability worldwide. It is estimated that smoking is responsible for nearly one in five deaths in the United States each year (American Lung Association, 2006) and 12 million premature deaths can be attributed to smoking since the publication of the first Surgeon General's report on smoking consequences published in 1964 (United States Department of Health and Human Services, 2004). Smoking causes disease and death in smokers by causing several forms of cancers, (notably lung cancer, a leading cause of cancer death among women and men, and also acute myeloid leukemia, cervical cancer, kidney cancer, pancreatic cancer, and stomach cancer); cardiovascular disease, and respiratory illnesses. Among adults, most deaths attributable to smoking are due to lung cancer, coronary heart disease, and chronic obstructive pulmonary disease and other respiratory impairments (ALA, 2006). Smoking also damages reproductive health and functioning. Indeed, smoking has been found to damage "nearly every organ of the body," (USDHHS, 2004, p. 25) and diminish the overall health of smokers.

**Lung Cancer.** Lung cancer was one of the first diseases to be causally linked to tobacco smoking. Lung cancer is of grave concern because the case fatality rate is extremely high (USDHHS, 2004). Even after the identification of tobacco smoking as a major cause of lung cancer, this cancer remains one of the leading types of cancer as well as a leading cause of cancer death. It has been estimated that lung cancer accounts for

as many as 28% of all cancer deaths in the United States, and represents 13% of new cancers each year (American Cancer Society, 2003).

**Cardiovascular Disease.** Heart disease and stroke continue to be the first and third leading causes of death in the United States, respectively (USDHHS, 2004). Cardiovascular disease affects over 61 million Americans and includes conditions such as high blood pressure (BP), coronary heart disease (CHD), stroke, congestive heart failure (CHF), and other conditions. Nearly thirty years have passed since the Surgeon General of the United States confirmed that the scientific evidence was available and abundant to support a causal relationship between smoking and coronary heart disease (CHD) (United States Department of Health, Education and Welfare, USDHEW, 1979). Later reports reaffirmed smoking as an independent cause of CHD and importantly, a modifiable risk factor for the development of heart disease (USDHHS, 1983). By the 1990's, evidence and research were available to also demonstrate the reduction in CVD morbidity and mortality risk achieved after smoking cessation (USDHHS, 1990).

**Respiratory Illness.** Chronic obstructive pulmonary disease (COPD) and other acute respiratory illnesses (asthma, upper and lower respiratory tract infection, pneumonia) are major leading causes of morbidity and mortality in the United States and globally (USDHHS, 2004). Because smoking adversely affects the entire lung, it impedes defensive mechanisms that prevent infection and inflicts damage on the lung that can promote the development of COPD. Not only are smokers at increased risk of pulmonary infection, those who do experience infection may be affected more severely. For those with COPD, respiratory infection can further exacerbate their underlying disease. Evidence has emerged that helps to elucidate the mechanisms by which smoking

renders smokers more susceptible to infection. The most recent Surgeon General's Report on the Health Effects of Smoking concludes that there is sufficient evidence to establish a causal relationship between 1) smoking and acute respiratory illness, including pneumonia, in individuals without underlying lung disease; 2) maternal smoking and reduced lung function in infants and 3) active smoking in adulthood and the early onset of and accelerated decline in lung function (USDHHS, 2004). Importantly, this report (USDHHS, 2004) notes sufficient evidence to establish a causal relationship between smoking cessation and a return to the rate of lung function seen in non-smokers.

**Other Health Harms.** Among the most detrimental health effects of smoking not described above are the harms to reproductive function, and to the development and health of the fetus, in particular. Smoking has been associated with low birth weight, smallness in relation to gestational age, impaired fertility, increased risk for ectopic pregnancy, spontaneous abortion, pregnancy complications, fetal death and still birth, infant mortality (related to placental complications, maternal hemorrhage, sudden infant death syndrome [SIDS], infant respiratory difficulty), congenital malformation, impaired childhood development, and lowered sperm count (USDHHS, 2004). In addition to the reproductive harms described here, smoking has been associated with other systemic health problems including overall diminished health, loss of bone mass, dental disease, eye disease, and gastrointestinal problems (USDHHS, 2004).

**Environmental Tobacco Smoke.** Environmental tobacco smoke (ETS) also causes health harm to smokers and non-smokers. ETS is sometimes also called second-hand smoke and is comprised of the smoke generated by burning cigarettes (sidestream smoke) and the smoke exhaled by smokers (mainstream smoke). People may be exposed

to ETS in public places such as restaurants and bars, in their homes if they live with smokers, in vehicles, or at work. There is sufficient evidence to demonstrate that exposure to ETS is a cause of lung cancer and coronary heart disease and mortality in non-smokers (USDHHS, 2006). In addition, women exposed to ETS during pregnancy may also suffer complications and the health of the fetus or new born may also be impaired. Children are particularly susceptible to the harmful effects of exposure to ETS which increases their risks of developing serious respiratory problems, such as provoking asthma attacks, increases respiratory tract and ear infections. Minimizing non-smokers' exposure to ETS is an important goal of the *Healthy People 2010* objectives (USDHHS, 2000).

**Smoking Prevalence and Incidence.** In 2004, nearly 21% of the adult population in the United States, numbering 44.5 million, smoked (ALA, 2006). The annual prevalence of smoking in the United States declined steadily between the 1960s and 1990, however, since 1990, the annual prevalence of smoking has remained nearly unchanged. In 2004, smoking prevalence was greatest for those aged 25-44 years (23.8 percent) and lowest among those over 65 (8.8 percent). Recently, smoking rates among people aged 18-24 has also risen to levels similar to those in the 25- 44 year group (ALA, 2006). Current smoking is also more common among men than women although smoking has not declined as markedly among women as men over the past 40 years.

Due to the high rates of continuing smoking, attention is being devoted to assist treatment-resistant smokers (Bollinger *et al*, 2001; Fagerström, 1999; Jiminez-Ruiz, Kunze, & Fagerström, 1998; Shiffman, Mason, & Henningfield, 1998) , as well as to generating additional strategies to reduce the health burdens of smoking (Stratton *et al*,

2001). While many tobacco users want to quit, few are successful during any given quit attempt and few are prepared to make an immediate quit attempt (Etter, Paernegger, & Ronchi, 1997, Prochaska & Goldstein, 1991). One strategy involves supplying nicotine from an alternate source either to help smokers reduce or quit smoking cigarettes. Many smokers are unable to quit or reduce cigarettes without assistance because they are addicted to nicotine and regulate their smoking behaviors as a means of maintaining nicotine intake (Hofer, Nil, & Battig, 1991; Petitti & Friedman, 1983; Russell, Sutton, Feyerabend, & Saloojee, 1980; Scherer, 1999; Sutton, Feyerabend, Cole, & Russell, 1978; Sutton, Russell, Iyer, Feyerabend, & Saloojee, 1982).

**Summary and Relevance.** Millions of Americans are current smokers and millions more are regularly exposed to ETS, causing an excess of morbidity and mortality in smokers and non-smokers. The direct health care costs of smoking are estimated to be at least \$50 billion dollars per year with additional costs stemming from premature deaths, disability, absenteeism, and reduced productivity (USDDH, 2000). A comprehensive program of tobacco control that prioritizes prevention of tobacco use and smoking initiation, cessation of tobacco and smoking among current users, the prevention of relapse among quitters, and minimizes the exposure of non-smokers to ETS is needed to reduce the burden of smoking related morbidity and mortality. While the primary goals of tobacco control efforts remain prevention of smoking and tobacco initiation and promoting cessation, tobacco harm reduction has also been recognized as having a place within a comprehensive tobacco control program (USDHHS, 1989, 1990).

## **Overview of Tobacco Harm Reduction**

**The Role of Harm Reduction within Tobacco Control Efforts.** In 2001, the Institute of Medicine (IOM) published a report on potential reduced exposure products, (“PREPs”) entitled, *Clearing the Smoke*, to address concerns with these emerging tobacco products and their risk claims (Stratton, *at al*, 2001). The report concluded with three main questions: (1) Does the use of these products decrease exposure to the harmful substances in tobacco as claimed by the tobacco industry? (2) Is this potential decreased exposure associated with decreased tobacco-related morbidity and mortality? and (3) What are the public health implications of these products? A main concern about the public health implications of PREPs is that regardless of risk reduction to individual users, there could be detrimental effects at the population level, especially if overall tobacco use increases rather than decreases. Examples of specific concerns about the population impact of PREPs include continued tobacco use among those who might have quit, former tobacco users resuming use, and initiation of tobacco use in those who would not have otherwise tried tobacco. These concerns are grounded in the idea that claims of reduced risk will be believable, will undermine acknowledgement of the risks of tobacco use, especially smoking, and will increase the acceptance of tobacco use, in general. The report recommends that research is needed to anticipate the possible population impact of PREPs, citing an, “urgent need for information on a broad range of elements . . . including attitudes, beliefs, product characteristics . . . usage patterns, marketing messages such as harm reduction claims, and advertising.” (Stratton, *at al*, 2001, p. 197).

In addition, support of regulation favoring harm reduction uses of some non-smoked tobacco products has been advocated by experts in tobacco control and policy. For

example, in a recent report Bates and colleagues (2003, p. 361, *emphasis in original*)

argue:

Even allowing for cautious assumptions about the health impact, snus – and other oral tobaccos – *are a very substantially less dangerous way to use tobacco than cigarettes*. Smokeless tobaccos are not associated with major lung diseases, including chronic obstructive pulmonary disease (COPD) and lung cancer, which account for more than half of smoking related deaths in Europe. If there is a CVD risk, which is not yet clear, it appears to be a substantially lower CVD risk than for smoking. Smokeless tobacco also produces no environmental tobacco smoke (ETS) and therefore eliminates an important source of disease in non-smokers and children. These are very substantial benefits in reduced risk to anyone that switches from smoking to smokeless tobacco and we believe the public health community has a moral obligation to explore this strategy.”

Low-nitrosamine smokeless tobacco, in particular, has attracted attention as a promising tobacco harm reduction product (Hatsukami & Hecht, 2005; Hatsukami, Lemmonds, Zhang, Murphy, Le, Carmella *et al*, 2004; Mendoza-Baumgart, *et al*, unpublished manuscript). More research is needed to examine the whether low TSNA products have a viable role to play within tobacco harm reduction efforts. The consensus opinion of experts within tobacco control is that in comparison to cigarette smoking, such products pose at least a 90% reduction in relative risk (Levy, Mumford, Cummings, Gilpin, Giovino, Hyland, Swenor, & Warner, 2004). These experts have advocated that the relative risks of low-nitrosamine smokeless tobacco products not be portrayed as comparable with the risks of smoking.

Importantly, they have also suggested that the harm reduction potential of these products will depend in part on their marketing and governmental regulation because these factors will influence the extent to which they are used. In order to achieve the greatest public health benefit, experts continue to call for governmental regulation requiring tobacco products identified as low-nitrosamine to meet established standards

for production and manufacture. One such standard is the Gothiatek standard ([www.gothiatek.com](http://www.gothiatek.com)) which sets an upper limit on detectable levels of certain toxicants, establishes requirements for the raw materials used, dictates the manufacturing process, and requires the provision of information to consumers. A warning that describes relative risk of cigarettes and smokeless tobacco has also been proposed for placement on smokeless tobacco products (Levy, Mumford, Cummings, Gilpin, Giovino, Hyland, Sweanor, Warner, & Compton, 2006).

Although the concept of “safer” tobacco use seems to be desirable to smokers, as evidenced by the popularity and misconceptions about “light” and low tar cigarettes, the amount of reduction in toxin exposure achieved by new tobacco products varies (and in some cases there is no reduction at all), and raises many concerns among health advocates, many of which are articulated in the IOM report (National Cancer Institute, 2001; Stratton *et al*, 2001). While the goals of harm reduction are straightforward, to reduce the morbidity and mortality caused by tobacco use, several factors (such as the variability in the amount of exposure reduction achieved and product design) complicate the creation of a unified conceptualization of what strategies and products tobacco harm reduction approaches ought to explore or include in order to achieve these goals.

**Potential Reduced Exposure Products.** New tobacco products vary widely in their design and marketing claims. For example, Advance Lights®, Omni®, Quest®, Scor®, Eclipse®, and Accord® are types of modified cigarettes. Advance is made with Star-cured® tobacco and uses a “trionic filter” that the manufacturer claims may reduce toxin exposure. Quest® is made with genetically modified, non-nicotine tobacco. Eclipse® contains nicotine, glycerin, and a small amount of tobacco which are heated by a carbon



fuel element, resulting in full nicotine exposure, higher CO readings, and the delivery of glass fibers to the mouth and lungs (Hickman, Klonoff, Landrine, Kashima, Parekh, Fernandez, Thomas, Brouillard, Zolezzi, Jensen, & Weslowski, 2004).

Ariva®, Exalt®, Revel®, and Stonewall® are smokeless tobacco products.

Ariva™ and Stonewall® are compressed powdered tobacco pieces that dissolve in the mouth. Exalt® and Revel® are smokeless, spitless tobacco sachets. Smokeless tobacco products that are available in the United State and Sweden, in general, convey less risk than smoked tobacco, because they do not burn or produce second-hand smoke, thereby eliminating the respiratory health risks of smoking tobacco (Foulds, Ramström, Burke, & Fagerström, 2003). Ariva®, Exalt®, and Stonewall®, are made from tobacco low in carcinogenic tobacco-specific nitrosamines (TSNAs), further reducing cancer risk.

**Mechanisms of Toxin Exposure Reduction.** Ariva®, a smokeless low nitrosamine tobacco lozenge, is among the most promising of new reduced exposure products because of the amount of toxin exposure reduction as well as seemingly good acceptability to smokers (Hatsukami, personal communication, December 2005; Stepanov, Jensen, Hatsukami, & Hecht, 2006; Mendoza-Baumgart, *et al*, unpublished manuscript). Exposure reduction is achieved through several mechanisms compared to smoking. First, there is no combustion or burned tobacco. This eliminates many of the toxic compounds that are created in the burning process and eliminates respiratory health risks to the user or the public (Hatsukami, Lemmonds, & Tomar, 2004). Second, this product is manufactured from tobacco cured by a process found to create very low levels of carcinogenic TSNAs, (Stepanov *et al*, 2006). Significantly lower levels of these carcinogens reduce the cancer risks of the product. For example, Rodu & Jansson (2004)

found that the mouth cancer risk from low nitrosamine smokeless tobacco was approximately 2% the risk of smoking. Asplund *et al* (2003) concluded that smokeless tobacco poses significantly less risk to health than smoking, in terms of cancer risks, respiratory risks, and cardiovascular risks. One of the main risks associated with this product is that it may not offer a reduction in the amount of overall nicotine exposure. Nicotine carries a high risk of causing addiction, as well as exerting cardiovascular effects (USDHHS, 1988).

**Public Knowledge of Relative Tobacco Product Risks.** Smokers remain ill-informed about the relative risks of various tobacco products, particularly the risks of light and low tar cigarettes compared to regular cigarettes and the risks of cigarettes compared to non-combusted products. Recent research by O'Connor and colleagues (O'Connor, Highland, Giovino, Fong, Cummings, 2005) indicates that smokers continue to believe, incorrectly, that light cigarettes are less harmful to health than regular cigarettes and conversely, they fail to recognize that some tobacco products confer substantially lower risks than cigarette smoking. The authors of this study explain that, “smokers hold beliefs about the relative safety of supposedly less-harmful tobacco products that are opposite to existing scientific evidence. These results highlight the need to educate smokers about the risks of alternatives to conventional cigarettes.” Additional survey research found similar results regarding smokers’ beliefs about the relative risks of cigarettes and smokeless tobacco, with only a small percentage (13%) reporting SLT as being less harmful than smoking (Jensen, Babb, Hatsukami, & Avery, 2004). Understandably, very few smokers in this sample expressed willingness to use non-smoked tobacco to reduce smoking (7%) or to quit smoking (9%). Slightly more

smokers in this relatively small sample ( $n = 150$ ) said they would be willing to use a modified SLT to reduce smoking or to quit (20%). The investigators in this study reached conclusions similar to those of O'Connor and colleagues that smokers have a poor understanding of relative risks and are unlikely to use SLT products as reduction or cessation tools.

### **Studies of Smokers' Knowledge, Attitudes, and Experiences with PREPs.**

Recently, Caraballo, Pederson, & Gupta (2006), conducted focus groups with smokers in two cities to explore smokers' reasons for and reactions to use of reduced exposure tobacco products, including Eclipse®, Omni®, Advance Lights®, Accord®, and Ariva®. Eclipse was the most commonly reported product tried by smokers in this study. The authors found that most smokers did not like the products they tried and discontinued use while continuing smoking. Smokers' reasons for trying these products included receiving a free sample or the products were inexpensive, they wanted to stop smoking, they believed claims of lower health risks, or they were curious. Participants reported learning of the products through advertising and promotion, family, friends, and co-workers. Most did not like the products and would not recommend them to anyone, although the authors report a minority believed that there may be a market for them.

There has also been concern expressed over the marketing of PREPs (Stratton, *et al*, 2001), specifically about marketing claims of reduced risk and the possible effects and interpretations of marketing campaigns. There are concerns over both the accuracy of risk reduction claims, as well as the interpretation of this information by consumers. In addition, there is concern that reduced risk claims by any tobacco product could have a

detrimental impact on the public and smokers' perceptions and understanding of the magnitude of the risks of smoking (Stratton *et al*, 2001, Hickman, *et al*, 2004).

In fact, there is little research available to date that provides data on the marketing of these products. One study (Hickman, *et al*, 2004) examined advertising and availability of PREPs. The authors conducted a review of tobacco advertisements in 10 popular magazines and found that only 1% of these ads were for PREPs, although there were differences noted by the authors in the content and style of the advertisements by the type of magazines in which they appeared. The authors concluded that this may suggest that tobacco companies might use a targeted approach to advertisement of PREPs as they have done for traditional tobacco products. One of the limitations of this study is that the investigators did not include non-smoked PREPs in their review of advertisements. The authors explained this omission was due to their focus on PREPs that might compete with cigarettes and that they excluded PREPs meant to replace smokeless tobacco products. However, it is worth noting that Ariva®, a smokeless product, includes the marketing slogan on the box that reads "When you can't smoke." This suggests that the makers of this product do not plan to market it as a replacement for traditional smokeless tobacco products but as a smoking substitute.

This study also examined the availability of some PREPs, including Omni, Accord, Eclipse, and Ariva® in a sample of San Diego neighborhoods. They attempted to purchase each product in 113 stores in primarily White, Black, Latino, and Asian American stores. Of the four products sought, only Omni and Ariva® were actually available in any stores to purchase. The authors have concluded that tobacco makers may not yet be heavily invested in PREP marketing and advertisement.

**Areas for Further Research.** Recently, a multi-disciplinary expert panel convened to develop a framework of methods to assess multiple domains of potential reduced exposure products (Hatsukami, Giovino, Eissenberg, Clark, Lawrence, & Leischow, 2005). The proposed framework and resulting strategy have been praised as landmark developments in tobacco science and public health, particularly for providing guidelines for national and international evaluation and regulatory efforts (Henningfield, Burns, & Dybing, 2005). The report provides a model that outlines progression through three main steps of the process necessary to fully evaluate the potential of risk reducing products, including: 1) preclinical evaluation, 2) clinical evaluation of exposure reduction, health effects, and market research, and 3) population effects. Specific methods of evaluation are presented that represent the consensus of workgroups devoted to substantive topic areas (i.e. human clinical trials, consumer perceptions, and post-marketing surveillance)

**Pre-Clinical Evaluation & Clinical Trials.** Clinical trials that assess exposure reduction, health effects, abuse liability, and patterns of product use have been recommended (Hatsukami *et al*, 2005). Both preclinical and human clinical trials are necessary. Among the important goals of clinical trials are 1) assessing the likelihood of products to substantially reduce risks, particularly with regard to existing medicinal NRT products, and 2) assess the utility and desirability of pursuing additional pre-market testing (Kozlowski, Strasser, Giovino, Erickson, Terza, 2001; Hatsukami, *et al*, 2005). Another important goal of conducting human trials is to determine how actual usage patterns impact individual risk and exposure reduction. This point in the evaluation process has also been suggested as an important opportunity to examine perceptions of

health risks or harms associated with various products, as these perceptions may play a role in affecting decisions to use them and ultimately the extent to which their use is disseminated in the larger population. The authors of this report on methods for assessing PREPs emphasize the importance of, “determining how the consumers perceive and interpret the information and images delivered to them and if these perceptions and processing of information are accurate or misleading,” (Hatsukami *et al*, 2005, p. 830). Additionally, they explain that one purpose of consumer product testing is to, “ensure that claims and marketing of a product will lead the consumer to make an informed decision based on accurate understanding of valid information . . . “ (p. 830). Finally, the authors have also called for recognition of the bi-directionality of the assessment processes, or that results from all areas of testing can and should be used to inform and improve each of the other areas.

**Methods of Assessment.** A variety of moderating factors that can influence the impact and utility of PREPs have been identified, including characteristics of the tobacco user, such as type, amount, duration and intensity of tobacco use, interest in quitting, gender, ethnicity, physical and mental health, and addiction (Hatsukami *et al*, 2005). Several methodological strategies that can account for moderating factors in the evaluation of PREPs have been suggested. Specifically, the authors call for studies that 1) use participants similar to the population most likely to use the product, 2) employ unbiased assignment to careful control conditions, 3) include consideration of both controlled and *ad libitum* use of the product and smoking, 4) employ collection of comprehensive assortment of biomarkers of exposure, 5) include careful consideration of goals, outcome measures and use behaviors of PREPs over time, 6) give attention to

assessment and verification of compliance with study protocols, and 7) collect data regarding adverse events. Both naturalistic and laboratory studies have been suggested to 1) assess exposure reduction in situations where consumers might use multiple products with varying amounts of individual exposure reduction and 2) to, “reveal factors that might contribute to the extent to which PREPs are used, compared with conventional tobacco products (e.g. instructions and information provided about the PREP, PREP cost and access, availability of alternatives).” (Hatsukami *et al*, 2005, p. 834; Hughes & Keely, 2004; Hughes, Gust, Keenan, Fenwick, Skoog, & Higgins, 1991).

**Communication and Marketing of Relative Tobacco Product Risk.** Testing consumer perceptions of PREPs is another necessary aspect of overall PREP evaluation. These assessments should include evaluations of reactions to 1) product characteristics presented in advertisements, promotional materials, or other consumer outlets and 2) the implicit and explicit claims of harm reduction presented in these materials (Hatsukami *et al*, 2005, p. 835). It has been noted that while standardized methods for this type of evaluation have not been established, the need to conduct these assessments is evidenced by studies demonstrating smokers’ inaccurate perceptions of marketed tobacco products (Etter, Kozlowski, & Perneger, 2003; Kozlowski *et al*, 1998).

**Communicating Health Risk.** The Persuasive Health Message (PHM) Framework (Witte, Myer, & Martel, 1992) is an integrated approach to generating persuasive health campaign messages that draws on elements of the theory of reasoned action (Fishbein & Ajzen, 1975), the elaboration likelihood model (Petty & Cacioppo, 1986) and protection motivation theory (Rogers, 1983). The framework suggests that two sets of factors, transient and constant, must be addressed in the development of

effective persuasive health messages. The constant message components include threat or risk information, an efficacy message, cues (source and message), and an audience profile. One group of transient factors includes message goals, salient beliefs, and salient referents; the second set of transient factors includes culture, environment, and preferences.

### **General Summary**

Despite the overwhelming evidence of the health harms related to smoking, smoking remains prevalent in the United States. Cigarette smoking remains one of the most important and preventable causes of morbidity and mortality in the United States and globally (USDHHS, 1984). Smoking causes cancers, cardiovascular disease, and respiratory illness. These diseases are leading causes of death among smokers. In addition to the specific diseases caused by smoking, which are too numerous to describe here but have been described and reviewed in detail in several reports of the Surgeon General of the United States, smoking lowers the overall health status of smokers (USDHHS, 1988). In addition, smoking damages the reproductive health of men and women, causes harm to the developing fetus, and increases the risk of birth complications among infants and their mothers. Smoking also takes a toll on the health status of non-smokers. Children who are exposed to ETS are at particular risk for developing respiratory illness. Exposure to ETS is a cause of lung cancer in non-smokers, as well (USDHHS, 2006).

Although many smokers report that they want to quit smoking, successful quit attempts are relatively rare and relapse rates are high among quitters (Etter *et al*, 1997; Prochaska & Goldstein, 1991). Nicotine addiction is a major factor that sustains smoking



behavior, undermines smokers' motivation to quit, and results in relapse to smoking among quitters. Nicotine addition is not the only factor that maintains smoking, however. Smokers own reasons for smoking often include social, emotional, psychological, and automatic response dimensions that sustain their behavior in spite of the high costs to health and finances (Piper, McCarthy, & Baker, 2006). It has been suggested that individuals who continue to smoke may be the most dependent and most difficult to help achieve smoking abstinence. For these reasons, tobacco harm reduction has been recognized as one component of a comprehensive tobacco control effort that prioritizes (1) the prevention of initiation of smoking and other forms of tobacco use and (2) promoting cessation among smokers and other tobacco users (Stratton *et al*, 2001). Relapse prevention is another important goal. However, given the high prevalence of continued smoking, public health experts have agreed that harm reduction approaches to tobacco use and smoking have a role to play in minimizing the high toll of smoking related morbidity and mortality.

While a variety of harm reduction approaches have been considered, the evaluation process required to demonstrate and quantify harm reduction is challenging (Hatsukami, *et al*, 2005). The failure of light and low tar cigarettes to actually reduce smoking harm is a reminder that there is an urgent need to evaluate products that allege to offer reductions in health risks from smoking, as well as providing a difficult lesson on the complexity of the evaluation process (NCI, 2001). Despite the complexity and challenges in evaluating methods of tobacco harm reduction, the need to do so remains. Proposed methods of achieving tobacco harm reduction include: smoking reduction, the use or substitution of oral (non-smoked) tobacco, the use of potential reduced toxin

exposure products (in two classes: (1) products that are designed to ‘mimic’ smoking and (2) products that are not smoked), the use of NRTs in several capacities (i.e. long term use to reduce smoking or maintain smoking abstinence), and most recently, including physical activity to reduce the harm inflicted by smoking and improve overall health status (de Ruiter & Faulkner, 2006). Smoking reduction studies have shown some reduction in markers of smoking harm among those who reduce smoking, however, the results are sometimes difficult to interpret due to the variations among individual smokers (i.e. in compensatory smoking behaviors) and questions also remain as to whether smokers who achieve reductions as part of clinical trials are able to permanently maintain reductions (Hecht *et al*, 2004). The use of NRT products is a more effective method of reducing exposure to harm from smoking, however, underutilization of these products by smokers has limited the contribution of NRTs to harm reduction efforts, as well as cessation programs (Silagy *et al*, 2004; Mooney, Leventhal, & Hatsukami, 2006; Bansal *et al*, 2004; Cummings & Hyland, 2005).

Potential reduced toxin exposure products vary so immensely in design that it is nearly impossible to make definitive statements on these products as a group. Instead, it will be necessary to evaluate emerging and existing potential reduced exposure tobacco products on an individual basis. Researchers studying Ariva® have concluded that it is among the most promising of this class of products in terms the amount of reduction in toxin exposure and acceptability to smokers (Mendoza-Baumgart *et al*, unpublished manuscript). Toxicity and pharmacokinetic studies have examined this product’s nicotine content and evaluated levels of TSNAs (Stepanov *et al*, 2005, Mendoza-Baumgart *et al*, unpublished manuscript). Clinical trials have demonstrated that smokers

who use this product instead of smoking (during abstinence from cigarettes) significantly reduce their exposure to TSNA's and that reductions are similar to those seen with the use of NRTs (Mendoza-Baumgart *et al*, unpublished manuscript). Some work has evaluated a similar product (a low nitrosamine smokeless tobacco called snus, a tobacco sachet as opposed to a hard tobacco lozenge) in the context of smoking reduction (Foulds *et al*, 1997). Trials of smoking reduction with non-smoked tobaccos or NRTs demonstrated significant reductions in toxin exposure among participants, however, the authors felt the results needed to be interpreted with caution because of the substantial variation in individual smokers' exposure, which was heavily dependent upon the degree to which smokers engaged in compensatory smoking (i.e. deeper more frequent puffing when they did smoke) (Hecht, *et al*, 2004).

While Ariva® has shown promise as a product that contains lower levels of toxic TSNA's and confers less harm to health than smoking when used to replace cigarettes, it remains to be seen whether smokers who use Ariva® as it is marketed, to manage smoking restrictions, experience any reduction in the amount toxins to which they are exposed. Still, even if individual smokers don't experience significant reductions in their own levels of exposure to toxins, it is possible that those smokers who do use this product instead of smoking, could produce less ETS and consequently, harm to others. It is also not known whether smokers outside of the lab, will use this product as it is marketed – in situations when they can't (or don't want to) smoke. There are also legitimate and substantial concerns within the tobacco control and public health communities about the impact of informing the public and smokers about relative tobacco product risks, as well tobacco industry marketing of reduced exposure products.

## **Overview of Experiments**

This dissertation includes two studies of smokers' use of Ariva® in a lab trial and outside of the lab under guided and natural use conditions. The first study was designed with two aims: 1) to assess the importance of the harm reducing potential of Ariva® to smokers' evaluations of the product and 2) provide data on the acceptability of a non-smoked tobacco product to smokers. To explore the impact of information detailing the relative risks of Ariva® compared to smoking, an experimental manipulation was conducted. Participants were randomly assigned to evaluate one of two potential frames of marketing information about Ariva®. This manipulation addressed concerns that providing comparative risk information might lead to erroneous conclusions or judgments of this product as being safe. The product sample also provided an opportunity to 1) examine smokers' first reactions to a novel, non-smoked tobacco product after reading a strong argument advocating its use by smokers, and 2) to conduct in-depth interviews to query smokers' regarding their reactions to the product in terms of likeability and explore the conditions in which they might consider using this product. Participants in the first experiment were also offered a take home sample of the product as a 1) a behavioral measure of intentions to use the product again in addition to the direct survey and interview questions regarding intentions and 2) a behavioral measure of acceptability of the product to smokers. This was the first study to include examples of the types of marketing materials or messages smokers might encounter about Ariva® along with a sample of the product and to conduct evaluations of the specific product information.

The second study was conducted to replicate and extend the results of the first study. It was designed to provide a replication of the interest in Ariva® demonstrated by

smokers in the first study, as well as expand on this study to provide more complete follow-up data describing use of the product outside of the lab. It improved on the design of the first study by providing additional information about the effect of increased exposure to this product on behavioral measures as well as subjective responses to the product. In the second study, the lab trial was repeated, and all participants were randomized to either an 'experience' or 'no experience' condition outside of the lab. The second study provided additional points of follow-up data on smokers' behavioral and subjective responses to the product in the lab and in the context of daily life. The effect of the 'experience' period on subjective effects, product evaluations, and behavioral responses was examined. The second study had several additional benefits including 1) collecting more detailed data regarding exactly how much product was used and how much smoking occurred during that period, 2) including questions about the amount and types of smoking restrictions each smoker faced, 3) including pricing information in the product information, and 4) collecting additional biomarkers of exposure to tobacco. To our knowledge, this was the first study to examine smokers' use of Ariva® under instructions to replace some cigarettes as well as in a natural use condition, collect biomarkers of toxin exposure in these conditions, and collect measures of behavioral and subjective responses to the product in various contexts. Together, the first and second studies also provide an examination of how smokers evaluate persuasive messages advocating the use of reduced exposure tobacco products among smokers as has been recommended by experts in PREP evaluation and assessment.

## CHAPTER 2: EXPERIMENT 1

### **Overview**

Presently, there are no published studies available examining smokers' reactions to Ariva® tobacco pieces in a clinical trial or their evaluations of information about using Ariva® as part of a tobacco harm reduction strategy. Information about smokers' perceptions of the product and information about the product are needed for several reasons. Ariva® is presently available for purchase to all adults over the age of 18 and is also packaged with the trade marked slogan, "When you can't smoke." The packaging instructs that Ariva® pieces ought to be used "when you might otherwise have a cigarette but can't". Little is known about what smokers think about using non-combusted tobacco products to deal with smoking restrictions, as the product packaging suggests is the purpose of using Ariva® pieces.

Furthermore, although the packaging also contains both mandatory rotating government warnings for smokeless tobacco, such as, "WARNING: This product may cause mouth cancer" and the popular caution that "There are no safe tobacco products. Quitting or not starting is your best option," it has been argued (Kozlowski & Edwards, 2005) that these warnings do not provide meaningful relative risk information to smokers and that smokers have the right to be informed that some tobacco products, while not safe, pose fewer health risks than smoking. However, concerns have been raised as to about the effects of providing relative risk information and particularly how this information might be used as part of commercial product marketing efforts. Gaining a better understanding of how smokers respond to relative risk information and arguments

in favor of harm reduction through the use of reduced exposure products could help to inform the development of effective health tobacco harm reduction communications to be used by health professionals. It could also be useful as means of anticipating (and acting to counter, if needed) the effects of commercial marketing strategies. An enhanced understanding of how smokers think about or interpret tobacco harm reduction could also be beneficial by providing new opportunities to encourage smokers to change their behavior in positive ways. There is a need to understand not only how smokers conceptualize harm reduction, but an opportunity to employ this strategy as appropriate with smokers who are receptive to the idea.

Communicating harm reduction poses special challenges because the desired change in behavior is two-fold, with one behavior (complete abstinence) being preferred over another (harm reduction). However, both changes are characterized by a degree of difficulty because smoking is an addictive behavior, sustained by the effects of the drug nicotine as well as other reinforcers, such as socialization. Providing information alone about the health risks of a behavior may be sufficient to encourage changing that behavior if the change is relatively easy to make. However, in the case of behaviors that are difficult to change, the use of social marketing may be necessary to encourage a change by “offering positive reinforcement incentives and/or consequences in the environment,” (Rothschild, 2001, p. 19).

In this exploratory study, the main objectives were to examine (1) participants’ evaluations of information advocating the use of Ariva® hard tobacco pieces by smokers, (2) smokers’ evaluations of a sample of Ariva® (3) smokers’ evaluations of Ariva® in

comparison to cigarettes and (4) smokers' intentions to use Ariva® again. This study had two main components, an experimental message trial and a product sample.

The experimental message trial had three aims: (1) identify whether an argument emphasizing consumer benefits rather than reduced health risk was evaluated as more persuasive or personally relevant, (2) examine whether the message frame was related to how favorably smokers' evaluated the product sample, and (3) explore attitudes about risk reduction as opposed to continued smoking or cessation. It was also important to evaluate smokers' comprehension of harm reduction messages to examining whether comparative risk messages, especially those advocating harm reduction, have unanticipated or undesirable effects, such as diminishing motivation to quit smoking or fostering false beliefs that less harmful products are actually safe.

The aims of the product sample were to examine (1) smokers' reactions to and liking of Ariva®, (2) smokers' comparison of Ariva® pieces to cigarettes, and (3) smokers' intentions to use the product again and in what capacity (i.e., in addition to smoking, as a substitute when smoking is restricted or as a cessation tool). The results of the product trial could help to clarify whether Ariva® tobacco pieces are a viable tool for smokers to reduce smoking related morbidity and mortality as a substitute for some or all of their smoking. Finally, the exploratory results of this study may help to clarify whether smokers deem the use of a non-combusted tobacco product as relevant to their smoking behavior. More specifically, many harm reduction behaviors (i.e. condom use, wearing seatbelts, or applying sunscreen) require people to make a modification of a behavior they are already engaged in to reduce their health risks. It is not known however, if smokers consider the use of non-smoked tobacco as a modification of their tobacco use,



or as a behavior that is fundamentally different from smoking. This distinction is important because it is related perceptions of comparative risk, a fundamental concept in efforts to promote harm reduction behavior. For instance, it has been suggested that people may discount or even disbelieve risk comparisons they evaluate as unrelated (Holtgrave, Tinsley, & Kay, 1995 in Maibach & Parrot, eds.).

In this study, the message condition was manipulated. Participants were randomly assigned to read either a “harm reduction” or “consumer benefit” argument. Both arguments advocated that smokers try Ariva® tobacco pieces, but emphasized different reasons for doing so. The “harm reduction” argument provided a detailed explanation of the reduced health risks that could be achieved by using Ariva® pieces instead of smoking. The “consumer benefit” argument frame also informed that Ariva® tobacco pieces are less harmful to health than cigarettes, but focused on other aspects of the product that may be perceived as attractive to consumers, such as being able to use it in places where one can not smoke (convenience), not being identified as a smoker (avoidance of social stigma of smoking), and avoiding nicotine withdrawal symptoms (psychopharmacological). Each participant evaluated the argument he or she read on dimensions of persuasiveness. This was the first study to 1) present persuasive arguments advocating reduced exposure tobacco use for smokers and 2) to experimentally manipulate the content of the argument.

In the product trial, smokers’ sampled a piece of Ariva® in the lab and completed two sets of evaluations. The first evaluation exercise asked participants to rate aspects of Ariva®. In the second evaluation, participants compared Ariva® to cigarettes. Both sets of product evaluations were based on scales developed by Schneider and colleagues

(2004) to examine smokers' preferences for various nicotine replacement systems. In an open ended interview, participants shared their reactions to the product information, sample, and discussed their intentions to use the Ariva® in the future. Participants were offered a package of Ariva® to take as a behavioral measure of their intentions to use Ariva® again.

### **Hypotheses**

#### ***Hypothesis 1: Experimental Message Trial***

**It was hypothesized that participants reading the “consumer benefit” argument about Ariva® would evaluate the argument more favorably than those participants reading the “harm reduction” argument. It was also predicted that participants reading the consumer benefit argument would have more favorable evaluations of the product sample and express greater intentions to use the product again.**

**Rationale:** Presently, no trials have been published to examine the effect of providing smokers with detailed information about using Ariva® as a tobacco harm reduction option, although concerns have been raised about the effects of marketing tobacco products with relative risk information. The general knowledge that smoking is very bad for health, however, is not enough to help many smokers give up this addictive behavior. While it has been recognized that harm reduction must be included in a comprehensive tobacco control program, communicating about relative tobacco product risk has been a controversial topic. This study sought to provide smokers with comparative risk information that emphasized either specific mechanisms of risk reduction or emphasized reasons, in addition to health risk reduction, that smokers might choose a non-smoked tobacco. The messages presented included elements that are likely to be featured in the

marketing of these products as well as factual information about health behavior and choices to determine what elements of harm reduction health messages are most likely to resonate with smokers. Because smokers continue their habit despite the known health risks, it was hypothesized that information about a tobacco product with reduced health risk would be regarded as more persuasive by adding descriptions of additional benefits of using the product and that the more persuasive message would lead to more favorable evaluations of the message and product.

***Hypothesis 2: Product Trial***

**It was hypothesized that smokers would have favorable evaluations of Ariva®, independently and as compared to cigarettes. Further, it was predicted that participants would express interest in using this product again, possibly as a method for tobacco harm reduction or as an alternative to smoking.**

**Rationale:** It has been suggested by early clinical trials as well as practitioners with substantial clinical experience, that many smokers find Ariva® to be an acceptable product, however, there are presently no published trials available to confirm the acceptability of Ariva® to some smokers. The relevance of Ariva's acceptability to smokers is based on the comparative risks of using this tobacco product as opposed to smoking, or that Ariva® conveys far less risk to health than cigarette smoking. Not only do smokers have a right to know about tobacco products with less risk than smoking, they should be encouraged to consider their use if they are unable or unwilling to cease all tobacco use, particularly to deal with the effects of nicotine addiction. Communications with clinicians and researchers (Hatsukami, personal communication, 2005; Rodu, personal communication 2006; Mendoza-Baumgart *et al*, unpublished manuscript) also

suggest that smokers may prefer Ariva® to some medicinal NRTs and other non-combusted tobacco.

### **Design**

Participants were randomly assigned to read either the “harm reduction” or “consumer benefit” argument. The dependent variables were argument evaluation items, product evaluation items, comparative product evaluation items, intentions to use Ariva® again, and acceptance of a take-home sample. In line with the exploratory nature of this study, each participant also completed a thought-listing exercise immediately after reading the experimental message. It was hoped that the thought-listing exercise would 1) encourage participants to think in detail about the argument and 2) provide an opportunity to capture unanticipated reactions to the argument. All participants sampled the product in the lab and provided reactions.

### **Methods**

**Recruitment.** Forty-one participants (21 males, 20 females) were recruited to participate in a one-time laboratory session via announcements posted on the Penn State University Park campus, as well as through newspaper advertisements in the University paper and local paper. Data from 40 of the participants are reported. One participant’s data were not used due to harassing behavior toward the investigator. A decision was made in consultation with the chair and another committee member not to contact this participant for a follow-up interview, and to exclude data from the initial session, although these data have been retained and are available.

Those responding to recruitment materials were required to call the Behavioral Pharmacology Laboratory on Campus and were informed that smokers were being

recruited to participate in a study on campus examining attitudes and beliefs about tobacco products. Callers were informed that the study required about two hours to complete and was being run under the direction of Dr. Lynn Kozlowski in the Department of Biobehavioral Health. Callers were also informed that the research being conducted was independent and academic and not funded by the tobacco industry.

**Eligibility.** Callers gave verbal consent to answer questions to determine their eligibility to participate. In order to be eligible, callers had to be at least 18 years old, a current smoker of 10 or more cigarettes per day and have smoked at least 100 cigarettes in their lifetime. They were required to report not having any sores or cuts in their mouth, and female callers had to report not being pregnant or nursing an infant. Eligible participants were provided with additional details about what they would be asked to do if they agreed to participate in the study, including: give a breath sample, complete a questionnaire about their tobacco use, read a message about a tobacco product, complete a short writing exercise, sample the tobacco product, complete two additional surveys about the message and product, and complete a brief interview with the researcher. They were also instructed that they could not smoke for 1 hour prior to their lab session, informed that the compensation for participation was \$20 and asked if they wanted to schedule an appointment to participate. Those callers who were not eligible were informed that based on their answers to the screening questions, they were not eligible to participate in this study and asked if they wished to be contacted to learn about future studies.

### **Study Procedures**

**Informed Consent.** Upon arrival at the lab, each participant reviewed a detailed informed consent with the investigator. The consent form and study protocol were approved by Penn State's Biomedical Institutional Review Board (IRB #22611). The consent form provided details of all the procedures and tasks that would take place during the study session, the potential risks and benefits of participating, and compensation. Participants had the opportunity to ask questions during the consent process and throughout the study period. Participants kept one signed copy of the consent and another copy was retained by the investigator.

**Expired Carbon Monoxide (CO) Breath Sample.** After completing the consent process, participants provided an expired air carbon monoxide breath sample by blowing into a disposable cardboard mouthpiece attached to the Vitalograph CO Breath monitor (Lexington, KY; serial number BC24338). The investigator provided verbal instructions on how to properly give a breath sample by taking a deep breath and holding it in for 15 seconds then making one long continuous exhale into the mouth piece until there was no air left in the lungs. The CO measure was recorded and participants were then asked to complete a questionnaire about their tobacco use. After completing the first questionnaire, participants returned it to the investigator and received instructions on the next exercise.

**Tobacco Product Argument.** Participants were asked to read a prepared argument about why smokers should consider using the Ariva® tobacco lozenge. Participants were randomized to read either a "harm reduction" message about the Ariva® tobacco lozenge, which emphasized the reduced health risks of the product compared to cigarettes or a "consumer benefit message" that described the reduced health

risks of the product compared to cigarettes, but also emphasized other benefits compared to smoking, such as ease of use, not smelling like smoke, and being able to use the product discreetly in many setting where smoking wouldn't be permitted or desirable.

The messages were approximately equivalent in length and readability scores.

Participants were instructed to read the message carefully and to scrutinize it while they were reading because they would be asked to complete a brief writing exercise describing their thoughts about the message afterwards. Participants were told to take as long as they needed to read the message and inform the investigator when they were finished.

**Thought Listing Exercise.** After the reading exercise, participants returned the written message to the investigator and were instructed on how to perform a thought-listing exercise. They were given a set of sheets with instructions and blank boxes in which to list their thoughts. The investigator reviewed the instructions with each participant. Participants were asked to write down all the thoughts they had while reading the message, listing one thought per box. It was stressed that they may have had thoughts that were favorable, unfavorable, or irrelevant to the message, or any combination of thoughts, but that the important thing for this exercise was to write as many thoughts as they could remember. It was stressed that they should not censor themselves, worry about spelling or grammar, but simply write as many thoughts as they could remember and to please be "completely honest". They were also asked to try to record their thoughts as concisely as possible, a word or phrase being sufficient because the exercise was timed for 2 minutes. Participants were timed and after two minutes were instructed that the time was up and to finish writing. Next, they were asked to read each thought they had listed and to give it a score reflecting how favorable or unfavorable of a

thought it toward the message they had just read using a 1 to 7 Likert-type scale, where 1 was “completely unfavorable” and 7 was “completely favorable”. When they were finished with this rating task, participants returned the entire exercise to the investigator and received instructions for the next exercise.

**Argument Evaluation.** After completing the thought listing exercise, participants were given a questionnaire to evaluate the quality of the argument that they read about the tobacco product. This exercise consisted of 15 statements describing reactions to the information in the argument participants read. Again, they were asked to indicate the extent of their agreement with each item using a 7-point scale where 1 meant “Very definitely do not agree” up to 7 which meant “very definitely agree.” Items on the questionnaire were designed to evaluate aspects of the product message such as novelty, clarity, personal relevance, persuasiveness, as well as check for message comprehension. When the questionnaire was complete, participants returned it to the investigator and received instructions for the product sample.

**Product (Ariva®) Sample.** Next, participants were given a piece of Ariva® to sample, which they removed from a sealed packet. They were instructed that they should place the piece of Ariva® in the upper portion of their mouth, between the upper jaw bone and cheek and to let the product dissolve there and that this placement was recommended because it would stimulate the least amount of salivation. They were informed that they should not feel the need to spit, nor should they suck on, chew, or swallow the sample. Participants were informed that they could remove the sample at any time, but asked to leave it in their mouths for as long as it was comfortable to do so. Participants were asked to alert the investigator if they removed or discarded the sample.



After the sample began, participants were informed that they would take a 10 minute break, during which time they could sit quietly or read a newspaper. The investigator timed the break at ten minutes and noted the time in minutes of any discarded samples. After 10 minutes, participants received instructions on the next exercise.

**Product Evaluation.** At this point, participants received a questionnaire asking them to share reactions to the product. Some items on this questionnaire were adapted from rating scales developed by Schneider and colleagues (2001; 2004) in comparative tests of nicotine replacement therapies. The first part of the exercise listed 14 items describing the product on aspects such as overall quality, the amount of relief of nicotine withdrawal, relief of urges to smoke, ease of use, amount of nicotine, side effects, comfort using the product in public, and intentions to use the product again. Participants were to rate their agreement with each item using a 7-point scale (1 = Very definitely not, 2 = Definitely Not, 3 = Probably not, 4 = Possibly, 5 = Probably, 6 = Definitely, 7 = Very Definitely). A final item asked participants to rate their level of satisfaction with the product with a score from 1 to 10 where 1 meant the least amount of satisfaction possible and 10 represented the most satisfaction possible. Participants were specifically instructed to note the change in scale from 1-7 to 1-10 on this item.

The second part of the product evaluation asked participants to evaluate Ariva® *compared to cigarettes*. There were nine items that compared Ariva® to cigarettes on aspects such as overall comparison, ease of use, taste, harm to health, amount of nicotine, addictiveness, comfort using in public, and side effects. Participants were instructed to rate their agreement with each statement using the 7-point scale described above. The final item on this questionnaire asked participants to rate their satisfaction with the

product compared to cigarettes with a score of 1 to 10 where 1 meant the least satisfaction possible and 10 meant the most satisfaction possible. Again, in this part of the exercise, participants were reminded that these items were asking them to compare the Ariva® to cigarettes. They were also reminded of the change in scale on the very last item. Participants returned the form to the investigator when they were finished.

**Interview.** At this point, participants completed a brief semi-structured open-ended interview with the researcher. In the interview, participants were asked to discuss their first reactions to the product sample; they were also queried about how well the sample of the product matched their expectations of it from reading the message, what they liked and disliked about it, how likely they would be to use the product again, how likely they would be to use it as a substitute for smoking, and how likely they would be to use it if they were going to try to quit smoking. An assumption in the development of this study was that all participants would be naïve of Ariva® and that they would have no knowledge of the product or experience using it. It was noted by one committee member that there were no direct questions included in the survey to verify this; the open ended interview was used as an opportunity to verify this assumption. Participants were also asked if they would be interested in taking a sample pack of Ariva® with them, as a behavioral measure of intention to use the product again. Those who indicated interest were also asked if they agreed to be contacted with a brief follow-up survey in 3 days. Participants who requested a sample pack to take home were contacted for follow-up by the methods they noted they would prefer, either phone or email. A total of 33 (83%) participants requested a sample package to take with them and 21 of these (63%) completed a follow-up interview.

**Follow-up Interview.** Approximately 3 days after their initial lab session, each participant who accepted a take home pack of Ariva® was contacted by either email or phone (preference indicated at acceptance) with a brief follow-up survey. Those who did not respond or were unreachable were contacted at least 3 times, except for one participant who provided an unusable email address and did not provide a phone number. Of the 33 participants who accepted a take home product sample, 63% (n = 21, 8 male, 13 female) completed the follow-up interview. The follow-up interview asked about the number of pieces of Ariva® used since the lab session, provided an opportunity to discuss general reactions and problems, as well as asking the participants to complete the product evaluation exercise again. Participants were also asked about their intentions and ability to quit smoking in the next six months and their beliefs about whether they would still be smoking in 5 years.

## **Results**

**Statistical Analyses.** Due to the exploratory nature of the first study, power analyses were not conducted to determine sample sizes required to detect differences in mean outcome evaluations of the two message frames used to present arguments for Ariva® use by smokers or the product evaluations. The self-reported baseline characteristics of participants in each group were compared. Means  $\pm$  the standard error of the mean (SEM) are reported. Discrete variables were analyzed using the chi-square test of Fischer's exact test. Continuous variables were analyzed using a two-sample t test, or the Wilcoxon rank sum test where assumptions of normality were violated. Tests were two-tailed and a significance level of 0.05 alpha or less was used.

**Descriptive Statistics.** The average age of participants was 37.05 years ( $\pm 2.86$ ; range 19-76) and half ( $n = 20$ ) were male. They reported smoking on average 16.3 cigarettes per day ( $\pm 1.31$ ; range 9-50). Participants had a mean heaviness of smoking index (HSI) score of 2.37 ( $\pm 0.22$ ; range 0-5) and had been smoking, on average for 19.55 years ( $\pm 2.99$ ; range 1-58). The average CO score was 19.95 parts per million (ppm) ( $\pm 2.28$ , range 3-65).

There were an equal number of participants ( $n = 20$ ) randomly assigned to each message condition (“harm reduction” or “consumer benefit”). Participants receiving the harm reduction message were significantly older than those receiving the consumer benefit message [mean age =  $44 \pm 4.4$  years vs.  $30 \pm 3.0$  years;  $t_{(38)} = 2.63$ ,  $p = .01$ ] and reported smoking for a longer time [harm reduction mean years smoking =  $27 \pm 4.45$  vs. consumer benefit mean years smoking =  $12.1 \pm 3.21$ ,  $t_{(38)} = 2.71$ ,  $p = .01$ ]. In addition, of those participants who had ever made a serious attempt to quit smoking ( $n = 28$ ), participants in the harm reduction group reported having made more attempts to do so in the last 5 years than those in consumer benefit group, on average [ $4.8 \pm 1.17$  mean quit attempts vs.  $2.1 \pm .55$  mean quit attempts,  $t_{(26)} = 2.15$ ,  $p < .05$ ]. However, there were no other statistically significant differences between the groups for baseline characteristics including, sex, number of cigarettes smoked per day, HSI score, recorded CO level, or desire to quit smoking in the next 6 months.

**Argument Evaluation.** Two exercises were used to evaluate participants’ reactions to the messages about Ariva®. One was a qualitative thought listing exercise and the other was a rating exercise. Preliminary results of the thought listing exercise will be discussed briefly. The rating exercise measured persuasiveness of the argument,

as well as individual qualities of the messages that could contribute to persuasiveness, including: novelty of the information, how easy the message was to understand, perceived personal relevance, and perceived relevance to smokers in general. This exercise also included comprehension test questions about the content of the messages. An anchored 7-point scale was used, based on an adaptation of scales used by Schneider and colleagues (2001) in comparative evaluations of nicotine replacement therapies (NRTs).

**Thought Listing Exercise.** There was not a statistically significant difference in the average number of thoughts listed by participants in the harm reduction and consumer benefit message groups (mean number of thoughts listed =  $4.0 \pm .35$  vs.  $4.8 \pm .45$ ;  $t_{(38)} = -1.33$ ,  $p > .05$ ).

**Argument Evaluation Items.** There was one significant group difference on agreement with the statement “*I already knew most of the information in the argument.*” Those receiving the consumer benefit message had lower mean agreement scores on the 1-7 point scale than those receiving the harm reduction message (consumer benefit mean score =  $2.5 \pm .32$  vs. harm reduction mean score  $3.8 \pm .42$ ,  $t_{(38)} = 2.43$   $p < .05$ ).

Overall, participants in both groups expressed agreement with items that suggested the information in the argument was novel, easy to understand, and relevant to smokers in general. The highest mean agreement scores on the 7 point scale (means for both groups  $\geq 5.0$ ) were given for the following items: the information in the argument was mostly new to me (mean score  $5.5 \pm .27$ ), the information in the argument was easy to understand (mean score  $6.4 \pm .11$ ), the information in the argument was important for smokers to know (mean score  $5.5 \pm .23$ ), the information in the argument made sense

(mean score  $5.7 \pm .18$ ), the information in the argument was easy to remember (mean score  $5.9 \pm .14$ ), the information in the argument was believable (mean score  $5.6 \pm .19$ ). The mean scores for both groups were lower (means ranged from 4.4 – 5.0) on items that reflected personal relevance of the information, such as the information in the argument was important to me, the information in the argument was convincing, I will share the information with other smokers, and information in the argument was helpful to me.

**Comprehension Test Items.** Overall, participants demonstrated good comprehension of points in the argument regarding the addictiveness of nicotine and the addictive potential of Ariva®, the comparative health harm from smoking and use of Ariva®, the dominant health harm from smoking being due to tobacco smoke, and whether nicotine was described as the main cancer causing compound in tobacco. They generally expressed disagreement with the statements “The argument informed that Ariva® tobacco pieces are not addictive” (mean score =  $2.5 \pm .21$ ) and “the argument informed that nicotine is the main cancer causing compound in tobacco” (mean score =  $2.4 \pm .26$ ), and agreement with the statements, “the argument informed that Ariva® tobacco pieces are much less harmful to health than smoking cigarettes” (mean score  $5.7 \pm .23$ ) and “the argument informed that most of the health harm from smoking is due to tobacco smoke” (mean score =  $5.7 \pm .23$ ).

**Argument Salience Scale.** A scale score was created to provide a measure of overall argument salience to participants regardless of which argument they read. The scale score may be a useful measure of how personally relevant or persuasive the concept of harm reduction or product substitution was to individual smokers because both arguments contained harm reduction information and information about the danger of

smoking. Messages differed in how much detail was used to describe the source of harm reduction and possible benefits to using the product, but did both revolve around the concept of substitution of a less harmful product for cigarettes. The scale was created using the following 7 items from the argument evaluation: information in the argument was important to me, information in the argument is important for smokers to know, information in the argument is helpful to me, information in the argument made sense, information in the argument was convincing, information in the argument is believable, and I will share information in the argument with other smokers I know. Each item was scored by participants on the 7 point scale described above. The overall scale score is an average of the individual scores on each of the seven items listed (scores ranged from 1.9 to 7). Higher scores reflect higher salience of the message. The items on the scale demonstrate good reliability (Cronbach's  $\alpha = .91$ )

There were no statistically significant differences in the overall argument salience score by message group, sex, age, HSI, CO reading, quitting intentions or desire to quit. However, participants with a higher score on argument salience ( $\geq 5$ ,  $n = 24$ ) had statistically significantly more favorable product ratings. See Table 1. There was also a trend toward significantly fewer cigarettes smoked per day among those with high ( $\geq 5$ ) versus low scores on the argument salience scale (mean CPD =  $15 \pm 1.28$  vs.  $20.1 \pm 2.6$ ;  $t_{(38)} = -1.94$ ,  $p = .06$ ). There were no statistically significant differences on items testing comprehension between those with a high salience score and those with lower scores.

**Product Evaluation.** The product evaluation also consisted of two exercises, including a rating of the product itself and a comparison of qualities of this product

compared to cigarettes. These items were adapted from scale items used by Schneider and colleagues in rating and ranking evaluations of NRT products.

The rating items evaluate the overall quality of the product, relief of nicotine withdrawal and urges to smoke, amount of nicotine, ease of use, addictive potential, side effects, comfort using the product in public, likelihood of using the product again, likelihood of using the product again, intentions to tell other smokers about the product, and overall satisfaction with the product. The rating scale was a 7-point anchored scale for each item except the overall satisfaction scale, which was a 10 point scale, with anchors at 1 (least possible satisfaction) and 10 (most satisfaction possible) only.

**Differences in Product Evaluations by Message Condition.** There was one statistically significant difference in the product evaluation items by message group. Those in the consumer benefit group had higher agreement with the statement, “I did not need cigarettes while using the product” than did those reading the harm reduction message (mean score =  $5.4 \pm .32$  vs. mean score =  $4.2 \pm .34$ ,  $t_{(38)} = -2.45$ ,  $p < .05$ ). Scores were not statistically significantly different however for any other product evaluation items, including those measuring relief of withdrawal or urges to smoke.

**Favorable Product Evaluation Items.** Overall, participants in both groups expressed agreement (mean scores  $\geq 4$  on a 7 point scale) with favorable descriptions and evaluations of the product, including product is an excellent product overall (mean score =  $4.6 \pm .2$ ), the product provided relief of nicotine withdrawal (mean score =  $4.5 \pm .17$ ), product provided relief of urges to smoke (mean score =  $4.2 \pm .2$ ), I did not need to use cigarettes while using the product (mean score =  $4.8 \pm .25$ ), the product was easy to use (mean score =  $6.2 \pm .18$ ), the product provides enough nicotine (mean score =  $4.7 \pm .18$ ),



I would use the product again (mean score =  $4.7 \pm .25$ ), I would be comfortable using the product for a long period of time (mean score =  $4.2 \pm .25$ ), I would tell friends who smoke to use the product (mean score =  $4.7 \pm .28$ ). The mean overall satisfaction score on a scale of 1 to 10 was  $6 \pm .34$ .

**Unfavorable Product Evaluation Items.** Participants also expressed disagreement (mean score < 4) with all but one of the unfavorable descriptions and evaluations of the product, including “the product provides too much nicotine” (mean score =  $3.0 \pm .21$ ), “I believe I might become dependent on the product if I used it regularly” (mean score =  $3.6 \pm .25$ ), “the product has bothersome side effects” (mean score =  $2.9 \pm .25$ ), and “I would be uncomfortable using the product in public,” (mean score =  $2.1 \pm .25$ ). Participants expressed agreement, overall, with the statement “I believe I would still crave cigarettes if I used the product regularly,” (mean score =  $4.4 \pm .16$ ), which could be interpreted as an unfavorable evaluation of the product for tobacco harm reduction.

**Evaluations of Ariva® Compared to Cigarettes.** There were no statistically significant differences in how the participants evaluated Ariva® in comparison to cigarettes by the message types. Participants were asked to rate their agreement with a series of statements comparing Ariva® to cigarettes. The first nine items asked level of agreement, on a 7-point anchored scale. In the first 5 items, a higher score reflected greater agreement with a favorable comparison of Ariva® to cigarettes and each item had an overall mean of 4 or higher: “Compared to cigarettes, this is an excellent product overall,” (mean score =  $4.4 \pm .27$ ), “compared to cigarettes the product is easy to use,” (mean score =  $5.7 \pm .20$ ), “Compared to cigarettes, I like how the product tasted,” (mean

score =  $4.9 \pm .26$ ), “Compared to cigarettes, the product is less harmful to my health,” (mean score =  $5.5 \pm .18$ ), and “Compared to cigarettes the product provides enough nicotine,” (mean score =  $4.7 \pm .17$ ). In the next 4 items, a lower score indicated more disagreement with unfavorable comparisons of Ariva® to cigarettes: “Compared to cigarettes, the product provides too much nicotine,” (mean score =  $3.0 \pm .22$ ), “I believe the product is addictive as cigarettes,” (mean score =  $3.7 \pm .15$ ), “Compared to cigarettes, I would be uncomfortable using the product in public,” (mean score =  $2.2 \pm .25$ ), “Compared to cigarettes, the product had bothersome side effects,” (mean score =  $2.6 \pm .2$ ). Finally, the last item asked for an overall rating of the satisfaction provided by this product compared to cigarettes on a 10-point scale (mean score =  $5.4 \pm .37$ ).

**Overall Product Interest Score.** A scale score was created to provide a measure of overall interest in Ariva® among participants, using 4 items from the survey instruments. The items included in the scale score were each originally answered with a 7-point anchored scale. The items included were: the product is an excellent product, I would use the product again, compared to cigarettes this is an excellent product overall, how likely is it that you would try the product again. The items were analyzed with the reliability procedure in SPSS and demonstrated good reliability (Cronbach’s alpha = + .92). The raw score from each of the following items were summed and divided by 4 to generate an average overall interest score. Scores on the scale ranged from 1.3 to 7, where higher scores indicate higher interest in using the product. The mean product interest score for the entire sample ( $n = 40$ ) was  $4.6 \pm .23$ . There were no statistically significant differences in interest scores by sex of the participants, however interest scores were significantly higher among participants 25 years or older ( $n = 21$ ; mean

interest scale score =  $5.2 \pm .26$  vs. mean interest scale score =  $4.0 \pm .34$ ,  $t_{(38)} = 2.7$ ,  $p = 0.01$ ).

**Intentions for Future Use and General Reactions.** A semi-structured interview was conducted after the product sample and evaluation to explore the participants' reactions to the product, the information presented about the product, as well as any intentions to use the product again. There were 3 questions that asked participants to rate how likely they would be (on a scale of 1-7) to use Ariva® in three scenarios 1) ever use again (mean score =  $4.9 \pm .28$ ), 2) use as a substitute when smoking wasn't permitted (mean score =  $4.6 \pm .34$ ), and 3) use to try to quit smoking (mean score =  $5.0 \pm .32$ ). In general, most participants reported that they would consider trying Ariva® again (i.e. reported strength of likelihood  $\geq 5$  on rating scale): 68% (n=27) would try Ariva® again, 58% (n=23) would use it as a substitute when they could not smoke, and 75% (n=30) would use it if they were going to try to quit smoking.

Participants were also offered a trial pack of Ariva® to take home with them and asked if they agreed to be contacted in approximately 3 days to complete a brief follow-up survey (by phone or email) about their use of the product. Most participants accepted the take home sample (n = 33, 82.5%). Of the seven participants who did not take a product sample, 2 were in the harm reduction group and 5 were in the consumer benefit group, 4 were male and 3 female, the mean age of those refusing was 31.3 years ( $\pm 5.98$ ) compared to 38.3 years ( $\pm 3.23$ ) among those accepting. As might be expected, those refusing a take home sample had significantly lower scores than those accepting on the argument salience scale (mean argument salience score of those refusing sample =  $3.7 \pm .33$  vs. mean argument salience score of those accepting take home sample =  $5.4 \pm .18$ ,

$t_{(38)} = 4.04$ ,  $p = .000$ ) and product interest scale (mean product interest score of those refusing take home sample =  $2.6 \pm .45$  vs. mean product interest score of those accepting take home sample =  $5.1 \pm .18$ ,  $t_{(38)} = 5.47$ ,  $p = 0.000$ ).

**Follow-up Interview.** A total of 33 (83%) participants accepted a take home pack and of those 21 (63%) completed a follow-up interview either by phone or email. The mean number of pieces used since the lab session was  $6.0 \pm 2.33$  (range 0 – 50, IQR = 4.5) and the median number of pieces used was 3.0. Four respondents had not tried any additional Ariva® since the session, compared to one who reported using 50 pieces. The product evaluations remained consistent for individual aspects of the product. After the take home sample period, mean evaluation scores improved significantly for “overall, an excellent product” (mean score in lab =  $5.0 \pm .23$  vs. mean score at follow-up =  $5.6 \pm .26$ ,  $t_{(18)} = -2.27$ ,  $p < .05$ ) and “I would be comfortable using the product for a long period of time,” (mean score in lab =  $4.5 \pm .38$  vs. mean score at follow-up =  $5.3 \pm .32$ ,  $t_{(18)} = -2.42$ ,  $p < .05$ ).

### **Confirmation of Hypotheses**

#### **Hypothesis 1: Experimental Message Trial**

The hypothesis the participants reading the consumer benefit message would evaluate the product information and sample more favorably than those participants reading the harm reduction message was **not confirmed**.

#### **Hypothesis 2: Product Trial**

The hypothesis that smokers would have favorable evaluations of Ariva®, independently and as compared to cigarettes was **confirmed**. The hypothesis that participants would express interest in using Ariva® again, possibly as a method for

tobacco harm reduction or as an alternative to smoking was **confirmed**. Participants also expressed interest in using Ariva® as a smoking cessation aid.

### **Summary and Conclusions: Experiment 1**

This experiment investigated the effects of providing smokers with two arguments advocating the use of Ariva® tobacco pieces, either primarily as a means to reduce the risks they face from tobacco use, or primarily as a method of using tobacco that may be more convenient than smoking. Participants evaluated the argument they read on dimensions of persuasiveness, including personal relevance, novelty, and clarity of the information. In addition, smokers were given a sample of the product in the lab and were asked to share their reactions to the sample. Participants were also offered a take home sample as a behavioral measure of intentions to use the product again. To our knowledge, this is the first experimental trial of social marketing style messages advocating tobacco harm reduction to smokers through the use of a reduced exposure non-smoked tobacco. The effects of marketing of reduced toxin exposure tobacco products are of particular concern within the tobacco control and public health communities. Early endorsement of the risk reducing potential of light cigarettes resulted in widespread and erroneous belief that light and low tar cigarettes to confer actual reductions in health risks to smokers and likely sustained smoking by diminishing smokers' sense of urgency to quit and actual quit attempts.

Over 80% of the participants in the first study accepted a take home sample of Ariva®, which is one behavioral measure of interest in using the product in the future. Additionally, the majority of participants indicated a willingness to use Ariva® again, with the most participants (75%, n=30) indicating interest in using Ariva® if they were

going to quit smoking. These findings are in line with clinical preference trials (Mendoza-Baumgart, et. al, unpublished manuscript) indicating that Ariva® has good acceptability among smokers who are abstaining. The interest in using this non-smoked, reduced toxin tobacco for smoking reduction or cessation was also substantially greater than reported in earlier survey research (Jensen, Babb, Hatsukami, & Avery, 2004).

Additionally, there are no published studies available at this time describing how smokers compare the merits or drawbacks of a non-smoked tobacco product to cigarettes. The results of the first study indicate that smokers generally gave favorable comparative ratings to Ariva®, particularly on dimensions such as ease of use, taste, and comfort using in public. Smokers also demonstrated understanding that Ariva® is less harmful than smoking.

The findings that smokers had favorable responses to the information presented in both message frames and the product are encouraging in the sense that 1) smokers may be amenable to making changes in their tobacco use that could reduce the health related harm they face from smoking, even if they are not prepared to immediately make a quit smoking attempt and 2) Ariva® may be a viable tool to help some smokers change their smoking behaviors. It is important to note that not all participants found the information or the product relevant to them. This finding may have implications that address some of the concerns about the effects of marketing materials presenting relative tobacco risk information and reduced toxin exposure tobaccos, at least with regard to this low TSNA, non-smoked tobacco product. Another finding of interest was the difference between message groups regarding the degree to which participants felt they already knew the information in the argument. Participants in the harm reduction group had significantly

higher agreement scores, suggesting that participants reading the consumer benefit argument evaluated the information as being somewhat more novel than those reading the harm reduction message. This evaluation may also reflect an interpretational difference in the framing of the messages, with the harm reduction message being read as primarily concerning the health risks of smoking and the consumer benefit message being read as relating primarily to the use of a non-smoked product.

The finding that not all participants are interested in the product or harm reduction with a non-smoked tobacco also highlights the complexities involved in motivating health behavior change. More specifically, even after reading messages that advocated strongly that smokers consider using Ariva® or a product like it to possibly reduce the health risks they face from smoking, not all participants were interested in doing so. Also, scores on argument evaluation items asking participants if they agreed that the information they read informed that using Ariva® was much less harmful to health than smoking did not exhibit 100% agreement. This finding seems to be in line with research demonstrating that many smokers feel concerned about the effects of using even FDA-approved NRT products, and are likely to be wary of tobacco products other than cigarettes (Bansal *et al*, 2004). In addition, most participants who agreed to provide follow-up data, used relatively little Ariva® outside of the lab, with the median number of pieces used being 3. Longer and more detailed follow-up data are needed to examine Ariva use within the context of smoking.

The finding that participants in this study expressed greater overall intentions to use Ariva® if they were going to try to quit smoking as opposed to adding this product to their tobacco use or using it when they cannot smoke was also noteworthy, for two

reasons in particular. First, Ariva® is marketed as a product to be used when smokers cannot smoke; however, this marketing effort may neglect the desires of smokers to quit smoking. Second, as a potential source of nicotine replacement for smokers making a quit attempt, this product has substantially lower cost than medicinal nicotine. Other research has demonstrated that the exposure to toxicants is markedly reduced among smokers who use Ariva® while abstaining and that nicotine exposure is similar to that seen in users of FDA approved medicinal NRTs (Mendoza- Baumgart, unpublished manuscript).

There were also limitations to this pilot study. First, the arguments presented to smokers may not have been different enough to capture differences in the impact of different marketing strategies. In addition, the smokers in this study were diverse in age and dependence on cigarettes. They may also have been diverse in the amount of smoking restrictions they face, but this possibility was not systematically addressed and deserves further attention. Another limitation of the first study was the description of the follow-up survey as optional which may have discouraged participants from completing the follow-up survey or led those participants who had not used any additional product to believe their responses weren't needed. Additional study is needed to explore how smokers use Ariva® in a natural setting and whether this product is useful to them to reduce smoking or as a cessation tool.

The results of the first study suggested additional experience with the product outside of the lab may have increased how favorably the product was perceived in terms of likeability and utility, but modest follow-up information limits the ability to make firm conclusions about the effect of additional experience on smokers' perceptions of Ariva®,



as well as how and when this product was used in relation to smoking. The second study was designed to 1) replicate smokers' interest in using Ariva® after evaluating marketing-type information about and a lab sample of the product 2) to provide more detailed follow-up data describing all participants' use of Ariva® and their smoking patterns outside of the lab, and 3) provide an experimental manipulation of the effect of experience with this novel product on participants' subjective and behavioral responses to it.

In the second study, an experimental manipulation of the level of participants' experience with Ariva® was conducted. Participants were assigned at random to either an "additional experience" or control condition. Those in the "additional experience" condition were instructed to replace at least 2 cigarettes each day with a piece of Ariva® for 5 days after the first lab session. Participants in the control condition were instructed to smoke as usual over the next five days and were not offered Ariva® or instructed to use any over the first 5 day follow-up period. After the manipulation, all participants returned to the lab for an additional trial of Ariva® and received 2 packs of the product to use over the next 7 days as they desired. Use of Ariva® was not required during this period by participants in either condition. It was hypothesized that the participants with more experience with Ariva® would 1) have more favorable evaluations of the product at the first follow-up period than those in the "lab only experience" group and 2) that those in the "additional experience group would use more of the product during the second follow- up period.

In order to more carefully explore the utility of Ariva® to smokers as a harm reduction product, participants in the second study were also instructed to record their

Ariva® use and smoking in daily diaries. The diaries provided more detailed data on use, including the time, amount, frequency, and duration of Ariva® use, the temporal relationship of Ariva® use to smoking, and descriptions of the context of Ariva® use. A second, longer follow-up period provided an opportunity to collect information on natural use of the product and smoking patterns without any additional use requirements for the research program, as had been advocated by scientists studying reduced toxin exposure tobacco products (Hatsukami, 2006; Hatsukami, Giovino, Eissenberg, Clark, Lawrence, & Leischow, 2005).

Table 1: Product Evaluation Scores by High or Low Argument Salience

| Evaluation Item                                | Argument<br>Salience |                 | t (df)        |
|--|----------------------|-----------------|---------------|
|  | Low vs. High         |                 |               |
|  | Score Group          | Mean Score      |               |
|  | N                    | ( <u>±</u> SEM) |               |
| Excellent product<br>overall                   | 18                   | 3.8 (0.31)      | -3.76** (38)  |
|  | 22                   | 5.1 (0.19)      |               |
| Provided relief nicotine<br>withdrawal         | 18                   | 4.0 (0.23)      | -3.04** (38)  |
|  | 22                   | 4.9 (0.22)      |               |
| Did not need cigarettes<br>while using product | 18                   | 4.2 (0.38)      | -2.33* (38)   |
|  | 22                   | 5.3 (0.30)      |               |
| I might become<br>dependent                    | 18                   | 2.8 (0.34)      | -3.29** (38)  |
|  | 22                   | 4.2 (0.27)      |               |
| I would still crave<br>cigarettes              | 18                   | 4.9 (0.25)      | 3.19**(38)    |
|  | 22                   | 4.0 (0.17)      |               |
| I would use product<br>again                   | 18                   | 3.6 (0.29)      | -5.65*** (38) |
|  | 22                   | 5.7 (0.24)      |               |
| Be comfortable using for<br>a long time        | 18                   | 3.6 (0.32)      | -2.34* (38)   |
|  | 22                   | 4.7 (0.35)      |               |
| I would tell other<br>smokers to use           | 18                   | 3.4 (0.39)      | -5.82*** (38) |
|  | 22                   | 5.8 (0.20)      |               |
| Overall Satisfaction<br>(1-10)                 | 17                   | 4.7 (0.53)      | -3.77** (37)  |
|  | 22                   | 7.0 (0.36)      |               |

\*  $p \leq .05$ ; \*\* =  $p \leq .01$ ; \*\*\* =  $p = .000$

## CHAPTER 3: EXPERIMENT 2

### Overview

Cigarette smoking remains the leading cause of preventable morbidity and mortality in the developed world and increasingly in developing nations, as well (ACS, 2006). While tobacco prevention and cessation efforts remain the foremost strategies for reducing the burden of morbidity and mortality caused by tobacco use, additional strategies are needed to reduce the suffering caused by tobacco related death and disability to the greatest extent possible (Stratton *et al*, 2001). Efforts that support prevention and cessation include individual interventions, population level interventions, policy formation, and regulation efforts. Support for the role of tobacco harm reduction strategies to further reduce tobacco harm in those unwilling or unable to abstain from tobacco has been recognized by the Institutes of Medicine (IOM) in the United States (Stratton *et al*, 2001) and the government of Canada (Health Canada, 2005).

Furthermore, several public health researchers and scientists propose that reductions in risk could be expected were smokers to switch from more harmful cigarettes to less harmful non-smoked products (Levy *et. al*, 2004; Levy *et. al*, 2006) and that smokers' and the public have the right to accurate information about the relative health risks of types of tobacco use (Kozlowski, 2002; Kozlowski, O'Connor, & Quinio Edwards, 2003; Kozlowski & O'Connor, 2003). In addition, non-smoked tobacco products with very low levels of tobacco specific nitrosamines (TSNAs), a groups of toxic carcinogens in tobacco and tobacco smoke, have been proposed as the most promising tobacco products to produce the largest reduction in individual exposure to tobacco toxicants (Levy *et. al*, 2004; Levy *et. al*, 2006; Stepanov, Jensen, Hatsukami, &

Hecht, 2006; Mendoza-Baumgart, unpublished manuscript). Another potential benefit of non-smoked tobaccos in harm reduction efforts is the fact that their use produces no toxic environmental tobacco smoke (ETS) recently identified by the U.S. surgeon general as an important cause of morbidity and mortality in non-smokers (USDHHS, 2006).

The rationale for tobacco harm reduction as a viable method for reducing the harms caused by tobacco use is two-fold. First, despite the long term availability of information describing the risks of tobacco use, particularly cigarette smoking, the addictive nature of tobacco use makes it very difficult for most tobacco users to give up tobacco. Additionally, the reinforcing properties of the drug nicotine and behavioral components of tobacco use may also diminish the desire and ability of tobacco users to stop (USDHHS, 1988). Reduced exposure tobacco products may still provide some of the rewarding properties smokers experience from cigarettes because they contain nicotine. Therefore, they may satisfy some or all of the smokers' addiction to nicotine and tobacco, however, their use may confer less exposure to the toxicants in cigarettes (Mendoza- Baumgart, unpublished manuscript, Stepanov, et al., 2005). Second, nicotine replacement therapies (NRTs) have been used successfully to help tobacco users cease tobacco use by easing the withdrawal symptoms they experience when abstaining from use of nicotine containing tobacco products, while also diminishing the rewarding properties of tobacco use and eventually enabling the smoker or tobacco user to wean him or herself from all tobacco and nicotine (Silagy, Lancaster, Stead, Mant, & Fowler, 2004). Therefore, it is possible that non-smoked reduced exposure tobacco products could be used to reduce or eliminate smoking as effectively as or more so than nicotine replacement therapies.

Evidence is emerging to suggest that abstaining smokers find Ariva® to be preferable to the Commit lozenge, a medicinal nicotine replacement lozenge (Mendoza-Baumgart, unpublished manuscript, Hatsukami, personal communication, December 2006). This is important because although NRTs have been demonstrated to help smokers quit, underuse of these products has been cited (Bansal, Cummings, Hyland, & Giovino, 2004) as a major limitation to achieving the greatest health benefits possible. There are many reasons for underuse, including smokers' dislike of the products, product cost, a lack of or misunderstanding of how and why these products help smokers quit, as well as a preference among many smokers to quit "cold turkey" (Bansal, *et al*, 2004).

A product such as Ariva® may have advantages over NRTs, such as palatability and lower cost (Hatsukami *et al*, 2005; Mendoza-Baumgart *et al*, unpublished manuscript; Stepanov *et al*, 2005). It is also possible that smokers who are not ready to make a quit attempt would consider substituting some cigarettes with non-smoked tobacco products. For example, several studies of smoking reduction have demonstrated that smokers offered a substitute source of nicotine are able to reduce their smoking and that smoking reduction is associated with future cessation (Fagerstrom, Tejding, Westin, & Lunell, 1997; Batra, Kllinger, Landfeldt, Friederich, Westin, & Danielsson, 2005). If NRTs can be used to reduce smoking, it is possible that Ariva® and other non-smoked products could also serve this purpose.

Additional experience with a non-smoked tobacco product may serve to familiarize smokers with how to use it, influence expectancies, decrease fear of an unfamiliar product, and build smokers' confidence in their ability to use the product and to use it in a manner that supports efforts to reduce smoking. As such, experience with

the products may play an important role in smokers' subjective evaluations of them and also their use patterns. Comparisons of NRTs by smokers indicates that although there does not appear to be one particular therapy that is more effective than others, smokers do exhibit personal preferences for different products and a preference of a product is related to more use of that product (Schneider, *et al*, 2001; Schneider *et al*, 2003; Fagerstrom, Tejding, Westin, & Lunell, 1997; Batra, Killinger, Landfeldt, Friederich, Westin, & Danielsson, 2005).

### **Hypotheses**

#### ***Hypothesis 1: Effect of level of experience on evaluations of Ariva®***

**It was hypothesized that after a guided sample in the lab, participants instructed to replace at least 2 cigarettes each day for 5 days (additional experience group) would have more favorable product evaluations following a second trial of Ariva® than those participants without any additional experience (control group). It was also expected that those participants who had the most experience with the product outside of the lab would have the most favorable evaluations of the product at each follow-up period.**

**Rationale:** The results of the first study demonstrated that participants who used Ariva® outside of the lab gave the product higher evaluations at follow-up than immediately after the lab sample. The current study investigated the role of experience with Ariva® on evaluations of the product overall, compared to cigarette smoking, and as a potential tool to either reduce or eliminate smoking.

***Hypothesis 2: Subjective Effects of Ariva® in Experienced and Novice Users***

**It was hypothesized that after a guided sample in the lab, participants instructed to replace at least 2 cigarettes each day for 5 days (additional experience group) would report more favorable subjective effects of a second lab trial of Ariva® than those participants without any additional experience (control group). It was also expected that those participants who had the most experience with the product outside of the lab would report the most favorable subjective effects of the product at the final follow-up session. Subjective effect reports included product evaluation items related to drug effects, palatability, and convenience factors.**

**Rationale:** Additional experience with a non-smoked product may serve to familiarize smokers with how to use it, what to expect, decrease fear of an unfamiliar product, and build smokers' confidence in both their ability to use the product and to use it in a manner that supports their efforts to reduce smoking. As such, experience with the products may play an important role in smokers' subjective product evaluations and also their use of the product. Comparative trials of NRTs by smokers indicates that although there does not appear to be one particular therapy that is more effective than others, smokers do exhibit personal preferences for different products and a preference of a product is related to more use of that product (Schneider, *et al*, 2001; Schneider *et al*, 2003; Fagerstrom, Tejding, Westin, & Lunell, 1997; Batra, Kllinger, Landfeldt, Friederich, Westin, & Danielsson, 2005).



### ***Hypothesis 3: Behavioral Effects of Ariva® Experience***

**It was hypothesized that after a guided sample in the lab, participants instructed to replace at least 2 cigarettes each day for 5 days (additional experience group) would exhibit more favorable behavioral responses to Ariva® during a period of natural use outside of the lab than participants in the control group. Specifically, it was predicted that those participants in the experience group, would use more pieces of Ariva® than the control group during the natural use period. Additionally, it was predicted that the experienced Ariva® users would smoke fewer cigarettes per day during the natural use period than those in the control group.**

**Rationale:** The results of study one suggest that even participants who had very favorable evaluations of the lab sample of Ariva® demonstrated modest levels of *ad libitum* during the follow-up period. However, product evaluations increased moderately among those reporting discretionary use of the product out of the lab. It was expected that providing a period of guided discretionary use would result in more product use and subsequently improve product evaluations.

### **Design**

**Overview.** This study was an extension and expansion of the exploratory project conducted in Experiment 1. In Experiment 2, smokers' behavioral and subjective responses to information and a sample of a potential reduced exposure tobacco product, marketed under the name Ariva®, were examined. In line with the exploratory nature of Experiment 1, participants were offered an optional take home sample of Ariva® and the option of providing follow-up reactions to their experience with the sample. The current

experiment provided a more comprehensive and refined examination of smokers' responses to information about tobacco harm reduction and samples of Ariva®.

This study expanded on one of the major findings from study one, namely the substantial interest expressed by participants to use Ariva® as a smoking cessation aid or to reduce their smoking. A significant enhancement in this study was the addition of a longer, non-optional follow-up period during which participants were randomly assigned to a reduced smoking or ad lib smoking condition for 5 days following the initial laboratory trial. All participants were asked to provide follow-up data after the 5-day trial and again 7 days after the first follow-up session, including biological samples and questionnaire data to examine the amount of Ariva® use, the amount of smoking, to determine the situations in which smokers chose to use Ariva® instead of smoking, and to examine patterns of natural use of Ariva® in the context of smoking. In additions, smokers' future intentions to quit smoking and use Ariva® were measured.

Prior studies of smoking reduction aided by concomitant use of NRT have shown that smoking reduction with concurrent use of NRTs, have demonstrated that nicotine replacement products (most with higher nicotine content than Ariva®) are well tolerated and adverse reactions are few and mild in nature (Fagerstrom *et al*, 1997, Batra *et al*, 2005; Foulds, Burke, Steinberg, Williams, & Ziedonis, 2004). This study was conducted under the supervision of Drs. Laura Klein and Lynn T. Kozlowski in the Department of Biobehavioral Health at The Pennsylvania State University.

**Experimental Procedure.** See Figure 1 for a schematic representation of the study design and Figure 2 for timelines of each study session. The experiment was an open label, between-subjects study, employing a random assignment design to compare

the effect of level of experience with Ariva® on subjective effects and behavioral responses to the product and smoking. After a lab trial of the product, participants were randomly assigned to either an additional experience condition or control condition for the first 5-day follow-up period. After the 5-day experience manipulation, participants returned to the lab for an additional sample and were given two packs of the product to use as they saw fit over the next 7 days. The second follow-up period lasted for 7 days and provided a natural use setting to examine the impact of additional experience with Ariva® on participants' evaluations of subjective effects as well as their use of the product and smoking. All comparisons were made with baseline levels within subjects, as well as between the comparison groups at baseline, follow-up session one (5 days post lab session), and follow-up session two (12 days post lab session). A non-nicotine placebo control was not included because (1) the goals of this study were to examine the effect of level of experience with Ariva® on subjective effects and behavioral responses to the product and (2) the role of nicotine replacement as an effective method to help smokers abstain and reduce smoking has already been well established in other work (Silagy *et al*, 2004).

## **Methods**

**Participants.** Forty smokers (20 women, 20 men) ages 18-65 (mean age  $32.95 \pm 1.97$  years) participated all 3 lab sessions and completed daily diaries and tobacco collections required in this study. Participants were recruited from State College and the surrounding communities via newspaper ads, radio ads, mailings to University employees, list-server announcements, and flyers inviting smokers participate in a trial evaluating a novel tobacco product.

**Eligibility.** An initial telephone interview was conducted by the investigator or trained research assistants after callers provided verbal consent to determine their eligibility to participate. Inclusion criteria allowed eligibility if (a) smokers were between 18 and 65 years of age; (b) had a score of at least 2 on the Heaviness of Smoking Index (HSI; Heatherton et al., 1992; Diaz, Jane, Salto, Pardell, Salleras, Pinet, & de Leon, 2005), and indicated at a desire to quit smoking in the future; (c) were willing to sample a tobacco product in the lab and during the follow-up periods outside of the lab; (d) were willing to be randomly assigned to a five day period of instructed product use outside of the lab; (e) were willing to return to the lab for two additional follow-up sessions; and (f) were willing provide breath and urine samples. The inclusion criteria were established to ensure participants were nicotine dependent, adult smokers who were willing and legally able to use tobacco. In addition, there is some evidence to suggest that smokers who indicate no interest in quitting smoking, or are primarily interested in reducing their smoking may have more health, psychiatric, or substance use problems than other smokers and therefore could differ in important ways from other smokers (Lemmonds, Mooney, Reich, & Hatsukami, 2004).

Exclusion criteria included: (a) (for women) reporting pregnancy or nursing an infant, or attempting to become pregnant (female participants were informed the urine sample they provided at each session would be tested to rule out pregnancy); (b) having any mouth sores or cuts or wearing dentures; (c) history of certain medical conditions (heart disease or recent heart attack, untreated hypertension, diabetes, stomach ulcer,) or diagnosed mental illness; (d) currently abstaining from smoking in an attempt to quit smoking, and (e) prior use of Ariva®. The exclusion criteria were established to protect

participants from the possibility of 1) increased toxicity exposure from the use of Ariva® in addition to smoking in vulnerable groups, such as women who are pregnant (there is not conclusive evidence to determine that the effects of nicotine exposure from medicinal products confer less harm than the effects of smoking to the fetus) or suffer from other health problems, 2) to exclude those who had contraindications for use of an oral nicotine or tobacco product (those with dentures or mouth sores), 3) those smokers who were currently abstaining or attempting to completely abstain from smoking and other tobacco use, and 4) who may already have had experience with the experimental product.

### **Study Procedures**

**Informed Consent and Initial Lab Session.** For the initial laboratory session, eligible participants reported to the lab after smoking as usual and completed the approved informed consent procedure with the investigator or research assistant. Next, participants provided an expired air CO sample and a urine sample. Participants also were weighed and their height measured before completing an exercise estimating the passage of time. Next, participants completed several questionnaires and read a prepared statement explaining why smokers who are not ready or able to quit might consider using a non-smoked low nitrosamine product to substitute for some or all of their cigarettes, reasons including reducing their exposure to health risks as well as other possible benefits of using a non-smoked product. Participants completed a thought listing exercise and an additional questionnaire to evaluate the information presented.

**Self-report measures.** Participants completed several surveys at each lab visit. At the first lab session only, participants completed a detailed tobacco history questionnaire, a modified social climate survey, and the WSDM-68. Questions about

daily smoking habits and history, intentions to quit, past quit attempts and strategies used, personal perceived health risks of smoking, and the extent of smoking restrictions experienced were included in this set of questions. Additionally, important measures of smoking behavior, effects, knowledge, and attitudes, and affect were embedded within the tobacco use questionnaire. At each lab visit, participants also completed questionnaires to measure their mood, physical symptoms, general traits, and risk perceptions. The following measures were collected [an asterisk (\*) indicates measures that were administered at the first lab session and double asterisk (\*\*) indicates items collected at each lab session]: (1) the Fagerström Test of Nicotine Dependence\* (FTND; Heatherton et al., 1991), a six item self-report measure derived from the Fagerström Tolerance Questionnaire, to assess level of nicotine dependence (the HSI is also derived from 2-items on from the FTND) demonstrating high test-retest reliability and internal consistency (Pomerleau, Carton, Lutzke, Flessland, & Pomerleau, 1994); (2) the Wisconsin Inventory for Determining Smoking Motives\* (WISDM-68, a 68 item survey of motivations for smoking); (3) the abbreviated version of the Questionnaire for Smoking Urges\*\* (QSU-Brief, Cox et al., 2001; Tiffany & Drobes, 1991), a 10-item measure of smoking urge characterized by two distinct factors: items in the first factor are indicative of strong desire and intention to smoke and items comprising the second factor are indicative of expectations of relief from negative affect (Cox et al., 2001); (4) the Minnesota Nicotine Withdrawal Scale\*\* (MNWS; Hughes & Hatsukami, 1998; Hughes & Hatsukami, 1986), a 7-item scale measuring symptoms of nicotine withdrawal including depression, insomnia, irritability/frustration/anger, anxiety, difficulty concentrating, restlessness, and increased appetite/weight gain, measured on a five point

scale from 0-4 (0 = not present, 1 = slight, 2 = mild, 3 = moderate, 4 = severe); and (5) items from the Social Climate Survey of Tobacco Control\* (SCS-TC) which measure the extent of smoking restrictions experienced and endorsed by participants at work, home, in social settings, in their automobile, the presence of non-smoker and children (McMillen, Winickoff, Klein, & Weitzman, 2003). Between laboratory sessions participants completed brief diary entries to record experimental product use, smoking, and the context of tobacco use.

**Product Information.** Following completion of the history questionnaire, participants were given information to read about the first product sample and asked to “read the information carefully and think about it” while they read it. The information included an argument suggesting reasons why smokers might consider using a reduced exposure non-smoked tobacco product like Ariva® instead of smoking. A main argument in support of this recommendation was an explanation of how the use of these products conveyed less health risk than smoking (eliminating combustion, or smoke; reducing exposure to other toxic or carcinogenic compounds such as TSNAs, and reducing the amount of nicotine exposure) and might be used either to reduce smoking or to quit completely. The information also included suggestions concerning other possible benefits of using these products instead of cigarettes, such as not producing second hand smoke or needing to interrupt work or social activities to have a cigarette. The health message and benefit argument were developed based on participants’ responses to the two message frames presented in experiment one. After reading the message, participants completed a brief thought listing exercise listing all the ideas they had while reading the information. Next, they completed evaluation of the information by

indicating the extent of their agreement with a series of 15 statements about the overall importance, personal relevance, persuasiveness, and factual content of the information, using a scale of 1-7 (1 = completely disagree to 7 = completely agree). The evaluation exercise was the same as used in experiment one and was based on elements of persuasive health communication (novelty of information, comprehensibility, the amount of thought provoked by the message) related to message quality, which has been shown to be important influence on persuasive message processing (Petty & Cacioppo, 1986).

**Lab Product Sampling.** Next, participants sampled the tobacco product Ariva®.

Prior to the sample, participants were instructed as follows:

The next part of this study is the product sample. I am going to give you a piece of Ariva® to remove from the bubble wrapper. Pull off the white backing and push the sample through the foil. Let me know if you need any assistance. Please place the sample between your gum and upper cheek and let it rest in that spot. The sample will dissolve against the lining of your mouth. This placement minimizes the amount of saliva you'll produce. You may have some saliva but you should not need to spit. You may move the sample if you want and doing so may help the product to dissolve more quickly. You don't need to suck on the sample and you should not chew it. You may feel a tingling sensation in your mouth from the nicotine in the tobacco. This is normal. If you experience any discomfort, you may remove the product and discard it at any time. Please alert me if you have discomfort or remove the product. I am going to make a note of the time you start your sample and then in about 10 minutes we will continue with the session. There are magazines if you care to read.

The time the product was placed into the mouth was recorded and if a participant removed or discarded the sample at any time over the remainder of the lab session, the time of removal and reason for removal, if stated, was recorded.

**Subjective Effects: Product Evaluation Exercises.** At 10 minutes following the initiation of the sample of Ariva®, participants began a series of exercises to evaluate their subjective responses to the product. Subjective responses are valuable in assessing



abuse liability as well as possibly tailoring PREPs or NRTs to smokers. These included (1) a rating exercise (adapted from Schneider et al. 2003, 2005) to evaluate aspects important to determining smokers' preferences for NRT systems (2 scales; one to measure subjective responses to the product, one to compare it to cigarettes, each scored on a 7 point scale 1 = "very definitely not – 7 = "very definitely" agreement with descriptive statements about the product on dimensions such as 'overall excellent product,' 'easy to use,' 'would feel uncomfortable using in public,' and 'would recommend to friends who smoke'); (2) a set of visual analog scales (VAS) allowing participants to rate (a) cigarette craving (4 items derived from Schuh & Stitzer, 1995); (b) drug effects (six items derived from Houtsmuller et al. 2003); and (c) product palatability (11 items derived from Houtsmuller et al. 2003; and Houtsmuller et al., 2002); (3) the QSU-Brief, a 10 item measure of urge to smoke (Cox et al. 2001; Tiffany & Drobes, 1991), and (4) the MNWS (MNWS; Hughes & Hatsukami, 1998; Hughes & Hatsukami, 1986), a 7-item scale measuring symptoms of nicotine withdrawal including depression, insomnia, irritability/frustration/anger, anxiety, difficulty concentrating, restlessness, and increased appetite/weight gain, measured on a five point scale from 0-4 (0 = not present, 1 = slight, 2 = mild, 3 = moderate, 4 = severe).

**Behavioral Responses: Semi-structured interview.** After completing the product sample and evaluation questionnaire set, participants completed a brief semi-structured interview with the researcher. During the interview participants described: (1) their initial reactions to the product sample; (2) whether the sample met their expectations based on the product information; (3) their intentions to use the product again (ever, in situations where they could not smoke, in situations where they did not want to smoke, if

they were going to try to cut down on smoking, and if they were going to try to quit smoking); (4) the most important factors in their decisions about their intentions to use the product again; (5) what they would tell another smoker about this product; and (6) how much they would be willing to pay for 1 box of this product. The interview also provided an opportunity to assess whether participants were willing to continue with the study protocol after the product sample. Those who were willing to be randomized to use additional Ariva® out of the lab were then informed of their assignment to additional experience or regular tobacco use for the next 5 days. Participants received instructions and materials for the first follow-up period and were compensated \$20. Participants were informed that they would be compensated an additional \$20 at each follow-up session with a monetary bonus of \$15 per visit for confirmed adherence to the study protocol, which included: following the product use instructions (i.e. sampling Ariva® as instructed), making diary entries to record their tobacco use, collecting their cigarette butts and Ariva® backings in provided containers, making compliance calls to the lab each day of the follow-up period, and returning for their next lab appointment.

**Product Use Instructions for follow-up period 1.** Participants randomly assigned to the additional experience condition were provided with 2 packages of Ariva® and instructed to replace at least 2 cigarettes each day with a piece of Ariva®. Participants in the experience group were advised not to try more than 15 pieces of Ariva® in any given day and not to engage in vigorous exercise while using Ariva®. These participants were also informed that it may take longer for them to feel the effects of nicotine in Ariva® compared to cigarettes and that they would be able to adjust their smoking throughout the follow-up period or Ariva® use if they experienced undesirable

effects of more nicotine than they were accustomed to using. Participants assigned to smoke as usual (control group) were asked to smoke as they normally would for the next five days and not to sample any additional Ariva® during this period.

**Daily Tobacco Use Diary.** During the follow-up periods all participants were required to record their daily smoking and Ariva® use in a diary provided to them. The diary consisted of pre-printed entry pages to be completed by the participant for every use of tobacco. The diary format included a space for the participant ID number, the date and time of the tobacco use, and a space to check off the type of tobacco use (cigarette or Ariva®). There were also spaces to record the place of tobacco use, who was present, and the participant's mood. Finally, in the case of Ariva® (or other tobacco use), there was a space to indicate whether smoking was permitted. A code list of categories that best described the circumstances of tobacco use was provided to make the diary entry procedure simple and convenient.

**Tobacco Collections and Compliance Calls.** In order to promote compliance with the instructions, participants in both groups were asked to collect their cigarette butts each day and retain them to return at the next follow-up session. Those in the additional experience group were also asked to collect the backing from used pieces of Ariva®. In order to promote prospective diary recording and tobacco collections, participants were required to phone into the lab each morning of the follow-up period and confirm that they planned to make record their tobacco use and collect their used tobacco products for the day. This call also provided an opportunity for participants to alert the investigator to any problems or questions experienced during the follow-up period.

**Follow-Up Lab Session 1.** Upon arrival at the first follow-up session, participants returned their diaries, tobacco collections, and any unused product. Next, each participant provided biological samples as described for the initial lab session. They were weighed and completed a time estimation exercise before completing the self-report measures described. Each participant then sampled an additional piece of Ariva® following the procedure and instructions described, took a 10-minute break, and then completed a series of questionnaires and interview with the investigator to evaluate the product. All participants were provided 2 packages of Ariva® to take for use during the next follow-up period and the proper use instructions described above were reviewed with all participants. Each participant was also informed that it was very important to the study for him or her to attend the next follow-up visit in 7 days even if no Ariva® was used. The instructions for making diary entries, tobacco collections, and compliance calls were reviewed. Participants were reminded to bring their diaries, collections, and unused sample product back to the final lab session. Participants were compensated \$20 (plus an additional \$15 if they complied with study protocol by returning the urine sample, unused and used product, diary, and cigarette butts).

**Follow-Up Lab Session 2.** Participants reported for the second follow-up session 7 days after session 2. Those participants who were not able to attend their scheduled session at 7 days follow-up completed the third lab session as soon as their schedules permitted. Upon arrival, participants returned 1) dairy records of smoking and/or Ariva® use, 2) their collected cigarette butts and Ariva® product backing, and 3) any unused Ariva®. They provided expired air and urine samples, were weighed, completed a final time estimation exercise and several questionnaires, as described.

Next, each participant completed a final product sample, completed the product evaluation questionnaire set and a final brief semi-structured interview with the investigator. Participants received \$20 compensation for the lab visit and an additional \$15 if they returned 1) a completed diary of smoking and Ariva® use, 2) collected cigarette butts, and 3) unused Ariva® or used product backing. See Figure 1 for detailed diagram of the timeline and procedures followed at each laboratory session.

### **Data Analytic Strategy**

Power analyses were performed to determine the number of participants required in each treatment to detect a difference of 2.2 standard deviations in the primary mean outcome (Ariva® pieces used), with 80% power and 5% significance via the use of a two-tailed test. Based on the results of previous smoking reduction trials (Fagerstrom *et al*, 1997; Foulds, Burke, Steinberg, Williams, & Ziedonis, 2004; Batra *et al*, 2005; Hecht, 2005) and the first experiment, it was expected that participants in the control group would use an average of 4 pieces of Ariva® during the 7-day follow-up period and that those in the experience group would use approximately 50% more Ariva® during the 7 day follow-up period. Therefore, it was hypothesized that participants in the experience group would use more Ariva® than those in the control group during the second follow-up period. Additionally, it was hypothesized that participants in the experience group would smoke fewer cigarettes than those in the control group during each follow-up period. It was also hypothesized that participants in the experience group would have more favorable evaluations of Ariva® compared to the lab only experience group at each follow-up. Aspects of the evaluation included overall satisfaction with the tobacco product alone and in comparison to cigarettes; specific aspects of the product (such as

palatability and drug effect,) and behavioral intentions concerning future use of the product.

Secondary outcomes of interest included smoking (CPD), biomarkers of smoking (expired CO,) and behavioral intentions (to quit smoking, continue use of Ariva® as a reduction/cessation tool) which were examined within subjects from baseline to follow-up periods one and two and between the two instruction groups.

Participants' self-reported baseline characteristics (including age, sex, number of previous quit attempts, years of tobacco use, and smoking restrictions) were compared between the two groups. In addition, baseline responses to the product trial were compared between groups. Discrete variables were analyzed using the chi-square test or Fischer's exact test. Continuous variables were analyzed using a two-sample t-test, or the Wilcoxon rank sum test where assumptions of normality were violated. All tests were two-tailed and statistical significance was determined at  $\alpha = 0.05$ . Means ( $\pm$  standard error of the mean) are presented in the text.

## **Results**

**Descriptive Statistics.** Eleven participants were not included in the analyses presented because they did not complete all the study session ( $n=7$ ), did not collect and/or record their tobacco use ( $n=3$ ), or refused to be randomized and continue participation in the remainder of the study ( $n=1$ ). Reasons for non-completion were lack of time ( $n=4$ ) and did not want to continue ( $n=3$ ). No participants discontinued participation due to reported adverse events. Participants who did not complete the study were significantly younger (mean age =  $25.18 \pm 2.35$  vs.  $32.95 \pm 1.98$ , respectively;  $t(49, 25.88) = 0.018$ ). The assumption of equal variances was not met for the age variable, therefore, Levene's  $t$

is reported here. There were no statistically differences between condition assignment or sex between the participants who did not continue and the remaining sample.

The average age of participants ( $n = 40$ ) was 32.95 years ( $\pm 1.97$ ; range 19-64) and half ( $n = 20$ ) were male. Most participants described their racial background as white ( $n = 32$ , 80%), fewer described their background as Asian ( $n = 4$ , 10%), Black ( $n = 3$ , 7.5%), and other ( $n = 1$ , 2.5%). Slightly less than half of the sample ( $n = 17$ , 42.5%) had completed some college; 14 (35%) had completed 4 or more years of college; 7 (17.5%) were high school graduates, and 2 (5%) completed 3 years of high school. Most participants reported having never been married ( $n = 21$ , 52.5%), 9 (22.5%) were divorced, 6 (15%) were married, and 4 (10%) described themselves as members of an unmarried couple.

**Smoking Characteristics.** Overall, participants reported smoking an average of 17.21 cigarettes per day ( $\pm 0.94$ ; range 8-40), and their average baseline CO score for was 24.95 parts per million (ppm) ( $\pm 2.28$ , range 9-94). Participants had a mean heaviness of smoking index (HSI) score of 3.25 ( $\pm 0.13$ ; range 2-5) and had smoked, on average for 14.58 years ( $\pm 2.02$ ; range 1-46). In addition, 15 participants (37.5%) reported having ever tried smokeless tobacco and 2 (5%) reported being current, non-daily users of smokeless tobacco in the form of snuff or dip.

**Quit Attempts and Intentions.** About two-thirds of participants ( $n = 27$ ; 67.5%) reported having ever made a serious attempt to quit smoking. Among those who had made a quit attempt ( $n = 27$ ), 85.19% ( $n = 23$ ) reported having made between 1 and 3 serious attempts to quit smoking in the past 5 years. Participants also described their interest in and intentions to make quit smoking attempts in the future. Slightly more than

two-thirds of the sample (n=27, 67.5%) reported wanting to quit smoking either somewhat or very much in the next 6 months. Nearly half (n = 19, 47.5%) stated it was somewhat or very likely that they would try to quit smoking in the next 6 months and that they were seriously considering quitting in the next 6 months. More than half (n=23, 57.5%) agreed it was somewhat or very likely that they would be able to quit smoking in the next 6 months if they tried. There were no statistically significant differences in quitting intentions expressed between the control and experimental groups at the baseline visit.

**Smoking Restrictions and Social Climate of Smoking.** At the baseline visit, participants provided information describing smoking restrictions in their homes, workplace, and automobiles. Overall, 45% (n = 18) reported that smoking is not allowed in any part of their home, with another 11 (27.5%) reporting that smoking is not allowed in some parts of their home. Participants also responded to a series of questions to measure their perceptions of the social climate regarding smoking behavior and norms in their community (McMillen, Winickoff, Klein, & Weitzman, 2003). The majority of participants agreed (n=35, 87.5%) that parents have a responsibility to prevent their children's exposure to second hand, or environmental tobacco smoke (ETS) and that inhaling smoke from parental cigarette smoking is harmful to the health of babies and children (n=38, 95%). Additionally, nearly all participants (n=38, 95%) supported penalizing retail outlets for selling tobacco to people under the age of 18. Somewhat more than half the sample (n=23, 57.5%) agreed that smoking should be permitted in some areas of indoor workplaces and anywhere in taverns and bars (n=21, 52.5%). Additionally, the majority of participants agreed that tobacco advertisements were



acceptable in grocery and convenience stores (n=26, 65%) and magazines (n=28, 70%).

There were no statistically significant differences in the reported smoking restrictions and social climate responses by group assignments at baseline.

### **Laboratory Session 1: Baseline**

**Participant Characteristics by Condition.** Participants were randomly assigned to either the control (n=19) or experience condition (n=21) and the condition assignment was revealed to the participant at the end of lab session one. Participants assigned to the control group (n=19), were older, on average, than those assigned to the experimental group [mean age =  $36.58 \pm 3.15$  years vs.  $29.67 \pm 2.3$  years, respectively;  $t_{(38)} = -1.8$  p = 0.08], and had higher Body Mass Index (BMI) scores [mean BMI =  $31.28 \pm 3.28$  vs.  $25.3 \pm 1.17$ , respectively;  $t_{(38)} = -1.79$  p = 0.08] although these differences were not statistically significant.

**Smoking Characteristics by Condition.** There were no statistically significant differences in Heaviness of Smoking Index (HSI) scores or reported average cigarettes smoked per day (CPD) between participants assigned to the control and experimental conditions [mean HSI score =  $3.42 \pm 0.21$  vs.  $3.09 \pm 0.18$ , respectively;  $t_{(38)} = -1.19$  p = 0.24; average cigarettes smoked per day =  $18.1 \pm 1.73$  vs.  $16.4 \pm 0.88$ , respectively;  $t_{(38)} = -0.90$  p = 0.37]. However, participants assigned to the control group reported having been regular smokers for significantly more years than those assigned to the experimental condition [mean years regular smoking =  $19.1 \pm 3.27$  vs.  $10.45 \pm 2.18$ , respectively;  $t_{(38)} = -2.23$  p = 0.03] and had statistically significantly higher levels of expired CO at baseline than those in the experimental condition [mean CO score in ppm =  $30.95 \pm 4.24$  vs.  $19.52 \pm 5.94$ , respectively;  $t_{(21.36)} = -2.58$  p = 0.01]. The assumption of equal

variances for expired CO at baseline was not met, therefore, Levene's T statistic is reported.

**Information Evaluation at Baseline.** As in experiment one, participants in this study evaluated a message that described arguments supporting harm reduction use of the study product by indicating their agreement with statements using a number from 1 to 7 where 1 indicated "very definitely do not agree," up to 7 indicating "very definitely agree." In general, participants ( $n=40$ ) evaluated the information as being new to them (mean agreement score =  $5.7 \pm 0.25$ ); easy to understand (mean agreement score =  $6.4 \pm 0.11$ ); and important for smokers to know (mean agreement score =  $5.8 \pm 0.22$ ). Participants also demonstrated fair comprehension of the information described. For example, 95% ( $n=38$ ) agreed that the information stated Ariva® pieces are less harmful than cigarettes, 80% ( $n=32$ ) disagreed that the information stated Ariva® is not addictive, and the majority (70%,  $n=28$ ) disagreed that the information described nicotine as the main cancer causing compound in tobacco.

**Product Evaluations at Baseline.** As described, all participants sampled and evaluated the product during the first lab session, before being informed of their assignment to either the control or experience condition. The general phrase product evaluations refers to overall product satisfaction items adapted from Schneider and colleagues, agreement with comparisons to cigarettes adapted from Schneider and colleagues, and items on the visual analog scale (VAS) exercise. Compared to those assigned to the experience group, participants assigned to the control group expressed statistically significantly greater agreement with the following two evaluation items at baseline: the product provides enough nicotine [mean agreement scores of control vs.

experience groups =  $5.0 \pm 0.28$  vs.  $4.24 \pm 0.27$ , range 1 – 7;  $t_{(38)} = -1.97$   $p = .05$ ] and compared to cigarettes, the product provides enough nicotine [mean agreement scores of control vs. experience groups =  $4.90 \pm 0.26$  vs.  $4.10 \pm 0.28$ ;  $t_{(38)} = -2.10$   $p = .04$ ]. There were no statistically significant condition group differences in responses to the VAS rating items or behavioral intentions to use Ariva® at the baseline session.

### **Laboratory Session 2: Follow-Up One**

**Confirmation of Experience Manipulation.** Participants in both conditions recorded their smoking and collected their cigarette butts daily during the first follow-up period. Those in the experience group also recorded Ariva® use and collected product backings daily. These procedures were followed during the second follow-up period, as well. Correlations were performed to compare daily smoking recorded in the diary to collections of cigarette butts. Specifically, daily diary recordings and collections of Ariva® were statistically significantly correlated for both follow-up periods one and two [ $r = 0.98$ ,  $p = .000$ , and  $r = 0.98$ ,  $p = .000$ , respectively]. Likewise, cigarette daily diary recordings and collections were statistically significantly correlated during both follow-up periods one and two [ $r = 0.91$ ,  $p = .000$  and  $r = 0.97$ ,  $p = .000$ ; respectively]. Due to the strong, positive correlation between diary entries and collections, the analyses of smoking and Ariva® use are based on daily diary entries. In cases where daily diary entries were missing or incomplete, data were imputed from Ariva® and cigarette collection tallies.

**Ariva® Use and Cigarette Smoking During Follow-Up Period 1.** During the first follow-up period, participants in the experience group ( $n=21$ ) reported using an average of 2.14 pieces of Ariva® per day ( $\pm 0.27$ , range 5-37 ) and an average total of

10.71 Ariva® pieces ( $\pm 1.36$ , range 5-37) for the entire period. Participants in the control group did not use any Ariva® during this period. Overall, participants ( $n = 40$ ) reported smoking an average of 12.1 cigarettes per day ( $\pm 0.96$ ) and a mean total of 60.64 ( $\pm 4.93$ ) cigarettes for the entire period. Although not a statistically significant difference, participants in the experience group ( $n=21$ ) reported smoking fewer cigarettes per day than those in the control group (mean cigarettes per day =  $11.11 \pm 0.94$  vs.  $13.16 \pm 1.74$ ,  $t(38)=2.95$ , n.s. respectively) and fewer cigarettes overall (mean overall cigarettes =  $55.75 \pm 4.94$  vs.  $65.79 \pm 8.69$ ,  $t(38)=-1.02$  n.s., respectively) during the first follow-up period. Additionally, repeated-measures ANOVA comparing average daily cigarettes smoked from baseline to follow-up one with condition as a between subjects factor revealed a main effect of time for the entire sample [ $F(1,38)=43.06$ ;  $p=0.000$ ] following a linear trend. The average number of cigarettes smoked per day decreased from 16.4 ( $\pm 0.88$ ) at baseline to  $11.11(\pm 0.94)$  at follow-up one for the participants in the experience group. Similarly, the average number of cigarettes smoked per day in the control group decreased from 18.1 ( $\pm 1.73$ ) per day at baseline to  $13.16 (\pm 1.74)$  at follow-up one. There was not a statistically significant interaction with condition.

### **Laboratory Session 3: Follow-Up Two**

**Ariva® use and smoking.** Table 2 presents Ariva® use and cigarette smoking over the course of the study. During the second follow-up period, participants in the experience group ( $n=21$ ) reported using an average of 1.27 ( $\pm 0.31$ ) pieces of Ariva® per day and an average total of 8.9 ( $\pm 2.14$ ) Ariva® pieces for the entire period. Note that the second follow-up period was seven days. Participants in the control group ( $n=19$ ) also had access to Ariva® during this period. During the second follow-up period,

participants in the control group reported using an average of 1.03 ( $\pm 0.27$ ) pieces of Ariva® each day and an average total of 7.21 ( $\pm 1.59$ ) pieces of Ariva® for the entire period. For the entire sample ( $n=40$ ), 82.5% ( $n=33$ ) voluntarily used at least one piece of Ariva® during the natural use period. Nearly 86% ( $n=18$ ) of the participants in the experience group opted to continue to use Ariva® during the natural use period. Approximately 79% ( $n=15$ ) of the participants in the control group opted to try Ariva® during the natural use period.

Although not a statistically significant difference, participants in the control group reported smoking fewer cigarettes per day on average than those in the experience group (mean cigarettes per day =  $11.50 \pm 1.87$  vs.  $12.08 \pm 1.24$ , respectively,  $t(38)=0.263$ , n.s.) and fewer cigarettes overall (mean overall cigarettes =  $80.21 \pm 13.08$  vs.  $84.57 \pm 8.66$ , respectively  $t(38)=0.28$ , n.s.) during the second follow-up period. A repeated measures ANOVA comparing average daily cigarette smoking at time two and time three with condition as the between-subjects factor revealed a significant time by condition interaction [ $F(1,38)=10.64$ ,  $p=0.002$ ], with average cigarettes per day increasing among participants in the experience group and decreasing among those in the control group.

### **Product Evaluations across Lab Sessions**

At each session, product evaluations, adapted from NRT preference evaluations developed by Schneider and colleagues (Schneider et al. 2003, 2005) were completed. Each item required the participant to indicate level of agreement with the statement on a Likert-type scale of 1 – 7. Evaluation items pertained to the product on its own merits (14 items) and in comparison to cigarettes (9 items). Additionally, participants were asked to give an overall satisfaction score to the product alone and in comparison to

cigarettes on a scale of 1 – 10 where 1 represented the least satisfaction possible and 10 represented the most satisfaction possible.

**Product Excellence.** Figure 4 presents level of agreement with the evaluation that the product was excellent overall, at the baseline lab session, lab session 2, and lab session 3. A repeated-measures ANOVA with condition as the between-subjects factor revealed a significant effect of time [ $F(2,76)=6.77, p=0.002$ ] that followed a linear trend [ $F(1,38)=10.71, p=0.002$ ]. Specifically, mean level of agreement on this item increased significantly from lab session 2 to lab session 3 [ $F(1,38)=7.6, p = 0.009$ ] while mean levels from baseline to follow-up one were similar. No time by condition effect was found for the evaluation of overall product excellence.

**Relief of nicotine withdrawal.** Figure 5 presents level of agreement with the statement: the product provided relief of nicotine withdrawal, at each of the three lab sessions. A repeated-measures ANOVA with condition as the between-subjects factor revealed a significant effect of time [ $F(2,76)=4.08, p=0.021$ ] that followed a linear trend [ $F(1,38)=6.12, p=0.018$ ]. Specifically, overall agreement with this evaluation item increased significantly from baseline to time 3, or follow-up session 2 [ $F(1,38)=6.12, p=0.018$ ]. However, changes between baseline and follow-up one, and follow-up one and follow-up two were not statistically significant. No effect of time by condition was found.

**Product provided relief of urges to smoke.** Figure 6 presents mean levels of agreement with the statement that the product provided relief of urge to smoke at each of the three lab sessions. A repeated-measures ANOVA with condition as the between-subjects factor revealed a significant effect of time [ $F(2,76)=3.02, p=0.05$ ] that followed a linear trend [ $F(1,38)=4.10, p=0.05$ ]. Specifically, there were no statistically significant

differences in average mean ratings between lab sessions 1 and 2, and in fact, endorsement dropped slightly from time 1 to 2 among those in the experience group. However, mean agreement increased significantly from time 1 to 3 and time 2 to 3 [ $F(1,38)=4.10$ ,  $p=0.05$  and  $F(1,38)=5.89$ ,  $p=0.02$ ; respectively]. There were no statistically significant effects of condition.

**I did not need cigarettes while using the product (drug effect).** Separate repeated measures ANOVAs conducted from baseline to follow-up session one revealed a statistically significant decrease in agreement with this evaluation item from baseline to follow-up session 1 [ $F(1,38)=4.86$ ,  $p=.03$ ] and also from baseline to lab session 3 [ $F(1,38) = 4.02$ ,  $p=0.05$ ]. Figure 7 illustrates the decrease in mean levels of agreement with the evaluation that cigarettes were not needed across the three lab sessions by condition. There were no interactions among participant condition.

**Provides enough nicotine.** Figure 8 presents mean levels of agreement with the evaluation that the product provided enough nicotine measured at baseline, follow-up one and follow-up two. A repeated-measures ANOVA revealed a significant effect of time [ $F(2, 76)=5.62$ ,  $p=0.005$ ], following a linear trend [ $F(1,38)=7.67$ ,  $p=0.009$ ]. Specifically, mean levels of agreement increased from baseline to follow-up session 1 [ $F(1,38)=5.90$ ,  $p = 0.02$ ]. In addition, there was a significant quadratic (i.e. an inverted U-shape pattern) time effect for participants in the experience group [ $F(1,20)=5.27$ ,  $p=0.03$ ]. Specifically, agreement that the product provides enough nicotine increased from baseline to follow-up session one and then decreased from follow-up session one to follow-up session two. No such effect was seen for those in the control group.

**Still crave cigarettes with regular use of product.** Figure 9 represents mean level of agreement with the statement, “I believe I would still crave cigarettes if I used

the product regularly,” at baseline, follow-up session one and follow-up session 2. A repeated-measures ANOVA with condition as the between-subjects factor demonstrated a significant time by condition interaction [ $F(2,76)=3.6$ ,  $p=0.032$ ], following a quadratic function (i.e. an inverted U shape curve) [ $F(1,38)=6.27$   $p=0.017$ ]. Specifically, a quadratic effect was seen among participants in the experience group [ $F(1,20)=10.76$ ,  $p=0.004$ ] such that endorsement of this evaluation item increased from baseline to follow-up session one and then decreased significantly from follow-up session 1 to follow-up session 2, among those in the experience group [ $F(1,38)=7.64$ ,  $p=0.009$ ].

**I would use the product again.** Figure 10 represents the mean level of endorsement of an intention to use the product again at each of the three lab sessions. A repeated-measures ANOVA with condition as the between subject factor showed a significant interaction effect for condition [ $F(2,76)=3.42$ ,  $p=0.038$ ], following a linear trend [ $F(1,38)=4.98$ ,  $p=0.032$ ]. Specifically, endorsement levels increased from baseline to session 3 among those in the control group and decreased in the experience group.

**I would tell my friends who smoke to use the product.** Figure 11 represents mean level of agreement that the participant would tell friends who smoke to use the product, measured at each lab session. A repeated-measures ANOVA revealed a significant effect of time [ $F(2,76)=8.13$ ,  $p=0.001$ ], following a linear pattern [ $F(1,38)=11.02$ ,  $p=0.002$ ]. Specifically, endorsement increased significantly from baseline to follow-up one [ $F(1,38)=8.56$ ,  $p=0.006$ ]. Endorsement level did not increase significantly from the second to third follow-up session.

**Product excellence, compared to cigarettes.** Figure 12 represents mean level of agreement with the excellence of Ariva® compared to cigarettes at each lab session. A repeated-measures ANOVA including ratings at baseline, follow-up session one and



follow-up session 2 revealed a significant effect of time [ $F(2,76)=3.67$ ,  $p=0.05$ ] that followed a linear pattern [ $F(1,38)=4.49$ ,  $p=0.041$ ], demonstrating an overall increase in agreement from baseline to the final lab session. Agreement did not increase significantly from baseline to follow-up one, or follow-up one to follow-up two. There were no statistically significant interactions with condition.

**Non-significant evaluation items.** Repeated measures ANOVAs comparing responses at baseline, follow-up one, and follow-up two revealed no statistically significant effects of time or interactions with condition for the following items: the product is easy to use; the product provides too much nicotine; I believe I might become dependent on the product if I used it regularly; the product had bothersome side effects; I would be uncomfortable using the product in public; I would be comfortable using the product for a long period of time; rate your level of satisfaction with the product; compared to cigarettes, the product is easy to use; compared to cigarettes, I liked how the product taste; compared to cigarettes, the product is less harmful to my health; compared to cigarettes, the product provides enough nicotine; compared to cigarettes, the product provides too much nicotine; I believe the product is as addictive as cigarettes; compared to cigarettes, I would be uncomfortable using the product in public; compared to cigarettes, the product had bothersome side effects; and rate your satisfaction with this product compared to cigarettes.

### **Visual Analog Scale (VAS) Evaluations across Lab Sessions**

At each lab session, participants also evaluated the product by completing an exercise asking them to read a statement about the product and indicate their agreement by making a mark on a vertical line between two anchoring end points. The left side of the scale was anchored by “Not at all” and the right side of the line, “Extremely.” The

items on the exercise represented standard characteristics of drugs related to abuse liability, including (a) cigarette craving (4 items derived from Schuh & Stitzer, 1995); (b) drug effects (six items derived from Houtsmiller *et al.*, 2003) and (c) palatability (11 items derived from Houtsmiller *et al.*, 2003; and Houtsmiller *et al.*, 2002).

**Drug effects of Ariva®.** Drug effect was measured using 7 items on the VAS exercise, including: (a) Do you feel any drug effect, (b) How strong is the drug effect; (c) Does the drug have any good effects; (d) does the drug have any bad effects; (e) do you like the drug effect; (f) do you dislike the drug effect; and (g) would you use this product just to get the drug effect. Figure 3 presents mean level of endorsement ( $\pm$  SEM) with feeling a drug effect measured at each lab session. Analysis of responses to item (a) do you feel any drug effect, using repeated measures ANOVA revealed a significant main effect of time [ $F(1,38)=4.38$ ,  $p=0.04$ ], such that self reports of experiencing a drug effect increased following a linear trend. Specifically, recognition of feeling a drug effect increased in a manner approaching significance from baseline to follow-up 1 [ $F(1,38)=4.4$ ,  $p=0.06$ ].

Figure 14 illustrates mean ratings of the drug's bad effects measured at each of the three lab sessions. A repeated measures ANOVA examining ratings of the experience of bad drug effects from Ariva® revealed a main effect of time from follow-up session 1 to follow-up session 2 [ $F(1,38)=6.32$ ,  $p=0.016$ ] with participants' stating that the experience of a bad drug effect decreased. Additionally, a time by condition interaction approaching significance [ $F(1,38)=3.5$ ,  $p=0.06$ ] was seen for participants in the experience group. A repeated measures ANOVA performed for all three lab sessions on item (f), do you dislike the drug effect, revealed a significant quadratic effect of time [ $F(2,76)=8.65$ ,  $p=0.006$ ]. Mean ratings of dislike of the drug effect are presented in

Figure 15. Separate repeated measures ANOVAs were completed from time 1 to 2 and time 2 to 3 to determine the nature of the effect. Reported dislike of the drug effect increased from baseline to follow-up one [ $F(1,38)=4.01$ ,  $p=0.05$ ] and decreased from follow-up session 2 to follow-up session 3 [ $F(1,38)=6.5$ ,  $p=0.015$ ] among those in the experience group only. Finally, repeated measures ANOVA performed with condition as the between groups factor from baseline to follow-up session one revealed a main effect of time [ $F(1,38)=6.18$ ,  $p=0.013$ ] such that participants expressed more agreement that they would use the product just for the drug effect from baseline to follow-up session 1. There were no statistically significant group differences across time points for the remaining drug effect items: (b) how strong is the drug effect, (c) does the drug have any good effects, and (e) do you like the drug effect.

**Drug effects on Cigarette Craving.** Cigarette craving was measured as an aspect of the subjective drug effects of Ariva® at all three lab sessions using a set of 4 questions on the VAS exercise as described. The four items pertaining to cigarette craving were (a) how pleasant would a cigarette be right now; (b) how much of an urge or desire to smoke do you have right now; (c) how much do you need to smoke right now, just for relief; and (d) how much do you want to smoke right now. Repeated-measures ANOVAs with condition as the between subjects factor were performed for each item (a-d) to compare responses at baseline, follow-up session one, and follow-up session two.

For item (a), how pleasant would a cigarette be right now, there was a significant main effect of time [ $F(2,76)=6.37$ ;  $p=.0003$ ] following a linear pattern [ $F(1,38)=8.02$ ;  $p=0.007$ ]. Specifically, the perceived pleasantness of having a cigarette decreased significantly within subjects from baseline to follow-up session one [ $F(1,38)=6.6$ ;

$p=0.014$ ], There was no significant interaction with condition at any time point, nor did responses change significantly from follow-up session one to follow-up session 2.

Concerning item (b), how much of an urge or desire do you have to smoke right now, a repeated measures ANOVA with condition as the between subjects factor was performed to examine responses at each of the 3 lab sessions (baseline, follow-up session 1, and follow-up session 2). There was a significant main effect of time [ $F(2,76) = 5.9$ ;  $p=0.004$ ] following a linear trend [ $F(1,38)=6.63$ ;  $p=0.014$ ] within subjects. Specifically, reported urge or desire to smoke decreased significantly from baseline to follow-up session one [ $F(1,18)=8.99$ ;  $p=0.005$ ] among all participants. Responses levels at follow-up session one and follow-up session two were similar and there were no interactions with condition at any time point.

In item (c) participants indicated how much of a need they felt to smoke for relief. A repeated measures ANOVA performed with condition at the between-subjects factors examined responses at baseline, follow-up session one and follow-up session two, revealing a significant main effect of time [ $F(2,76)=3.17$ ;  $p=0.048$ ] and a non-statistically significant linear trend [ $F(1,38)=3.3$ ;  $p=0.079$ ]. A separate repeated measures ANOVA performed comparing responses at baseline to follow-up session one, demonstrated a significant decrease in reported need to smoke for relief from baseline to follow-up session one [ $F(1,38)=5.68$ ;  $p=0.02$ ] within subjects. There was no interaction with condition and Responses did not change significantly from follow-up session one to follow-up session 2.

Item (d) measured desire to smoke “right now.” Similar to the previous cigarette craving items, a repeated-measures ANOVA performed with condition as the between-subjects factor comparing responses at each lab session, demonstrated a significant main

effect of time [ $F(2,76)=8.1$ ;  $p=0.001$ ] following a linear pattern [ $F(1,38)=9.44$ ;  $p=0.004$ ] indicating that the desire to smoke “right now” decreased significantly from baseline to follow-up session one [ $F(1,38)=12.59$ ;  $p=0.001$ ] while responses did not change significantly from follow-up session one to follow-up session 2. There was not a significant interaction with condition.

**Palatability.** Eleven VAS items on the VAS exercise pertained to product palatability, including (a) do you like the product’s taste, (b) do you like the feel of the product in the mouth, (c) does the product taste good, (d) does the product taste bad, (e) would you use this product just for its taste, (f) would you use this product just to get the drug effect, (g) does the product have a strong taste, (h) how sweet is the product, (i) how bitter is the product, (j) how much do you like the product overall, taste plus drug effect, and (k) how much do you dislike the product overall, taste plus drug effect.

Repeated-measures ANOVA comparing all three time points revealed a significant effect of time on item (j) would you use this product just to get the drug effect [ $F(2,76)=4.67$ ,  $p=0.037$ ] that followed a quadratic pattern. Additional repeated measures ANOVAs were performed to determine the nature of the differences. A significant increase in levels of endorsement of this item were seen from baseline to follow-up session 1 [ $F(1,38)=6.8$ ,  $p=0.013$ ] while endorsement did not change significantly from follow-up session 2 to 3. There was no interaction with condition. In addition, there were no statistically significant changes in responses to any of the other product palatability items when repeated measures ANOVAs were performed for all three time points, and from baseline to follow-up one, and follow-up one to follow-up two.

### **Secondary Outcomes of Interest**

**Behavioral Intentions Regarding Ariva® Use.** Participants were queried about their intentions to use the product again. They responded to a set of questions indicating how likely they would be to use the product again on a Likert-type scale where 1 represented their intentions to ever use the product again where 1 meant very definitely would not and 7 meant very definitely would. Specific behavioral intention questions were how likely is that you would: (a) ever use this product again, (b) use this product in situations where you could not smoke, (c) use this product in situations where you did not want to smoke, (d) use this product to try to cut down on your smoking, and (e) use this product to try to quit smoking. Additionally, participants were asked to indicate how much they would be willing to pay for 1 box of this product. Table 3 presents mean responses to each intention item at each of the three lab sessions separated by condition. Repeated-measures ANOVA comparing responses at all three lab sessions (baseline, follow-up one, and follow-up two), revealed no statistically significant effects of time on any behavioral intention items. Additionally, there were no significant group interactions for any item.

**Quitting Intentions.** Participants' intentions to quit smoking were also secondary outcomes of interest in this study. Several self-report questionnaire items assessed intentions to quit smoking and self-efficacy in making a quit attempt. Responses were measured on a 4 point likert-type scale where one stood for 'not at all likely' and 4 stood for 'very much/likely'. Repeated-measures ANOVA with condition as the between subjects factor compared quitting intentions at baseline, follow-up one and follow-up period 2, for each of the following questions: (a) how much do you want to quit smoking in the next 6 months, (b) how likely is it that you will try to quit if

smoking in the next 6 months, (c) what is the possibility that you will still be smoking 5 years from now, and (d) how likely is it that you would be able to quit smoking if you tried in the next six months. The first two items pertain to quitting intentions and the latter to self-efficacy in quitting.

A repeated-measures ANOVA performed on desire to quit smoking in the next 6 months at each lab session (baseline, follow-up one, and follow-up 2) revealed no statistically significant effect of time and no interaction with condition. A repeated measures ANOVA performed on likelihood of trying to quit in the next 6 months revealed a significant effect of time [ $F(2,74)=5.17$ ,  $p=0.008$ ] following a linear pattern [ $F(1,37)=7.56$ ,  $p=0.009$ ]. Specifically, reported intentions to quit in the next six months increased significantly from follow-up period 1 to follow-up period 2 [ $F(1,37)=3.96$ ,  $p=0.05$ ]. Quitting intentions increased, but not significantly, from baseline to follow-up session 1. There were no interactions with condition for likelihood of trying to quit smoking in the next six months. A repeated measures ANOVA performed on likelihood of still being a smoker after five years performed on responses at all three time points (baseline, follow-up one, and follow-up two) revealed a significant effect of time [ $F(2,74)=11.9$ ,  $p=0.000$ ] following a quadratic pattern [ $F(1,37)=11.17$ ,  $p=0.002$ ]. Specifically, participants felt they would be less likely to still be a smoker after five years from baseline to follow-up period 1 [ $F(1,37)=21.3$ ,  $p=0.000$ ]. Changes from follow-up session 1 to follow-up session 2 were not statistically significant. There were no interactions between time and condition. Finally, a repeated-measures ANOVA comparing participants' perceived ability to quit smoking during an attempt in the next six months performed for baseline, follow-up session one, and follow-up session 3

revealed a significant effect of time [ $F(2,76)=6.16, p=0.003$ ], following a linear pattern [ $F(1,38)=10.99, p=0.002$ ]. Participants' belief in their ability to quit increased significantly from baseline to follow-up session 1 [ $F(1,38)=7.37, p=0.01$ ]. Responses did not change significantly from follow-up session one to follow-up session 2.

**Tobacco Risk Perception.** Participants in this study also completed a risk perception exercise at each visit to evaluate the possibility of changes in their perception of the risk of tobacco use to their personal health over the course of their participation. Participants indicated their agreement with four items concerning perceived personal risk of tobacco use using a number from 1 to 7, where 1 indicated disagreement and 7 indicated agreement. Items measured were: (a) it would be harmful to my health if I smoked a cigarette right now, (b) it would be harmful to my health if I smoked a pack of cigarettes right now, (c) it would be harmful to my health if I smoked a cigar right now, and (d) it would be harmful to my health if I chewed tobacco or snuff right now. Repeated-measures ANOVA was performed on each item at baseline, follow-up session one, and follow-up session two with condition as a between-subjects factor.

**Perceived Personal Risk of Smoking a Cigarette.** A significant effect of time was found for perceptions of harm from smoking a cigarette right now [ $F(2,76)=3.95, p=0.023$ ] following a quadratic pattern [ $F(1,38)=4.28, p=0.045$ ]. Figure 16 presents the mean level of agreement with perceived personal harm from smoking a cigarette right now at each lab session. Specifically, agreement dropped slightly in the control group only between baseline and follow-up session one [ $F(1,38)=0.78, p=n.s.$ ] and then increased from follow-up session one to follow-up session two [ $F(1,38)=7.85, p=0.008$ ]. A time by condition interaction approaching significance [ $F(1,38)=3.92; p=0.055$ ] was



seen for those participants in the control group, whose mean agreement scores increased significantly [ $F(1,19)=5.99$ ,  $p=0.025$ ] from follow-up session one to follow-up session 2.

**Perceived Personal Risk of Smoking a Pack of Cigarettes.** Figure 17 presents the mean level of agreement that it would be personally harmful to health to smoke a pack of cigarettes right now, measured at each lab session. Repeated-measures ANOVA examining personal perceptions of the harm from smoking a pack of cigarettes was performed for each of the three lab sessions with condition as a between-subjects factor revealed an effect of time approaching significance for the entire group [ $F(2,76)=3.13$ ,  $p=0.055$ ]. Specifically, perceived harm remained similar from baseline to follow-up session one [ $F(1,38)=1.79$ ,  $p=n.s.$ ] and then increased significantly from follow-up session one to session two [ $F(1,38) = 6.27$ ,  $p=0.017$ ]. There were no interactions with condition observed on this item.

**Perceived Personal Risk of Smoking a Cigar.** Repeated measures ANOVA was performed across all three lab session with condition as a between-subjects factor to examine the perceived personal harm of smoking a cigar. Perceived risk did not change significantly over the course of the entire study [ $F(2,76)=1.73$ ,  $p=n.s.$ ] and there was not a significant interaction with condition. However, perceived harm of smoking a cigar did increase significantly for the entire group from follow-up session one to follow-up session two [ $F(1,38)= 5.71$ ,  $p=0.022$ ]. Mean levels of agreement with perceived harm measured at each lab session are presented in Figure 18.

**Perceived Personal Risk of Using Chewing Tobacco or Snuff.** Repeated measures ANOVA was performed across all three lab session with condition as a between-subjects factor to examine the perceived personal health harm of using chewing

tobacco or snuff. The mean levels of agreement are presented in Figure 19. Perceived risk did not change significantly over the course of the entire study [ $F(2,76)=1.22$ ,  $p=n.s.$ ] and there was not a significant interaction with condition. Perceived risk also remained similar between baseline and follow-up session one and follow-up session one and two. On a scale of 1 to 7, where 7 indicates the highest level of agreement, mean agreement scores with the statement “It would be harmful to my health if I chewed tobacco or snuff right now,” for the entire group at sessions 1, 2, and 3 were  $5.8 \pm 0.19$ ,  $5.5 \pm 0.27$ , and  $5.8 \pm 0.27$ , respectively.

### **Confirmation of Hypotheses**

#### **Hypothesis 1: Effect of level of experience on evaluations of Ariva®.**

It was hypothesized that after a guided sample in the lab, participants who were instructed to try at least 2 pieces of Ariva® for 5 days outside of the lab (experience group) would have more favorable product evaluations following a second trial in the lab than those participants without additional experience with Ariva® outside the lab (control group). This hypothesis was **not supported** with respect to the overall product evaluation items, including product excellence, excellence compared to cigarettes, overall satisfaction with the product, and overall satisfaction compared to cigarettes.

It was also hypothesized that participants with the most experience with Ariva® would have more favorable evaluations on the overall evaluation items at the third lab session. This hypothesis was **not supported**. Instead, a statistically significant increase in mean levels of endorsement of overall product excellence was seen among both groups from follow-up session one to follow-up session 2. No statistically significant differences

were found in the remaining overall evaluation items either between the groups or across evaluation points.

## **Hypothesis 2: Subjective Effects of Ariva® in Experienced and Novice Users**

It was hypothesized that participants in the experience group would report more favorable subjective effects of lab trial of Ariva® at each follow-up session than participants in the control group. Subjective effects include product evaluation items related to drug effects, palatability, and convenience factors. This hypothesis was **not supported** for items pertaining to drug effects on the product evaluation items or the VAS items at follow-up session one. There were no statistically significant group differences in the evaluation of the product relating to drug effects from baseline to follow-up period one. Instead, statistically significant linear trends were observed within subjects from baseline to follow-up period one for these items: endorsement of the statement “I did not need a cigarette while using the product” decreased; endorsement of the statement “the product provides enough nicotine” increased, endorsement of the statement “I would use the product just to get the drug effect,” increased, and finally, reported dislike of the drug effect increased. Additionally, there was no interaction of condition on VAS drug effect items pertaining to cigarette craving. Instead, a significant decrease in cigarette craving was seen in all participants from baseline to follow-up session one. Hypothesis two was **not supported** with regard to palatability at follow-up session one or follow-up session two. There were no statistically significant group differences in ratings of palatability at follow-up session one or follow-up session two. Additionally, palatability ratings also did not change significantly across time points within subjects, with the exception of reported intent to use the product, “just to get the

drug effect,” which increased from baseline to follow-up session one. Hypothesis two also was **not supported** in regard to ratings of convenience factors. There were no statistically significant differences in response to convenience factors by condition at follow-up session one or two. There were no statistically significant within subject changes across sessions. Finally, hypothesis two was **partially supported** with regard to subjective effects of the product in reducing cigarette craving. At the final lab session, participants in the experience group expressed they would be significantly less likely to still crave cigarettes if they used the product regularly than those in the control group.

### **Hypothesis 3: Behavioral Effects of Ariva® Experience**

It was hypothesized that after a guided sample in the lab, participants in the experience group would exhibit more favorable behavioral responses to Ariva® during a period of natural use outside of the lab than participants in the control group. Specifically, it was predicted that participants in the experience group would use more pieces of Ariva® than the control group during the natural use period. This hypothesis was **not supported**. Participants in the experience group did not use statistically significantly more Ariva® during the natural use period (i.e. follow-up period two), nor did they use statistically more pieces of Ariva® on average, each day, than those participants in the control group. Overall and average daily Ariva® use was similar among participants in both groups. In addition, it was hypothesized that participants in the experience group would smoke fewer cigarettes per day during the natural use period than participants in the control group. This hypothesis was **not supported**. In fact, average daily cigarette use increased among participants in the experience group during the natural use period and decreased among participants in the control group.

### **Summary and conclusions: Experiment Two**

The main goals of experiment two were 1) to replicate the acceptability of Ariva® among smokers demonstrated in study one and the preliminary investigations of other researchers and 2) to explore the impact of increased experience with Ariva® outside of the lab. Specifically, it was hypothesized that participants in the second experiment, who had additional guided use of the product outside of the lab, would evaluate the merits of the product and its subjective effects more favorably than participants who did not have guided use outside of the lab. This hypothesis was not supported. In general, there were not extensive differences in measures of the product's merits or subjective effects between the two experimental groups. In other words, using a minimum daily amount of Ariva®, on a self determined schedule, in daily life did not result in substantially more favorable assessments of the product at follow-up lab visits or during a period of *ad libitum* use outside of the lab compared to lab trials only. Rather, the perceived merits and favorable subjective effects of Ariva® generally increased over time among both groups. For example, participant endorsement of overall product excellence, increased significantly from baseline to session 3. In addition, over the course of the study, participant also agreed more strongly that Ariva® is an excellent product, compared to cigarettes.

This is the first report, to our knowledge, of smokers' evaluations of a reduced exposure non-smoked tobacco product in the context of continued smoking that included repeated lab trials, a period of guided use, and an *ad libitum* period of use. This design provided an opportunity to examine smokers' assessments of this product on its own merits, in the context of harm reduction (or smoking reduction), and when used at

smokers' discretion. A clinical trial comparing Ariva® to medicinal nicotine replacement lozenges (Mendoza-Baumgart, *et al*, unpublished manuscript) provided essential evidence that Ariva® could reduce tobacco toxin exposure when used by abstinent smokers to levels that were comparable to reductions observed with NRT. Smokers' preference for Ariva® over medicinal nicotine lozenges also provided preliminary evidence in support of suggestions that smokers who substituted Ariva® for smoking could achieve reductions in toxin exposure consistent with the premises of harm reduction. However, participants in this clinical trial were only queried about their preference for Ariva® versus NRT. Clarifying details concerning general evaluations of Ariva®, on its own merit and in relationship to cigarettes, were not collected. In study two, we demonstrated that smokers do have favorable evaluations of Ariva® outside of a forced comparison to NRT, and also in comparison to cigarettes. These findings provide support for theoretical arguments that some smokers might use non-smoked reduced exposure tobaccos for harm reduction and that non-smoked tobacco might also be a viable choice for some smokers as a smoking substitute.

It was further hypothesized that participants in the guided use, or experience group, would 1) use more Ariva® and 2) smoke fewer cigarettes during the natural use period than participants who did not have a guided use period outside of the lab. This hypothesis was also not supported. Participants in the experience group did not use significantly more (or less) Ariva® during the *ad libitum* use period than participants in the control group. On average, they used the instructed amount of at least two pieces of Ariva® per day during the guided use period and smoking decreased, on average, by about 5 cigarettes per day, from self-reported CPD smoked at baseline. Subsequently,

during the natural use period, the experience group's average daily use of Ariva® decreased from about 2 during the guided use period to about 1 piece per day during the natural use period. When Ariva® use decreased in the experience group, the amount of cigarette smoking also rebounded, but not to self reported levels at baseline. This is not entirely unexpected because participants in the experience group were specifically asked to replace at least two cigarettes per day during the guided use period.

It was unexpected to find that during the natural Ariva® use period, participants in the control group exhibited a significant decrease in smoking compared to follow-up period one. After two guided samples in the lab, smokers provided with Ariva® to use at their discretion, appeared to exhibit a small voluntary decrease in smoking. Ariva® use during the discretionary period was quite modest, averaging about one piece per day. This corresponded to a modest reduction of about 1.7 cigarettes per day.

These findings add to our understanding of the potential of non-smoked reduced exposure tobacco products to impact smoking behavior, and subsequently, effect tobacco harm reduction. The voluntary use of Ariva® by the majority of participants provides some support for the viability of substitution of non-smoked tobacco among some smokers. However, neither guided exposure to Ariva® outside of the lab, nor persuasive arguments advocating use of this product, appeared to have a strong impact on either 1) discretionary use of Ariva® or 2) smokers' evaluations of the product's utility. A lack of tremendous excitement about Ariva®, in particular, and harm reduction achieved via non-smoked tobacco, in general, suggests that smokers are unlikely engage in the degree of large scale substitution or product switching as might be hoped. Since most smokers were receptive to sampling this product, it is possible that use in the general population of

smokers would indeed, occur intermittently, and perhaps in situations of extended smoking restrictions.

The finding that Ariva® use and smoking reduction were modest despite relatively positive product evaluations provides additional evidence that any product intended to reduce smoking, be it a reduced exposure tobacco or a NRT product, will have to be very enticing and likable to compete with cigarettes. Certainly, this is in line with the calls of NRT researchers to make nicotine therapies more palatable (Schneider *et al*, 2005). It also highlights the complexity of the reinforcing qualities of smoking in addition to the drug effects of nicotine. This study did provide support for the assertion that liking Ariva® was related to greater voluntary use. While this may seem self-evident, it is also in line with research concerning the difficulty in predicting a preference for any particular NRT. However, smokers do tend to use more of products they like. Given the low TSNA levels and nicotine levels in Ariva®, even compared with medicinal nicotine products, it may be worth offering this product as a possibility to smokers who have not been able to tolerate any NRT products. It has been recommended by other researchers that allowing smokers to “sample” or “pre-test” NRT products during clinical office visits to promote voluntary use of these products and prevent failed quit attempts due to poor product acceptability and failed expectations (Schneider, *et al*, 2006; Schneider *et al*, 2004). This study provides support for the utility of product lab trials in identifying those individuals with the most positive reactions and greatest likelihood of successfully using a substitute source of nicotine to reduce smoking.

Regardless of the potential of Ariva® to reduce tobacco harm among smokers, there are substantial concerns about the impact of 1) relative tobacco risk information and



2) experience with reduced exposure products on smokers' (and others') perceptions of the risk related to tobacco use and smoking. Some specific concerns include the ability of smokers to understand the concept of relative risk accurately. It is of concern that smokers may mistakenly interpret information about "safer" tobacco products as meaning that those products are safe. In addition, there is concern that suggesting any degree of relative risk among tobacco products will diminish the perceived risk of cigarette smoking. This study explored smokers' perceptions of risk at each lab session. Specifically, participants provided a baseline assessment, prior to reading the product information and sampling the product, of the risk to their personal health from 1) smoking a cigarette right now, 2) smoking a pack of cigarettes right now, 3) smoking a cigar right now, and 4) using snuff or chewing tobacco right now. They also provided assessments of these items at each of the follow-up lab sessions.

The results did not support concerns that providing relative tobacco risk information or exposure to a reduced risk tobacco might diminish perceived harm from tobacco. Instead, these results suggest that smokers were able to accurately interpret elements of the relative risk information presented to them concerning the role of tobacco smoke in causing health harm. For example, agreement that it would be harmful to health to "smoke a cigar right now," increased significantly for the entire sample from baseline to time 1. Although no information was presented to participants expressly concerning the risks of cigar smoking, the increase in perceived health harm demonstrated at time 2 suggests that participants clearly understood the emphasis in the product information on the role tobacco smoke in causing harm to health.

Perceived risk of smoking a cigarette also did not change significantly among the participants in the experience group over the lab sessions; however, participants in the control group demonstrated a slight decrease in their perceived risk from smoking a cigarette right now from baseline to time 2, when they were instructed to smoke as usual instead of being offered Ariva®. However, from time two to time three, control participants' perceived harm from smoking a cigarette increased significantly. Similarly, perceived harm from smoking a pack of cigarettes did not change from baseline to time two, after participants read a message describing arguments supporting the use of Ariva® by smokers. Instead, perceived harm increased significantly for the entire sample from time 2 to time 3. Finally, it might have been expected that the use of a non-smoked tobacco product in this research would decrease participants' perceived risk of using smokeless tobacco products, but this was not the case. Participants' continued to perceive smokeless tobacco as harmful to health over the course of the study. Taken together, these results suggest that neither information about reduced exposure non-smoked tobacco, nor actual experience with such a product had a negative impact on participants' perceived harm from smoking and tobacco use. These results emphasize the complexity of smoking behavior and highlight the need to continue to strive to identify viable strategies to reduce smoking.

Clearly, there were limitations to this study. First, a relatively small sample may have limited the ability to detect effects of the manipulation on certain aspects of the product evaluations. In addition, despite randomization to the study conditions, some differences in baseline product evaluations and years as a smoker limit the ability to make definitive conclusions about the impact of the intervention. As harm reduction may be

less relevant to individuals who have not smoked for long periods, it was hoped that stricter study inclusion criteria would reduce the difference in years as a regular smoker. However, recruitment limitations in this college community required the relaxation of requirements concerning heaviness of smoking, in particular. Future studies might benefit from focusing specifically on individuals who have smoked for many years. In addition, it is possible that the increases in favorable product evaluations and liking demonstrated were due to selection bias. For example, West and colleagues (2004) suggested such an effect among smokers in their study who pre-viewed information about NRT systems but knew which drug they would be assigned. In this case, participants came to like any NRT system to which they were assigned and it is possible that such a phenomenon could explain the reactions to Ariva® in this study.

Several additional factors also limit the ability to make generalizations utility of Ariva® in promoting smoking reductions demonstrated in this study. First, although substantial efforts were made to ensure the accuracy of participants' reported tobacco use, these measures were ultimately self-reported and may not have precisely reflected actual smoking and tobacco use outside of the lab. Efforts to develop simple, efficient and accurate methods of self reports of tobacco use must continue. Second, the short time frame of this study prevents speculation concerning whether demonstrated smoking reductions would continue over time. Indeed, some researchers studying smoking reduction programs have reported smokers' difficulty in maintaining smoking reductions, even with the aid of NRT therapies (Hecht, *et al*, 2004). Third, it is unknown whether or how long smokers might continue to use Ariva® of their own accord. Samples were provided to participants in this study. It will be essential for future studies of harm

reduction products to develop mechanisms to continue to observe participants over time and track product use, including purchasing habits.

It is also important to bear in mind that the reductions in average daily smoking seen in this study may not translate directly to reduced health risks for smokers. It is possible that the relatively small reduction in smoking is not enough to impact health outcomes. It is also possible that use of a non-smoked product such as Ariva® could be accompanied by changes in smoking topography, such as smoking individual cigarettes more intensely. It is essential to continue to develop and refine methods of collecting and analyzing biomarkers of tobacco harm.

In conclusion, despite limitations, study two has contributed to our understanding of the role of a specific non-smoked, low TSNA hard tobacco, Ariva®, in tobacco harm reduction. This study has replicated the acceptability of this non-smoked product to cigarette smokers, by demonstrating that some smokers will use this product voluntarily and give it fair evaluations compared to smoking. Favorable evaluations increase over additional brief exposures. Ability to self regulate nicotine levels with this product may also increase after more intense exposure. These findings also provide a practical basis for theoretical arguments proposing the use of non-smoked, low TSNA tobaccos as a methods harm reduction among smokers, but emphasize that their utility will be limited by the extent to which smokers like the product. Smokers who find this product likable, and use it regularly may be able to achieve significant reductions in smoking. However, it is unlikely that Ariva® will be able to substitute for smoking among a large population of smokers. Certainly, more research is needed to replicate the usage patterns and

smoking reductions demonstrated in this study and evaluate subsequent harm reduction through the analysis of reliable and valid biomarkers of tobacco harm.

Figure 1: Study Time Line Experiment 2

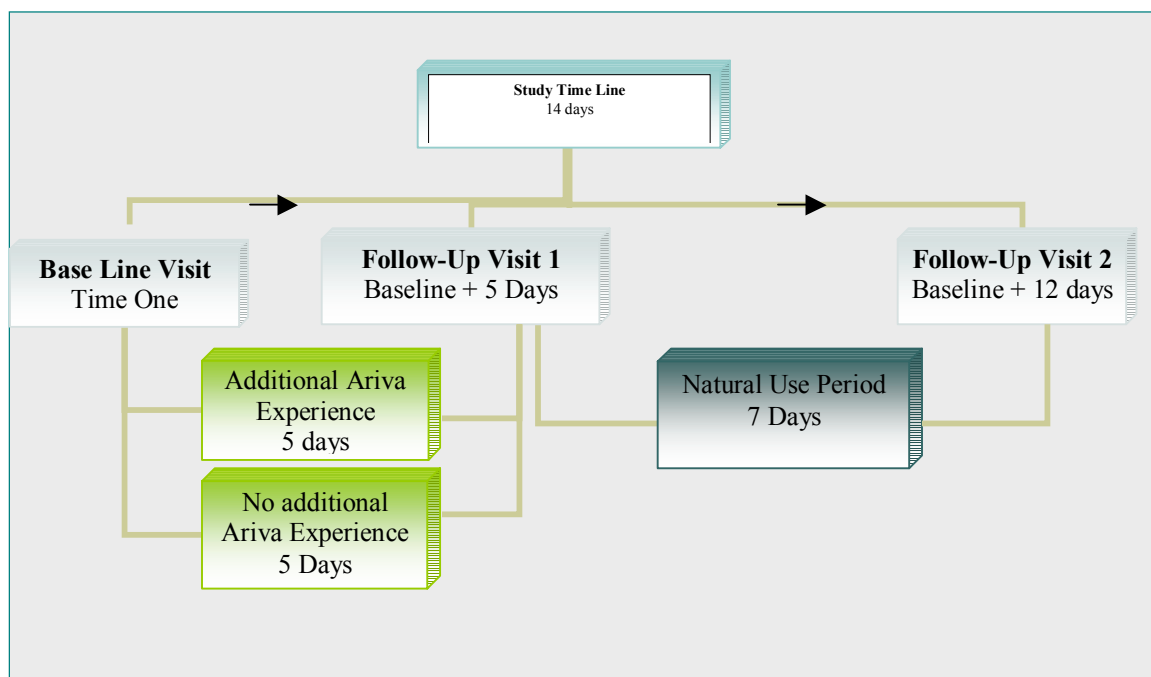


Figure 2: Lab Session Time Line Study Two

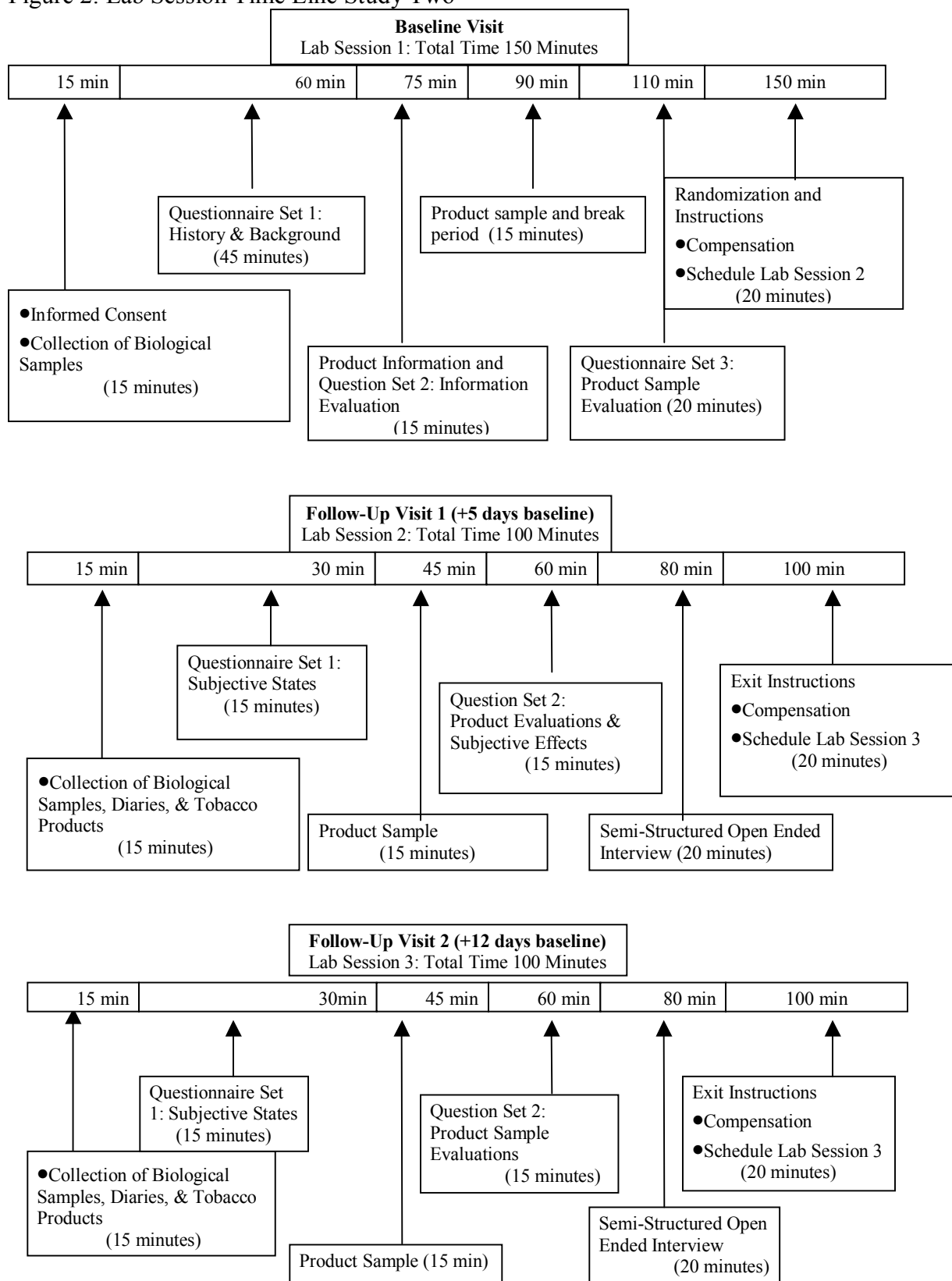


Figure 3: Average Daily Number of Cigarettes Smoked ( $\pm$  SEM) at Each Lab Session by Condition.

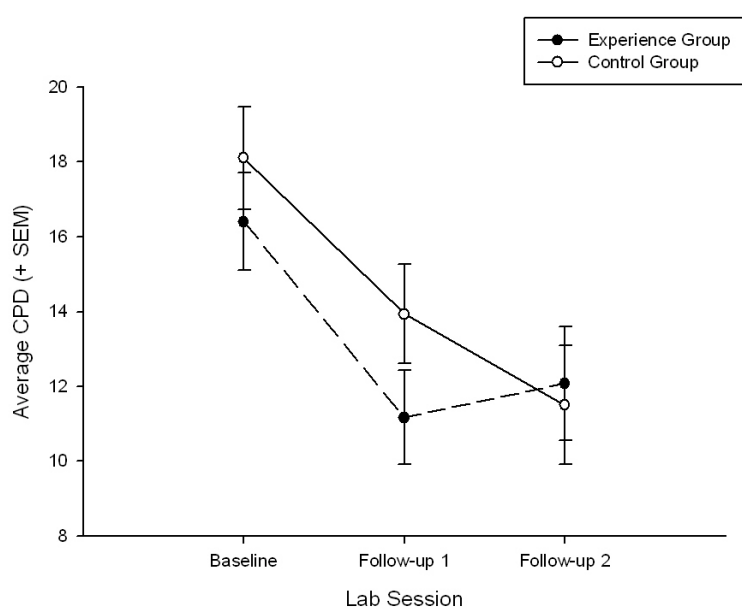




Figure 4: Mean Agreement ( $\pm$  SEM) with Overall Product Excellence at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent More Agreement.

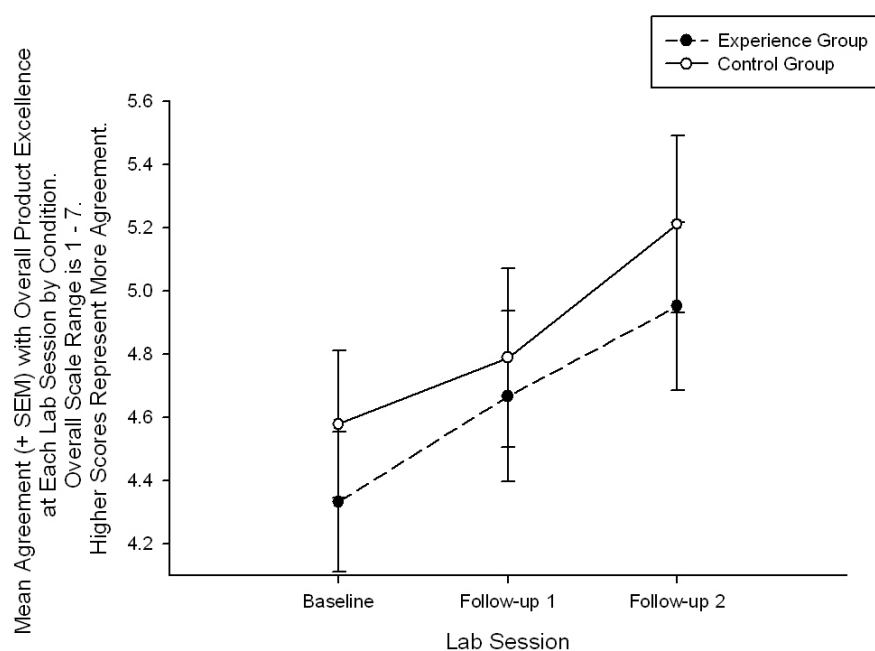


Figure 5: Mean Agreement ( $\pm$  SEM) Score with Product Provides Relief of Nicotine Withdrawal at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent More Agreement.

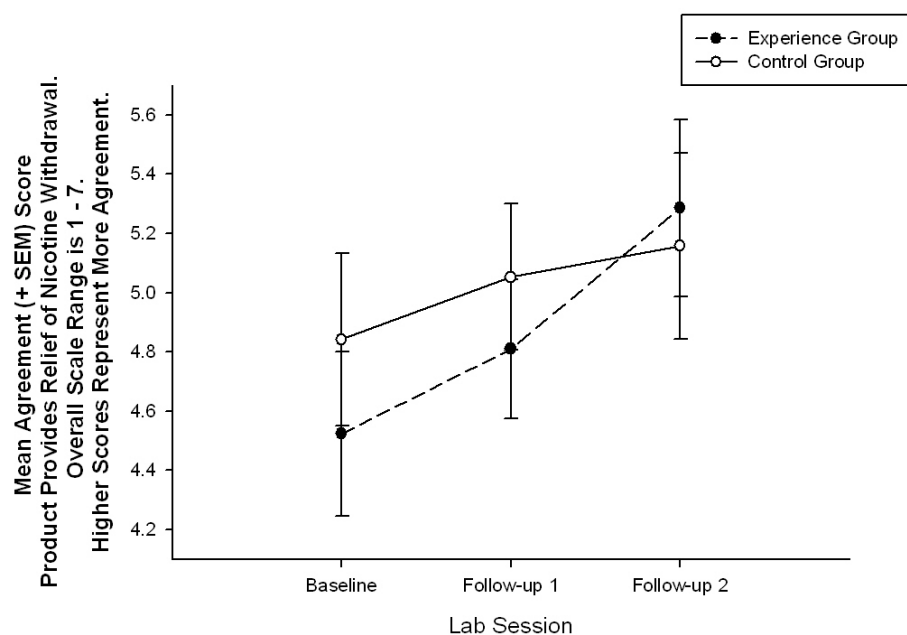


Figure 6: Mean Agreement ( $\pm$  SEM) Score with Product Provides Relief of Urge to Smoke at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent More Agreement.

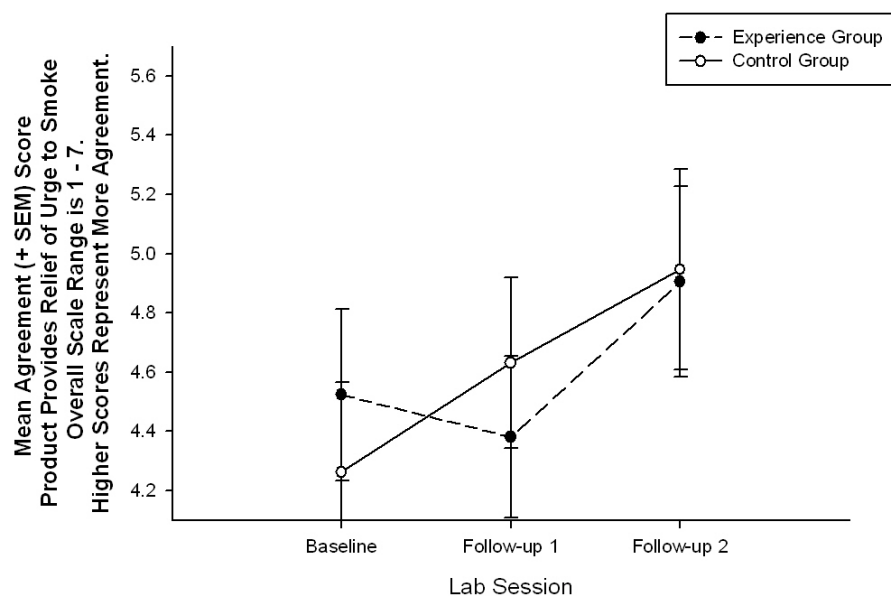


Figure 7: Mean Agreement ( $\pm$  SEM) Score with Did Not Need Cigarettes While Using Product at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent More Agreement.

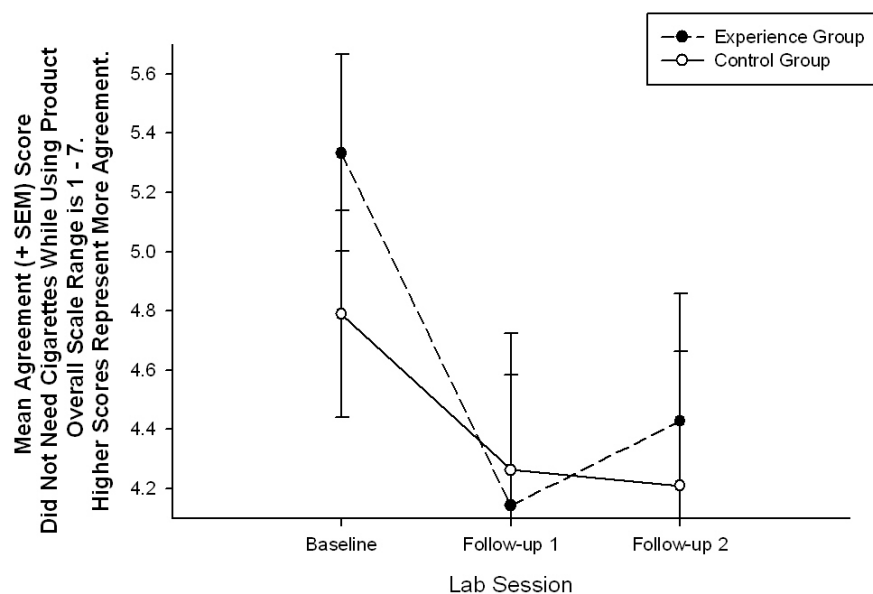


Figure 8: Mean Agreement ( $\pm$  SEM) Score with Product Provides Enough Nicotine at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent More Agreement.

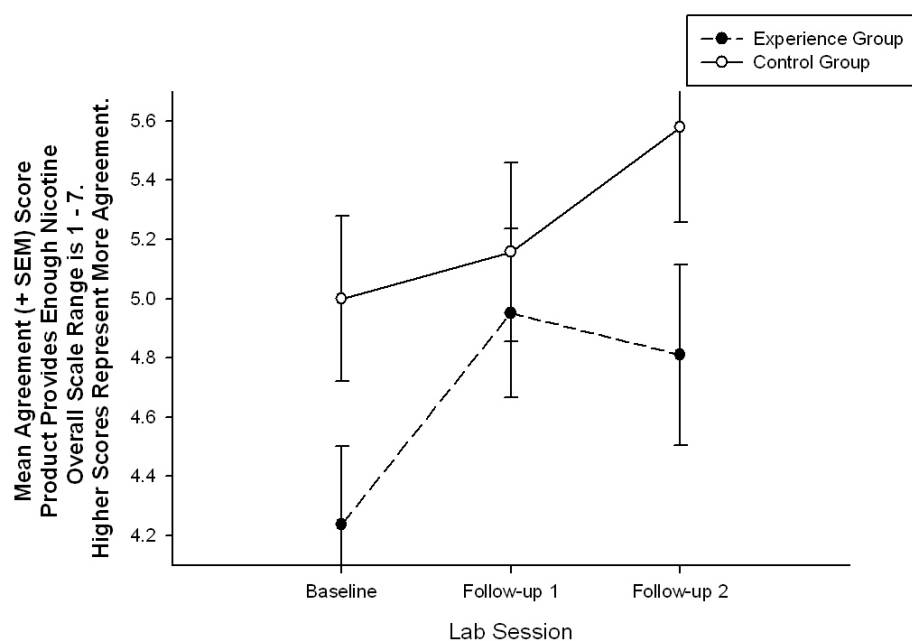


Figure 9: Mean Agreement ( $\pm$  SEM) Score with “I Believe I Would Still Crave Cigarettes if I Used the Product Regularly,” at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent More Agreement.

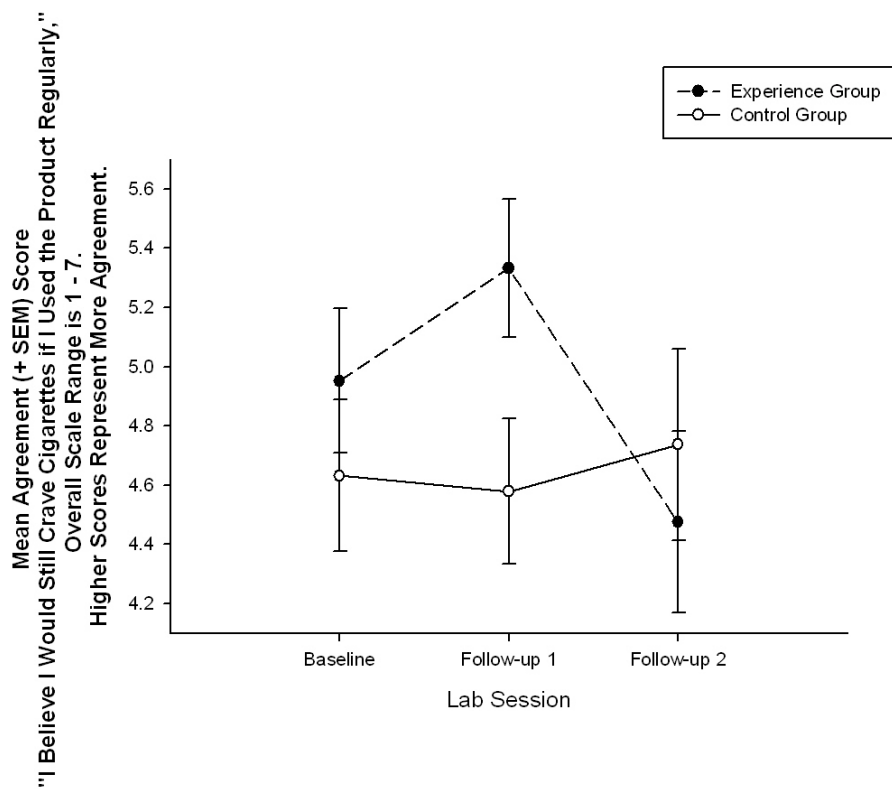


Figure 10: Mean Agreement ( $\pm$  SEM) Score with “I Would Use the Product Again,” at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent More Agreement.

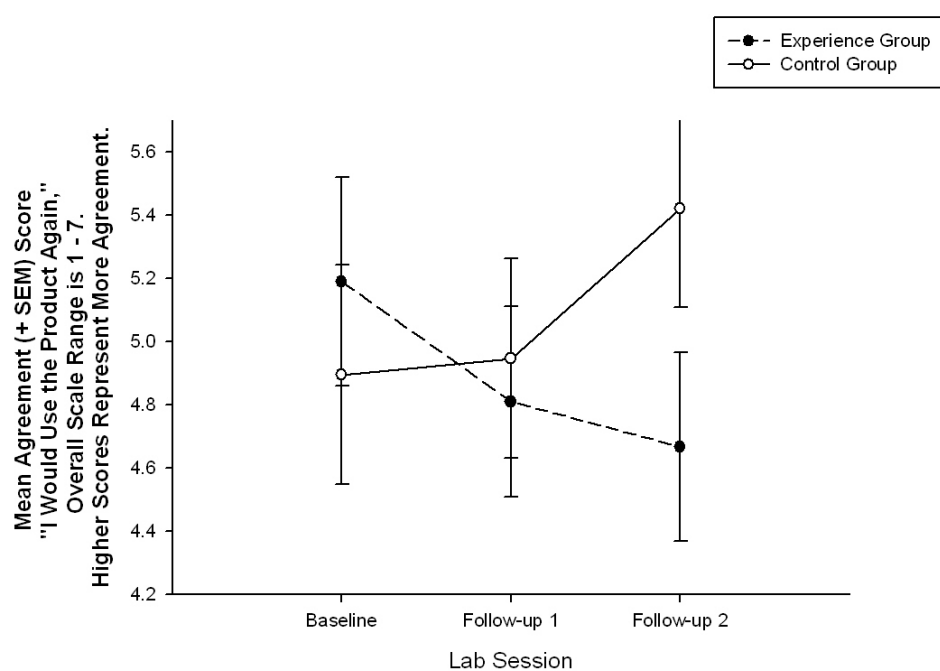


Figure 11: Mean Agreement ( $\pm$  SEM) Score with “I Would Tell My Friends Who Smoke to Use the Product,” at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent More Agreement.

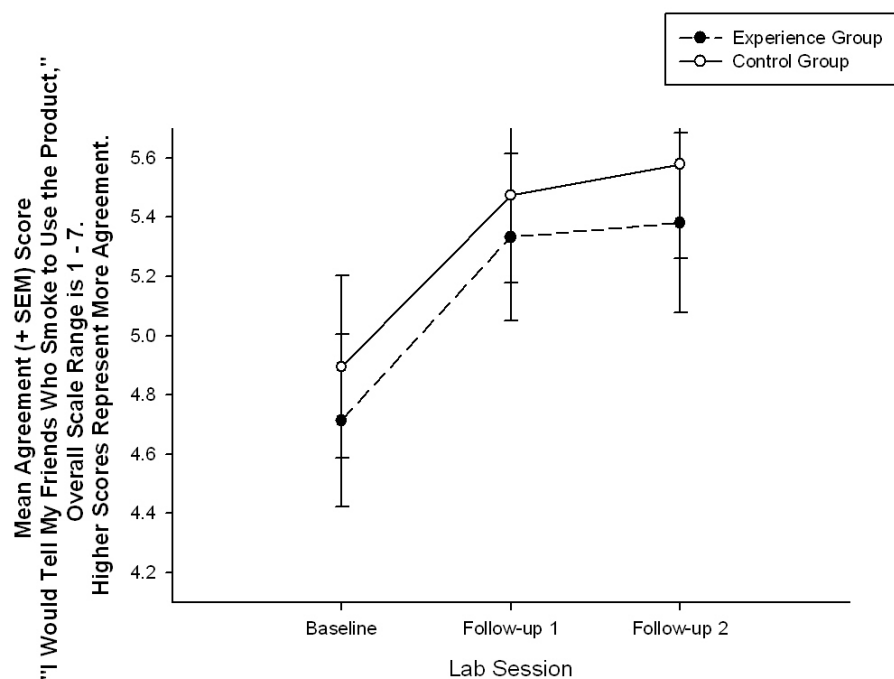




Figure 12: Mean Agreement ( $\pm$  SEM) Score with “Product is an Excellent Product, Compared to Cigarettes,” at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent More Agreement.

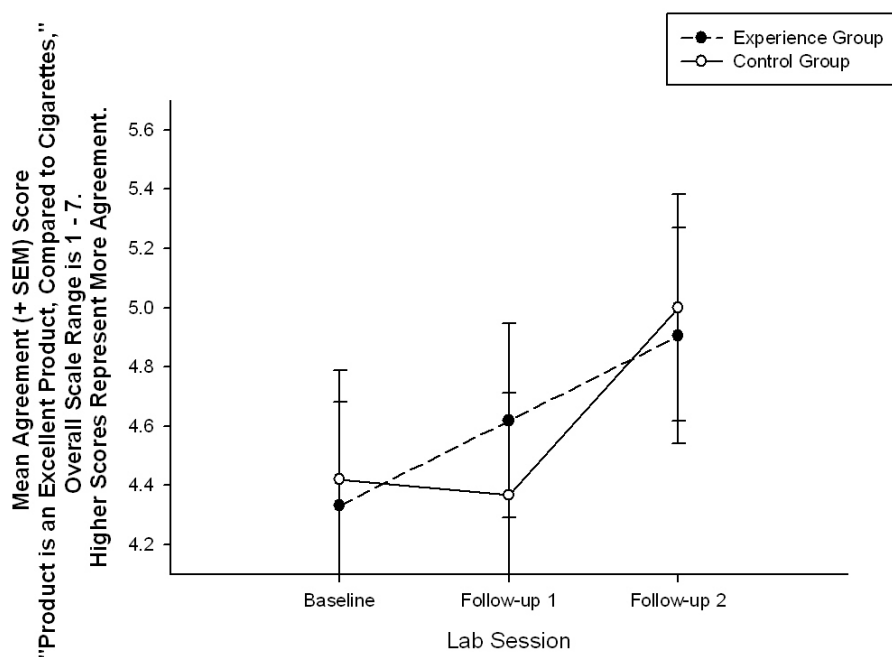


Figure 13: Mean Endorsement ( $\pm$  SEM)VAS Score for “Do You Feel Any Drug Effect?” at Each Lab Session by Condition. Overall Scale Range is 1 – 100. Higher Scores Represent Greater Endorsement.

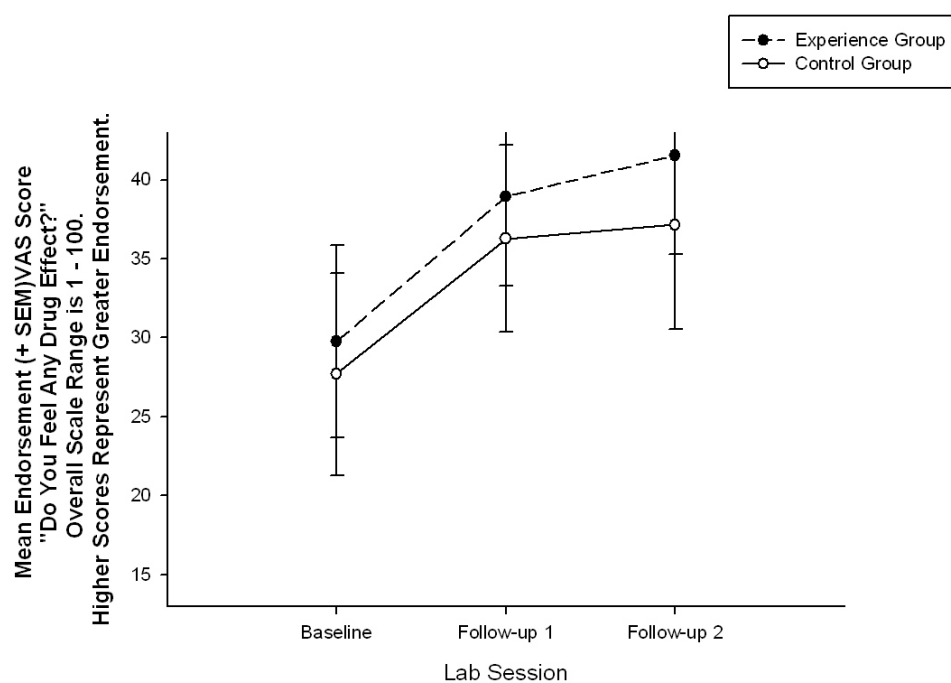


Figure 14: Mean Endorsement ( $\pm$  SEM)VAS Score for “Does the Drug Have Any Bad Effects?” at Each Lab Session by Condition. Overall Scale Range is 1 – 100. Higher Scores Represent Greater Endorsement.

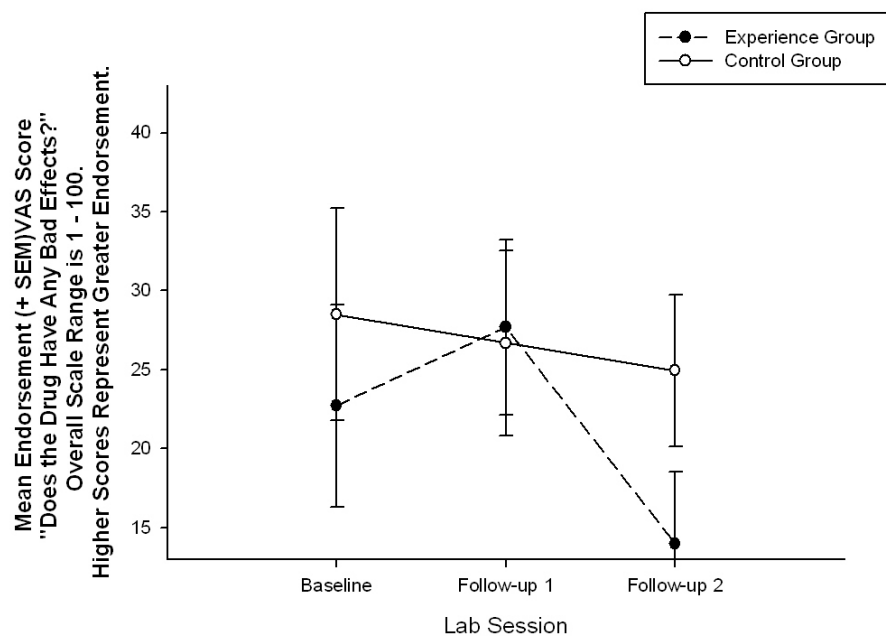


Figure 15: Mean Endorsement ( $\pm$  SEM)VAS Score for “Do You Dislike the Drug Effect?” at Each Lab Session by Condition. Overall Scale Range is 1 – 100. Higher Scores Represent Greater Endorsement.

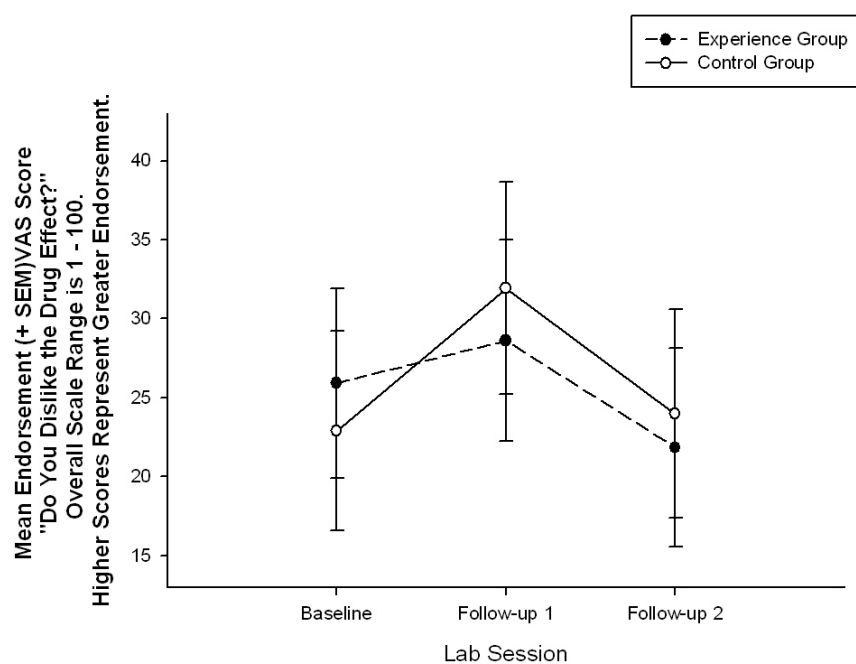


Figure 16: Mean Level of Perceived Personal Risk ( $\pm$  SEM) of Smoking a Cigarette measured at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent Greater Perceived Risk.

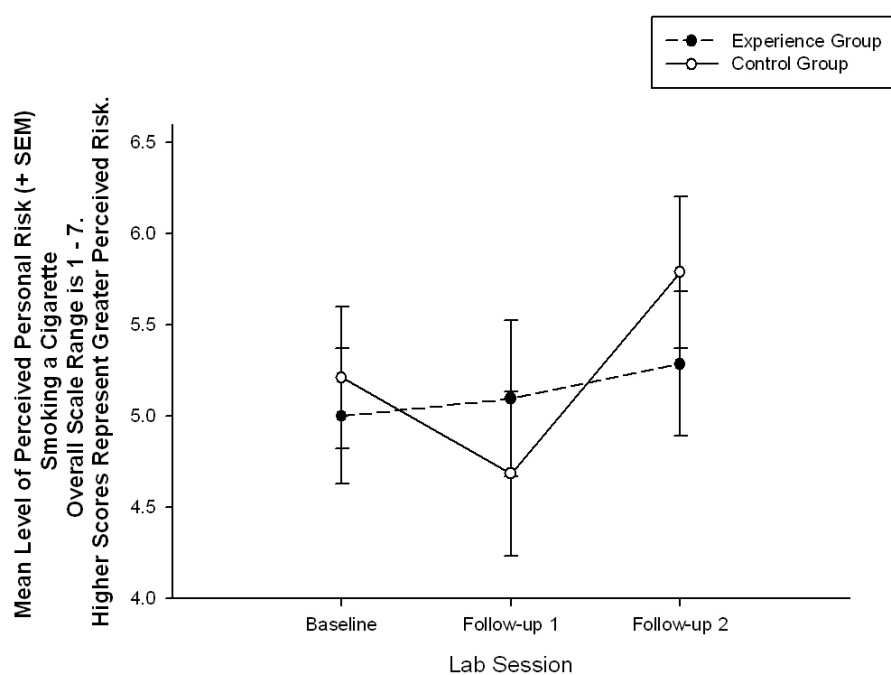


Figure 17: Mean Level of Perceived Personal Risk ( $\pm$  SEM) of Smoking a Pack of Cigarettes measured at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent Greater Perceived Risk.

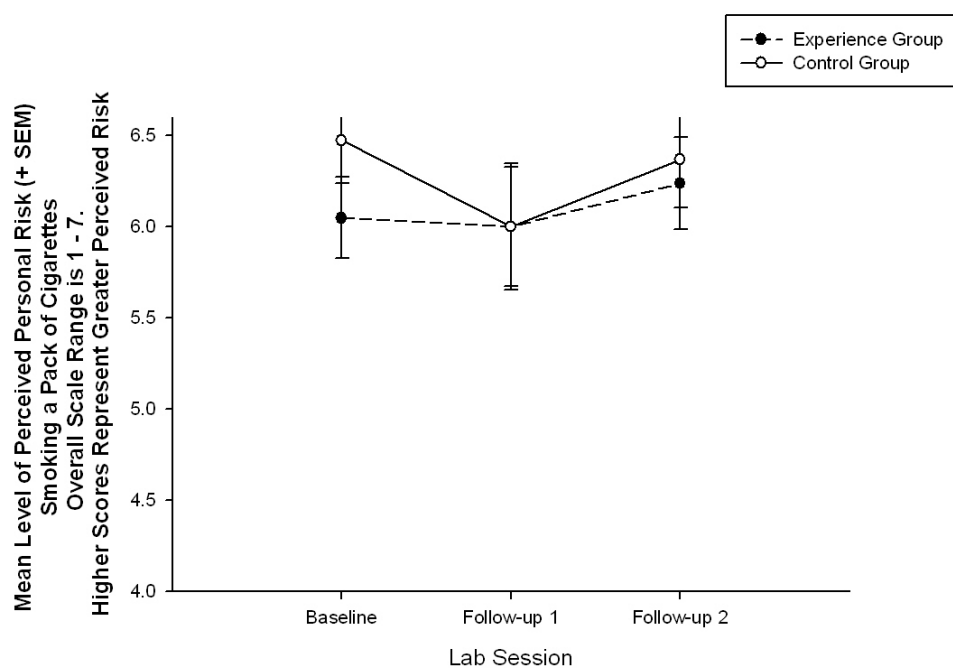


Figure 18: Mean Level of Perceived Personal Risk ( $\pm$  SEM) of Smoking a Cigar measured at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent Greater Perceived Risk.

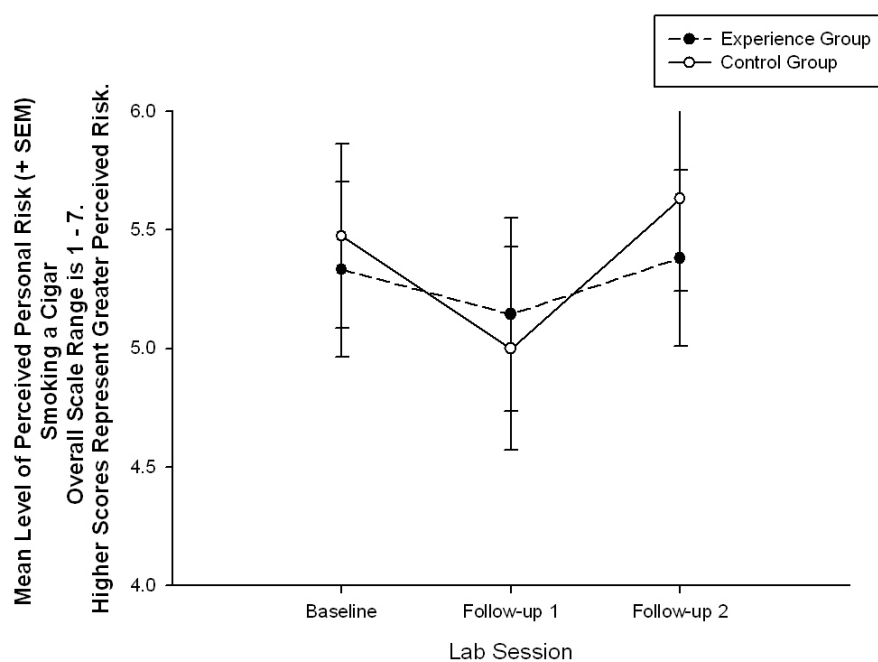


Figure 19: Mean Level of Perceived Personal Risk ( $\pm$  SEM) of Using Snuff or Chewing Tobacco measured at Each Lab Session by Condition. Overall Scale Range is 1 – 7. Higher Scores Represent Greater Perceived Risk.

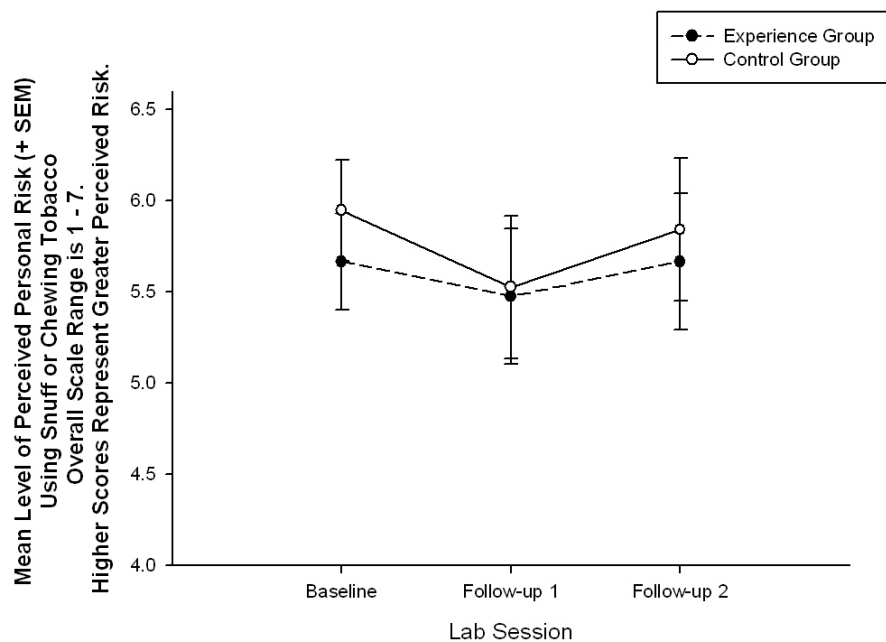




Table 2: Average Daily Ariva® Use vs. Average Cigarettes per Day (CPD)  
(Mean  $\pm$  SEM)

| <b><u>Group</u></b>                | <b><u>Baseline</u></b><br><i>CPD</i> | <b><u>Follow-Up Period 1</u></b><br>Ariva®/CPD | <b><u>Follow-up Period 2</u></b><br>Ariva®/CPD |
|------------------------------------|--------------------------------------|--|--|
| <b>Experience</b><br><b>(n=21)</b> | 16.40 ( $\pm 0.88$ )                 | 2.14 ( $\pm 0.27$ )/11.17 ( $\pm 0.94$ )       | 1.27 ( $\pm 0.31$ )/12.08 ( $\pm 1.24$ )       |
| <b>Control</b><br><b>(n=19)</b>    | 18.11 ( $\pm 1.73$ )                 | n/a / 13.94 ( $\pm 1.61$ )                     | 1.03 ( $\pm 0.23$ )/11.50 ( $\pm 1.86$ )**     |

Note: CPD = Cigarettes per day. Control group participants used no Ariva® during Follow-up period 1. Baseline CPD are self-reported. \*\*Average CPD decrease is significant from Follow-up period 1 to Follow-up period 2 for control group participants [F(1,38)=10.64, p<0.01].

Table 3: Intentions to Use Ariva® across study sessions by condition

|   | <b>Baseline</b><br>Experience/Control<br>(Mean ± SEM) | <b>Lab Session 2</b><br>Experience/Control<br>(Mean ± SEM) | <b>Lab Session 3</b><br>Experience/Control<br>(Mean ± SEM) |
|---|---|--|--|
| <b>How likely would you be to use Ariva®:</b>           |   |  |  |
| <b>Ever again</b>                                       | 4.57 (±0.29)/4.84 (±0.42)                             | 4.29 (±0.30)/5.00 (±0.32)                                  | 4.95 (±0.30)/5.16 (±0.31)                                  |
| <b>In situation where you can't smoke</b>               | 5.57 (±0.28)/5.32 (±0.38)                             | 5.71 (±0.29)/5.58 (±0.35)                                  | 5.71 (±0.29)/5.89 (±0.24)                                  |
| <b>When you don't want to smoke</b>                     | 4.76 (±0.44)/5.21 (±0.47)                             | 4.57 (±0.32)/5.21 (±0.43)                                  | 4.90 (±0.38)/5.11 (±0.40)                                  |
| <b>To cut down on smoking</b>                           | 5.00 (±0.30)/5.37 (±0.34)                             | 5.10 (±0.32)/5.26 (±0.27)                                  | 5.29 (±0.35)/5.58 (±0.31)                                  |
| <b>To quit smoking</b>                                  | 4.81 (±0.44)/5.32 (±0.42)                             | 5.10 (±0.37)/5.63 (±0.38)                                  | 4.90 (±0.46)/5.79 (±0.26)                                  |
| <i>About how much are you willing to pay for a box?</i> | \$4.27 (±0.50)/\$4.33 (±0.42)                         | \$4.10 (±0.47)/\$3.72 (±0.23)                              | \$3.79 (±0.44)/\$4.00 (±0.24)                              |

Note: **BOLD** items scored on a scale of 1 – 7 where 1 represents the least agreement and 7 represents the most agreement. Payment is the average dollar amount (±SEM). No statistically significant differences.

## CHAPTER 4: GENERAL DISCUSSION

### **Overview**

The overall goal of this dissertation was to examine the effect of information about and experience with a non-smoked potential reduced exposure tobacco product on smoking behavior. Cigarette smoking continues to be the leading cause of preventable morbidity and mortality in the United States and globally (ACS, 2006). Prevention and cessation programs are critical components of efforts to reduce the burden of disease and death caused by smoking; however it has been recognized that additional strategies, including tobacco harm reduction must be considered to continue to achieve the maximum possible reduction in smoking and smoking related health harm (Stratton *et al*, 2001).

**Background and Relevance.** Tobacco harm reduction is a broad term that can include any efforts to reduce the harm caused by tobacco use. The phrase has been used to describe activities as seemingly disparate as recommending the use of nicotine replacement therapies in smoking cessation, to promoting exercise for current smokers, to the possible substitution of less harmful forms of tobacco for cigarettes (de Ruiter & Faulkner, 2006). Traditional smokeless tobacco, such as marketed and sold in the United States, while a very hazardous product, has been acknowledged as a less harmful form of tobacco use than cigarette smoking (Asplund, 2003). Recent research has found that users of traditional smokeless tobacco exhibit higher levels of some important carcinogens than smokers (Hecht, Carmella, Murphy, Riley, Le, Luo, Mooney, & Hatsukami, 2007) however, new non-smoked tobacco products with very low levels of TSNA are now available. Theoretically, these products have the benefits of eliminating the health harm associated with tobacco combustion and reducing exposure to a primary

tobacco carcinogen. In fact, it has been suggested multiple public health experts that smokers who cannot quit or who are unable to do so could reduce some of the health risk they face from smoking by switching to a less harmful non-smoked tobacco (Ault, Ekelund, Jackson, & Saba, 2004; Levy et al., 2004; Levy *et al*, 2006; McNeill, 2004; Rodu & Cole, 2004). Despite theoretical promise, it has also been recognized that substantial switching seems unlikely in light of 1) smokers' erroneous belief that non-smoked tobacco conveys similar or greater health risk than cigarettes, and 2) lack of knowledge of the existence of reduced exposure products, other than so-called "light" cigarettes (O'Connor, *et al*, 2005; Jensen, Babb, Hatsukami, & Avery, 2004). Furthermore, little is known about smokers' actual use of reduced exposure tobacco, especially non-smoked products. Therefore, questions exist concerning the ability of reduced exposure tobacco to confer significant risk reduction to smokers, particularly within the context of ongoing smoking.

To begin to address these questions, experts in tobacco control and public health have recommended a comprehensive framework outlining specific research questions and a model to explore them that includes conducting 1) preclinical evaluation, 2) clinical evaluation of (a) exposure reduction, (b) health effects, and (c) marketing research; and 3) population effects. It is hoped that research in these domains will produce insight into tobacco use behaviors that can inform prevention and cessation efforts, in general, and the development of accurate and comprehensible relative risk information, in particular. In light of persistent misunderstanding of relative tobacco risks among smokers (O'Connor *et al*, 2005) there are significant questions about how to properly and accurately convey relative tobacco risk to smokers.

Consistent with calls for more research of reduced exposure tobaccos, the goal of this dissertation research was to explore smokers' use of a low TSNA, non-smoked hard tobacco, marketed under the name Ariva®. This product was selected as the focus of research for several reasons. First, there is evidence that the level of toxin reduction in Ariva® is substantial compared to cigarettes and traditional smokeless tobacco products (Levy *et al*, 2004; Levy *et al*, 2006; Stepanov, *et al*, 2006). Furthermore, this product was found to have the lowest levels of TSNA, primary carcinogens in smokeless tobacco and tobacco smoke, among several reduced exposure tobacco products (Stepanov, *et al*, 2006). Finally, preliminary studies of Ariva® compared to other reduced exposure tobaccos and NRTs, suggested it had the greatest acceptability of several PREPs and NRTs among smokers (Mendoza-Baumgart, *et al*, unpublished manuscript; Hatsukami, *personal communication*, December 2005). Two experiments were conducted among dependent, adult smokers who were not currently making an attempt to quit smoking to examine three main points of investigation, including: 1) examining smokers' reactions to marketing-type information about a non-smoked, low TSNA tobacco; 2) replicating the acceptability of this product among smokers seen in preliminary investigations (Mendoza-Baumgart, *et al*, unpublished manuscript; Hatsukami, *personal communication*, December 2005) and 3) exploring the role of level of experience with this product on usage patterns and smoking in a clinical lab trial and *ad libitum* setting.

### **Review of Study One**

**Impact and Evaluation of Harm Reduction vs. Convenience Aspects of Product Information.** Study one was conducted to test the relevance of information about the reduced health risks of Ariva® compared to smoking. It was hypothesized that

participants who read differently framed persuasive messages about Ariva® pieces would differ in their evaluations of the information and the product sample. Specifically, one message emphasized reduced health risks and the other, convenience factors of using a discreet, non-smoked tobacco. This hypothesis was not confirmed with either regard to the product information or sample. Smokers who read messages emphasizing the harm reducing aspects of this product did not have significantly different information or product evaluations than participants who read a message emphasizing convenience factors (i.e., being able to use in non-smoking situations).

Furthermore, participants in the first experiment did not differ significantly in their evaluations or use of the product outside of the lab depending on the framing of the product information they read. A summary scale was created to reflect overall argument salience to participants, regardless of message frame. Consequently, high argument salience scores predicted more favorable product evaluations and use out of the lab. This suggested that personal receptivity to the concept of use of a non-smoked tobacco is an important factor in preferences and behaviors. This is consistent with previous reports that attitudes toward tobacco harm reduction predict are the best predictors of feelings toward harm reduction products (Stark, Borgida, Kim, & Pickens, in submission). However, because of incomplete follow-up data, it was not possible to draw firm conclusions about the extent to which behavioral intentions, as measured via acceptance of the take home sample, corresponded with actual use. Study two was conducted in order to address this limitation.

**Acceptability of Ariva® Among Smokers.** An additional goal of study one was to test the acceptability of Ariva® among smokers and confirm the findings of other

preliminary studies (Mendoza-Baumgart, *et al*, unpublished manuscript; Hatsukami, personal communication, December 2005). It was hypothesized that Ariva® would demonstrate good acceptability of smokers after a guided sample in the lab. This hypothesis was confirmed. Over 80% of the participants in the first study (n=33) accepted a take home sample of Ariva® and agreed to be contacted for a follow-up interview to discuss their use of the product and further impressions of its utility and tolerability. Acceptance of the sample was considered indication of a behavioral intention to try the product in the future. However, as previously discussed incomplete participation in the follow-up interview following the lab session in the first study prevented firm conclusions about *ad libitum* use and examine reactions. Study two was conducted to address this limitation and provide more complete data concerning the extent of voluntary product use.

### **Review of Study Two.**

To our knowledge study two was the first to examine the extent to which Ariva® can serve as a viable tobacco harm reduction tool among some smokers who are not abstaining from smoking. This investigation included an examination of smokers' responses to a marketing-style message advocating the use of Ariva® for harm reduction; repeated lab trials and product evaluations; a period of semi-guided use out of the lab in conjunction with smoking; and a period of discretionary use in conjunction with smoking. Smoking behaviors were examined along with perceptions of risk related to several forms of tobacco use. These methods followed recommendations for necessary research proposed by experts in the field of tobacco harm reduction evaluation (Hatsukami, *et al*, 2005).

Previous lab trials have focused specifically on lab trials with the goal of collecting biomarkers and pharmacological data, or on comparing preferences and subjective effects of Ariva® to other non-smoked tobaccos or medicinal NRT products used during abstinence from smoking. While total substitution of Ariva® (or other non-smoked low TSNA tobaccos) for cigarettes smoking has been proposed as a possible harm reduction strategy for smokers unable or willing to quit, this study attempted to more closely replicate the conditions in which smokers might use Ariva® as it is marketed, in other words, as a substitute when smoking is not permitted or desired, rather than a complete substitute for cigarettes.

**Subjective Effects.** Subjective effects of drugs are important factors in determining the extent to which individuals will use the drug. In addition to the effect of the drug, subjective effects can include palatability and convenience factors. In the case of NRTs and Ariva®, as proposed substitutes for cigarettes, the effect on cigarette craving was also considered an important subject effect in this study. Different methods of drug delivery can impact subjective effects of the drug, which can, in turn influence factors such as abuse liability and preference. Smokers in this study were already dependent on the drug nicotine, but accustomed to obtaining it from cigarette smoking. While the effect of nicotine in sustaining cigarette addiction is indisputable, other factors can also sustain smoking (i.e. the act of inhaling smoke, behavioral reinforces, etc.). Therefore, it was important to examine smokers' reports of subjective effects of Ariva® independently and compared to cigarettes. Subjective effects of Ariva® were measured following each lab trial using items derived from NRT preference studies conducted by Schneider and colleagues and adapted visual analogue scales (adapted from Houtsmuller



*et al*, 2003; Houtsmuller *et al*, 2002; and Schuh & Stitzer, 1995) to assess overall liking, drug effects, effects on cigarette craving, palatability, comparisons to cigarettes, and convenience factors. It was hypothesized that those participants assigned to try additional Ariva® outside of the lab on a semi-guided schedule ( $\geq 2$  pieces per day for 5 days) during the first follow-up period would report more favorable subjective effects at each subsequent lab session than participants without additional guided use. This hypothesis was not supported. Participants in the experience group did not have significantly more favorable evaluations than those in the control group. Rather, in most cases favorable subjective effects increased over time.

**Convenience Factors.** In addition to subjective product effects, participants in this study also described convenience factors that could influence their decisions to use Ariva® in the future. Cost and discretion were among the most prominent convenience factors noted by smokers as important factors in their evaluations of and intentions to use Ariva®. As such, these are clearly significant issues to examine as part of an overall assessment of Ariva®'s viability as a legitimate harm reduction tool.

**Cost.** In addition to be less expensive than out of pocket expenses for NRTs, at approximately \$3.20 Ariva® is also less expensive than a pack of cigarettes in most places. This was an important consideration among smokers who felt that the lower cost of Ariva® compared to cigarettes might encourage them to use the product, at least some of the time, instead of cigarettes. Keeping the cost of Ariva® low compared to cigarettes may be one way to increase its utility as a smoking reduction tool. Similarly, however, participants also discussed the low cost of Ariva® as a reason they might use it instead of NRTs, even among those who felt NRTs would be preferable in terms of safety. In line

with the proposal of other experts in tobacco and health, the results of this study support lowering the price of NRTs or providing them free of charge to encourage their use (Bauer, Carlin-Menter, Celestino, Hyland, & Cummings, 2006; Cummings, Fix, Celestino, Carlin-Menter, O'Connor, & Hyland, 2006; Curry, Grothaus, McAfee, & Pabiniak, 1998; Fiore, Thompson, Lawrence, Welsch, Andrews, Ziamik, *et al*, 2000; Kozlowski, *et al*, 2007; West *et al*, 2005), particularly as a first choice over tobacco products for those trying to quit or substantially reduce smoking.

**Smoking restrictions.** A majority of participants in this study reported dealing with multiple areas of smoking restrictions, in their homes, cars, and workplaces. Smokers also discussed the notion that even in the absence of formal restrictions, they increasingly encounter situations where they do not want to smoke or feel it would be inappropriate to do so. Some situations discussed dealt with the health of others, including being in the presence of non-smokers, especially family members and children. Other situations described dealt with smoking as factor that can reflect poorly on one's image, such in the workplace or in formal social situations. Even smelling like smoke in these situations was deemed embarrassing, and participants reported that they would consider using Ariva® in situations like these to provide relief or urges to smoke and in fact, to delay or prevent smoking. These findings are important and provide insight into additional elements of information that could be included in relative tobacco risk and harm reduction information to enhance the salience of the information to smokers. To be more specific, harm reduction per se, was rarely cited by participants as their primary motivation to consider using Ariva® in the future. Rather, the convenience aspects of Ariva® seemed to enhance the relevance of its reduced health risks compared to

cigarettes. While it is critical to continue to inform smokers about the grave health risks of smoking, for most, health problems will remain a distant threat. Therefore, in crafting the most effective health messages about smoking cessation, it may also be beneficial to remind smokers more forcefully of the immediately salient aspects of cigarette smoking they dislike while concurrently offering suggestions for mitigating these factors with the use of reliably reduced exposure products.

**Ariva® Use and Smoking.** An important goal of study two was to explore the role of increased experience with Ariva® on discretionary use and smoking. In study two, it was hypothesized that participants in the experience group would use more Ariva® during the natural use period than participants who only sampled Ariva® in the lab. With greater Ariva® use, it was expected that smoking would be substantially decreased. However, this was not the case. Good compliance with the guided use instructions among the experimental group did not lead to greater use during the free choice period in comparison to control group. Ariva® use declined among the experience group during the natural use period. While most of the participants in the experience condition continued to use Ariva®, the amount of use was modest. Further, when Ariva® use decreased in the experience group, smoking increased, as might be expected.

The reduction in smoking observed among the control participants when they were provided with Ariva® to use at their own discretion was unexpected. Participants were not advised to alter their smoking during this period. In this study, it appeared that the use of about 1 Ariva® might reduce smoking by about 2 cigarettes per day. Average daily Ariva® use among the control participants during the natural use period was small,

about 1 piece per day, and similar to the average daily use seen during this period among participants in the experience condition. Overall, only 8 participants (20%) reported using an average of 2 or more Ariva® per day during the natural use period, with the maximum average number of Ariva® used per day being about 6.

In this study, it appeared that the use of about 1 Ariva® might reduce smoking by about 2 cigarettes per day. The small amount of Ariva® use among continuing smokers in study two seems reasonable considering that Mendoza-Baumgart and colleagues (unpublished manuscript) found that completely abstinent smokers used about 7.45 pieces of Ariva® per day. It is possible smoking reductions were due to diminished urge or desire to smoke related to the nicotine provided by nicotine in Ariva®. However, preliminary investigations demonstrate that the amount of nicotine obtained from 1 Ariva® is similar to or less than the amount obtained from the use of low dosage (2mg) acute medicinal nicotine products (Mendoza-Baumgart, *et al*, unpublished manuscript). It is commonly accepted that such low levels of nicotine will be insufficient to substantially diminish withdrawal and craving, especially among heavy smokers. It is also possible that the reduction could be due to the long amount of time required for an Ariva® to completely dissolve, reported to be anywhere between 20 minutes and 3 hours. Smokers may simply have had less available time in the day to smoke when using an Ariva®. In fact, it is worth noting that the time required to use an Ariva® was generally considered a drawback among participants in this study. In addition to being impatient to feel the effects of nicotine when using Ariva®, some participants also disliked that Ariva® remained intact for an extended period of time. The perception that using an Ariva® required a substantial time commitment may have been another factor that

discouraged participants from using more than 1 or 2 pieces per day. So, while smokers were not completely unreceptive to a non-smoked tobacco, certain dissimilarities with cigarettes were particularly relevant to smokers.

These preliminary findings provide support for the role of Ariva® use to reduce smoking, and potentially health harm, among some smokers. It also provides insight into what “natural use” of Ariva® might look like among continuing smokers and the expected impact of Ariva® use on smoking behavior. Specifically, despite fair acceptability of Ariva® in general, only select smokers used a substantial amount of the product out of the lab and use was minor compared to the amount of smoking. A period of guided Ariva® use out of the lab did not substantially increase liking or discretionary use of Ariva®. Furthermore, other factors that were expected to be related to Ariva® use, such the extent of smoking restrictions faced, desire to quit smoking, and perceived personal health harm from smoking were not statistically significantly related to actual Ariva® use.

Rather, as might be expected, liking and positive product evaluations were associated with the amount of Ariva® used voluntarily during the free choice period. This research did provide some additional evidence describing specific perceived benefits and drawbacks of Ariva® compared to cigarettes. Convenience factors such as lower cost, not making one smell like smoke, being able to use discreetly without the knowledge of family members and/or co-workers, and taste were seen as benefits compared to cigarettes. Conversely, a low level of nicotine, length of time required to feel the effects of nicotine, and the perception that using an Ariva® required a substantial time commitment were significant drawbacks. In addition, it is important to note that

while Ariva® use did not appear to have a negative impact on smoker's perceptions of the risks tobacco use, comparative health risks, in general, were not the most salient issue in determinations use of the product.

### **Limitations and Future Directions**

Taken together, studies one and two provide the first examination of the impact of marketing style messages advocating Ariva® use in the context of harm reduction to smokers as well as the first exploration of how smokers actually use Ariva® in the context of smoking. These studies incorporated recommendations of experts in the field of tobacco harm reduction and potential reduced exposure tobacco products that call for careful examination of the impact of relative risk information, such as may be used in marketing campaigns by the manufacturer, on smokers' perceptions and use of a specific reduced exposure product. Individual examination of reduced exposure products has been recommended because they can vary so dramatically in their potential to actually reduce exposure to tobacco toxins. Ariva® was chosen as the focus of this work because it has been recognized as being the most promising of all available reduced exposure products in terms of ability to reduce toxin exposure and demonstrated early acceptability among smokers. In addition, study two is the first to carry out recommended examinations of *ad libitum* use of Ariva® in the context of smoking.

Several important conclusions emerged. First, emphasizing health harm reduction over convenience factors associated with using Ariva® did not have a statistically significant impact on evaluations of information about the product, the product itself, or use of the product. Neither persuasive messages advocating the use of Ariva® nor actual use appeared to have a negative impact on smokers' perceptions of the risk of tobacco

use in general and smoking in particular. These findings illustrate the limitations of information describing and emphasizing the health risks of tobacco use in prompting behavioral change. Second, despite fair evaluations overall, Ariva® use was quite modest in comparison to smoking. Participants in this study did not exhibit a substantial degree of substitution with Ariva®. While most of the sample voluntarily used some Ariva® of their own discretion, the amount of use, even among the heaviest users, was only a fraction of the amount of smoking. Finally, small reductions in smoking overall provide support for the conclusion that Ariva® may have an impact on smoking in a subset of smokers who like it. Individual characteristics of smokers' that might predict preferences were not readily evident, suggesting that a reasonable approach for identifying smokers who like this product and might benefit from using it is to provide samples. This might be done in conjunction with programs allowing smokers to first sample NRT products, as preference among various NRTs has also been associated with greater use. Taken as a whole, these findings support the viability of Ariva® as a promising reduced exposure product that some smokers could use to reduce smoking, but argue against the likelihood that a substantial number of smokers would use this product to make substantially substitute for cigarettes.

This research followed the recommendations of top experts in the evaluation of potential reduced exposure tobacco products to examine the utility of Ariva® as a harm reduction tool for smokers. One of the strengths of this study, namely the inclusion of two periods of examination of smokers' use of Ariva® outside of the lab, was also a limitation in that data concerning smoking and Ariva® use were self-reported and may not have precisely reflected actual smoking and Ariva® use. As researchers investigate

existing and emerging reduced exposure products, it will be important to continue to refine methods of obtaining accurate and reliable data describing tobacco use in daily life. In addition, the short duration of this study prevents speculation on the long term impact of Ariva® exposure on product use and smoking behavior. Longer studies to examine whether harm reducing behaviors, namely Ariva® use and smoking reductions, can be maintained over time are needed. These studies ought to include data on the availability of both Ariva® and accurate information describing Ariva® in a variety of geographic locales. Continuing research of marketing practices and purchase patterns are also warranted.



## REFERENCES

- American Cancer Society (2003). *Cancer Facts and Figures, 2003*. Atlanta: *American Cancer Society*.
- American Lung Association (2006). *Trends in Tobacco Use*. American Lung Association Epidemiology and Statistics Unit Research and Program Services. Available online at: <http://www.lungusa.org/atf/cf/%7B7A8D42C2-FCCA-4604-8ADE-7F5D5E762256%7D/SMK1.PDF> . Accessed: November 15, 2007.
- Asplund, K. (2003). Smokeless tobacco and cardiovascular disease. *Prog Cardiovasc Dis.*;45:383–394.
- Ault, R.W., Ekelund, R.B., Jackson, J.D., & Saba, R.P. (2004). Smokeless tobacco, smoking cessation, and harm reduction: An economic analysis. *Applied Economics*, 36(1): 17-29.
- Bansal, M.A., Cummings, K.M., Hyland, A., & Giovino, G.A. (2004). Stop-smoking Medications: Who Uses Them, Who Misuses Them, and Who is Misinformed About Them? *Nicotine & Tobacco Research*; 6(Supplement 3):S303-S310.
- Bates, C., Fagerström, K.O., Jarvis, M.J.<sup>3</sup>, Kunze, M., McNeill, A., & Ramström, L. (2003). European Union policy on smokeless tobacco: a statement in favour of evidence based regulation for public health. *Tobacco Control*;12:360-367.
- Batra, A., Klingler, K., Landfeldt, B., Friederich, H. M., Westin, Å., & Danielsson, T. (2005). Smoking reduction treatment with 4-mg nicotine gum: A double-blind, randomized placebo-controlled study. *Clinical Pharmacology & Therapeutics*, 78(6), 689-696.
- Bauer, J.E., Carlin-Menter, S., Celestino, P., Hyland, A., & Cummings, K.M. (2006). Giving away free nicotine medications and a cigarette substitute – Better Quit to promote calls to a quitline. *Journal of Public Health Management and Practice*, 12, 60-67.
- Bolliger, C.T., Zellwegger, J.P., Danielson, T., van Biljon, X., Robidou, A., Westin, A., et al. (2000). Smoking reduction with oral nicotine inhalers: double blind, randomised clinical trial of efficacy and safety. *BMJ*; 321: 329-333
- Breland, A.B., Buchhalter, A.R., Evans, S.E., & Eissenberg, T. (2002). Evaluating acute effects of potential reduced-exposure products for smokers: Clinical laboratory methodology. *Nicotine & Tobacco Research*, 4(Suppl 2), S131-S140.
- Carmella, S.G., Han, S., Fristad, A., Yang, Y., & Hecht, S. S. (2003). Analysis of Total 4-(Methylnitrosamino)-1-(3-Pyridyl)-1-Butanol (NNAL) in Human Urine. *Cancer Epidemiology, Biomarkers & Prevention*, 12, 1257-1261.
- Carmella, S. G., Le, K., Hecht, S. S. (2004). Improved method for determination of 1-hydroxypyrene in human urine. *Cancer epidemiology, Biomarkers, & Prevention*, 13(7), 1261-1264.
- Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). Hillsdale, NJ: Erlbaum.
- Cox, L.S., Tiffany, S.T., & Christen, A.G.(2001). Evaluation of the brief questionnaire of smoking urges (QSU-brief) in laboratory and clinical settings. *Nicotine & Tobacco Research*, 3(1):7-16.

- Critchley, J.A. & Unal, B. (2003). Health effects associated with smokeless tobacco: A systematic review. *Thorax*, 58:435–443
- Cummings, K.M., Fix, B., Celestino, P., Carlin-Menter, S., O'Connor, R., & Hyland, A. (2006). Reach, efficacy, and cost-effectiveness of free nicotine giveaway programs. *Journal of Public Health Management and Practice*, 12(1): 37-43.
- Cummings, M.K. & Hyland, A. (2005). Impact of Nicotine Replacement Therapy on Smoking Behavior. *Annual Review of Public Health*, 26:583-599.
- Curry, S.J., Grothaus, L.C., McAfee, T., & Pabiniak, C. (1998). Use and Cost Effectiveness of Smoking-Cessation Services under Four Insurance Plans in a Health Maintenance Organization. *New England Journal of Medicine*, 339(10): 673-679.
- deRuiter, W. & Faulkner, G. (2006). Tobacco harm reduction strategies: the case for physical activity. *Nicotine & Tobacco Research*, 8(2):157-68.
- Etter, J.F., Kozlowski, L.T., & Perneger, T.V. (2003). What smokers believe about light and ultralight cigarettes. *Preventive Medicine*, 36(1):92-8.
- Etter, J.F., Perneger, T.V., & Ronchi, A. (1997). Distributions of smokers by stage: international comparison and association with smoking prevalence. *Preventive Medicine*. 26(4):580-5.
- Fagerström, K.O. (1999). Interventions for treatment resistant smokers. *Nicotine & Tobacco Research*, 1(1 Suppl 2): S201-S205.
- Fagerström, K. O. & Hughes, J. R. (2002). Nicotine concentrations with concurrent use of cigarettes and nicotine replacement: A review. *Nicotine & Tobacco Research*, 4(Suppl 2), S73-S79.
- Fagerström, K. O., Hughes, J., & Callas, P. W. (2002). Long-term effects of the Eclipse cigarette substitute and the nicotine inhaler in smokers not interested in quitting. *Nicotine & Tobacco Research*, 4(Suppl 2), S141-S145.
- Fagerström, K. O., Tejdin, R., Westin, Å., & Lunell, E. (1997). Aiding reduction of smoking with nicotine replacement medications: hope for the recalcitrant smoker? *Tobacco Control*, 6, 311-316.
- Fiore, M. C., Thompson, S. A., Lawrence, D. L., Welsch, S., Andrews, K., Ziamik, M., et al. (2000). Helping Wisconsin women quit smoking: A successful collaboration. *Wisconsin Medical Journal*, 99(2), 68–72.
- Fishbein, M., & Ajzen, I. (1975). *Belief, attitude, intention, and behavior : An introduction to theory and research*. Reading, Mass.; Don Mills, Ontario: Addison-Wesley Pub. Co.
- Foulds, J., Burke, M., Steinberg, M., Williams, J. M., & Ziedonis, D. M. (2004). Advances in pharmacotherapy for tobacco dependence. *Expert Opinion on Emerging Drugs*, 9, 39–53.
- Foulds, J., Ramström, Burke, M., & Fagerström, K.O. (2003). Effects of smokeless tobacco (snus) on smoking and public health in Sweden. *Tobacco Control*, 12(4), 349-359.
- Gilpin, E. A. & Pierce, J. P. (2002). The California Tobacco Control Program and potential harm reduction through reduced cigarette consumption in continuing smokers. *Nicotine & Tobacco Research*, 4(Suppl 2), S157-S166.

GothiaTek. Available online at:

[http://www.gothiatek.com/templates/start.aspx?page\\_id=27](http://www.gothiatek.com/templates/start.aspx?page_id=27) Last accessed: September 25, 2006.

Hatsukami, personal communication, December 2005.

Hatsukami, D.K., Giovino, G.A., Eissenberg, T., Clark, P.I., Lawrence, D., & Leischow, S. (2005). Methods to assess potential reduced exposure products. *Nicotine & Tobacco Research*, 7(6), 827-844.

Hatsukami, D. & Hecht, S. (2005). *Hope of Hazard: What research tells us about "potentially reduced-exposure" tobacco products*. Minneapolis: University of Minnesota Transdisciplinary Tobacco Use Research Center.

Hatsukami, D.K., Lemmonds, C., & Tomar, S. (2004). Smokeless tobacco use: Harm reduction or induction approach? *Preventive Medicine*, 38, 309-317.

Hatsukami, D.K., Slade, J., Benowitz, N.L., Giovino, G.A., Gritz, E.R., Leischow, S., et al. (2002). Reducing tobacco harm: Research challenges and issues. *Nicotine & Tobacco Research*, 4(Suppl 2), S89-S101.

Health Canada Tobacco Control Programme. (2006). *Canadian tobacco use monitoring survey (CTUMS) 2006*. Ottawa: Health Canada; 2007. Available: [http://www.hc-sc.gc.ca/hl-vs/tobac-tabac/research-recherche/stat/ctums-esutc/2006/index\\_e.html](http://www.hc-sc.gc.ca/hl-vs/tobac-tabac/research-recherche/stat/ctums-esutc/2006/index_e.html). Accessed 31 May 2007.

Heatherton, T.F., Kozlowski, L.T., Frecker, R.C., Fagerstrom, K.O. (1991). The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire. *British Journal of Addiction*, 86:1119-1127.

Hecht, S.S. (1998). Biochemistry, biology, and carcinogenicity of tobacco-specific N-nitrosamines. *Chemical Research In Toxicology*, 11, 559-603.

Hecht, S.S. (2002). Human urinary carcinogen metabolites: biomarkers for investigating tobacco and cancer. *Carcinogenesis*, 23(6), 907-922.

Hecht, S.S., Carmella, S.G., Chen, M., Koch, J.D., Miller, A., Murphy, S.E., et al. (1999). Quantitation of urinary metabolites of a tobacco-specific lung carcinogen after smoking cessation. *Cancer Research*, 59, 590-596.

Hecht, S.S., Carmella, S.G., Ye, M., Le, K.A., Jensen, J.A., Zimmerman, C.L., et al. (2002). Quantitation of metabolites of 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone after cessation of smokeless tobacco use. *Cancer Research*, 62, 129-134.

Hecht, S.S. & Hoffmann, D. (1988). Tobacco-specific nitrosamines, an important group of carcinogens in tobacco and tobacco smoke. *Carcinogenesis*, 9, 875-884.

Hecht, S.S., Murphey, S.E., Carmella, S.G., Zimmerman, C.L., Losey, L., Kramerckzuck, I., Roe, M.R., Puumala, S.S., Li, Y., Le, C.T., Jensen, J., & Hatsukami, D. (2004). Effects of reduced cigarette smoking on uptake of a tobacco-specific lung carcinogen. *Journal of the National Cancer Institute*, 96, 107-115.

Hecht, S.S., Carmella, S.G., Murphy, S.E., Riley, W.T., Le, C., Luo, X., Mooney, M., & Hatsukami, D. (2007). Similar Exposure to a Tobacco-Specific Carcinogen in Smokeless Tobacco Users and Cigarette Smokers. *Cancer Epidemiol. Biomarkers Prev.*, 16(8): 1567 – 1572.

Henningfield, J.E., Burns, D.M., & Dybing, E. (2005). Guidance for research and testing to reduce tobacco toxicant exposure. *Nicotine & Tobacco Research*, 7(6):821-6.

- Hickman, N., Klonoff, E.A., Landrine, H., Kashima, K., Parekh, B., Fernandez, S., Thomas, K., Brouillard, C., Zolezzi, M., Jensen, J. & Weslowski, Z. (2004). Preliminary Investigation of the Advertising and Availability of PREPs, the New "Safe" Tobacco Products. (2004). *Journal of Behavioral Medicine*, 27(4): 413-424.
- Hofer, I., Nil, R., & Battig, K. (1991). Nicotine yield as determinant of smoke exposure indicators and puffing behavior. *Pharmacology, Biochemistry, & Behavior*, 40(1):139-49.
- Hoffmann, D., Brunnermann, K.D., Prokopczyk, B., & Djordjevic, M.V. (1994). Tobacco-specific N-nitrosamines and areca-derived N-nitrosamines: chemistry, biochemistry, carcinogenicity, and relevance to humans. *Journal of Toxicology and Environmental Health*, 41, 1-52.
- Holtgrave, D.R., Tinsley, B.J. & Kay, L.S. (1995). Encouraging risk reduction: A decision-making approach to message design. In R. Parrott & E. Maibach (Eds.), *Designing health messages: Approaches from communication theory and public health practice*. Newbury Park, CA: Sage, 24-40.
- Houtsmuller, E.J., Henningfield, J.E. & Stitzer, M.L. (2003). Subjective effects of the nicotine lozenge: assessment of abuse liability. *Psychopharmacology*, 167(1): 20-27.
- Houtsmuller E.J., Fant, R.V., Eissenberg, T.E., Henningfield, J.E., & Stitzer, M.L.(2002). Flavor improvement does not increase abuse liability of nicotine chewing gum. *Pharmacology, Biochemistry, and Behavior*, 72(3):559-68.
- Hughes, J.R., Cummings, M., & Hyland, A. (1999). Ability of smokers to reduce their smoking and its association with future smoking cessation. *Addiction*; 269: 1268-1271.
- Hughes, J.R., Gust, S.W., Keenan, R., Fenwick, J.W., Skoog, K. & Higgins, S.T. (1991). Long term use of nicotine vs. placebo gum. *Archives of General Medicine*, 151, 1993-1998.
- Hughes, J.R. & Hatsukami, D.K. (1986). Signs and symptoms of tobacco withdrawal. *Archives of General Psychiatry*; 43:289-294.
- Hughes, J. & Hatsukami, D.K.(1998). Errors in using tobacco withdrawal scale. *Tobacco Control*, 7(1):92-93.
- Hughes, J. & Keely, J. (2004). The effect of a novel smoking system—Accord—on ongoing smoking and toxin exposure. *Nicotine and Tobacco Research*, 6(6): 1021-1027.
- Hughes, J.R., Pickens, R.W., Spring, W., & Keenan, R.M. (1985). Instructions control whether nicotine will serve as a reinforcer. *The Journal of Pharmacology and Experimental Therapeutics*, 235(1), 106-112.
- Jensen J., Babb, D., Hatsukami, D., & Avery, G. "Treating Tobacco addiction with Tobacco: What Does The Smoker Think?" poster presented at the 10 th Annual Meeting of the Society for Nicotine and Tobacco Research. Scottsdale AZ. February 18-21, 2004.
- Jimenez-Ruiz, C., Kunze, M. & Fagerström, K.O. (1998). Nicotine Replacement: A New Approach to Reducing Tobacco-Related Harm. *European Respiratory Journal* 11: 473

- Kozlowski, L.T., & Edwards, B.Q. (2005). "Not Safe" is not enough: Smokers have a right to know more than there is no safe tobacco product. *Tobacco Control*, 14:3-7.
- Kozlowski, L.T., Giovino, G.A., Edwards, B., DiFranze, J., Foulds, J., Hurt, R., Niarua, R., Sachs, D.P.L., Selby, P., Dollar, K., Bowen, D., Cummings, M., Counts, M., Fox, B., Sweanor, D., and Ahern, F. (2007). Advice on using over-the-counter nicotine replacement therapy-patch, gum, or lozenge-to quit smoking. *Addictive Behaviors*, 32, 2140-2150.
- Kozlowski, L.T., Goldberg, M., Yost, B., White, E., Sweeney, C., & Pillitteri, J. (1998). Smokers' misperceptions of light and ultra-light cigarettes may keep them smoking. *American Journal of Preventive Medicine*, 15, 78-79.
- Kozlowski, L.T., Strasser, A., Giovino, G., Erickson, P., & Terza, J. (2001). Applying the risk/use equilibrium: Use medicinal nicotine now for harm reduction. *Tobacco Control*, 10, 201-203.
- Kozlowski, L.T. (2002). Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. *Nicotine & Tobacco Research*, 4(Suppl 2), S55-S60.
- Lemmonds, C.A., Mooney, M., Reich, B., & Hatsukami, D. (2004). Characteristics of cigarette smokers seeking treatment for cessation versus reduction. *Addictive Behaviors*, 29(2): 357-64.
- Levy, D.T., Mumford, E.A., Cummings, K.M., Gilpin, E.A., Giovino, G., Hyland, A., Sweanor, D., & Warner, K.E. (2004). The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: Estimates of a panel of experts. *Cancer Epidemiology, Biomarkers, and Prevention*, 13(12), 2035-2042.
- Levy D.T., Mumford, E.A., Cummings, K.M., Gilpin, E.A., Giovino, G.A., Hyland, A., Sweanor, D., Warner, K.E., & Compton, C. (2006). The potential impact of a low-nitrosamine smokeless tobacco product on cigarette smoking in the United States: estimates of a panel of experts. *Addictive Behaviors*, 31(7):1190-1200.
- McMillen, R.C., Winickoff, J.P., Klein, J.D., & Weitzman, M. (2003). US Adult Attitudes and Practices Regarding Smoking Restrictions and Child Exposure to Environmental Tobacco Smoke: Changes in the Social Climate From 2000-2001. *Pediatrics*, 112(1):e55-e66.
- Mendoza-Baumgart, M.I., Hecht, S.S., Zhang, Y., Murphy, S.E., et al (in submission). Low nitrosamine oral non-combustible products compared to medicinal nicotine: toxicant exposure and behavioral preferences. *Nicotine & Tobacco Research*.
- Mooney, M., Leventhal, A., & Hatsukami, D. (2006). Attitudes and knowledge about nicotine and nicotine replacement therapy. *Nicotine & Tobacco Research*, 8(3): 435-446.
- National Cancer Institute. (2001). *Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine*. (Smoking and Tobacco Control Monograph No. 13; NIH Publication No. 02-5074). Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute.
- Petitti, D.B. & Friedman, G.D. (1983). Evidence for Compensation in Smokers of Low Yield Cigarettes. *International Journal of Epidemiology*, 12:487-489.

- Petty, R.E. & Cacioppo, J.T.(1986). *Communication and persuasion: Central and peripheral routes to attitude change*. Springer-Verlag: New York.
- Piper, M.E., McCarthy, D.E., & Baker, T. (2006). Assessing tobacco dependence: A guide to measure evaluation and selection. *Nicotine & Tobacco Research*, 8(3): 339-352.
- Pomerleau, C.S., Carton, S.M., Lutzke, M.L., Flessland, K.A., & Pomerleau, O.F.(1994). Reliability of the Fagerstrom Tolerance Questionnaire and the Fagerstrom Test for Nicotine Dependence. *Addictive Behaviors*, 19(1): 33-39
- Prochaska, J.O. & Goldstein, M.G. (1991). Process of smoking cessation. Implications for clinicians. *Clin Chest Med*, 12(4):727-35
- Richter, K.P., McCool, R.M., Okuyemi, K.S., Mayo, M.S., & Ahluwalia, J.S. (2002). Patients' views on smoking cessation and tobacco harm reduction during drug treatment. *Nicotine & Tobacco Research*, 4(Suppl 2), S175-S182.
- Riley, W., Jerome, A., Behar, A., & Weil, J. (2002). Computer and manual self-help behavioral strategies for smoking reduction: Initial feasibility and one-year follow-up. *Nicotine & Tobacco Research*, 4(Suppl 2), S183-S188.
- Rodu, B. Personal communication 2006.
- Rodu, B. & Cole, P. (2001). The fifty-year decline of cancer in America. *Journal of Clinical Oncology*, 19(1):239-241.
- Rodu, B. & Jansson, C. (2004). Smokeless tobacco and oral cancer: A review of the risks and determinants. *Critical Reviews in Oral Biology and Medicine*, 15(5):252-263.
- Rogers, R.W. (1983). Cognitive and physiological processes in fear appeals and attitude change: A revised theory of protection motivation. In J. Cacioppo & R. Petty (Eds.), *Social Psychophysiology*. New York: Guilford Press.
- Rothschild, M.L. Ethical Considerations in the Use of Marketing for the Management of Public Health and Social Issues. In Andreasen, A.R. (Ed), *Ethics in Social Marketing*. Washington, D.C.: Georgetown University Press.
- Russell, M.A., Sutton, S.R., Feyerabend, C. & Saloojee, Y. (1980). Smokers' response to shortened cigarettes: dose reduction without dilution of tobacco smoke. *Clinical Pharmacology & Therapeutics*, 27(2): 210-218.
- Scherer, G. (1999). Smoking behaviour and compensation: A review of the literature. *Psychopharmacology*, 145(1): 1-20.
- Schneider, N.G., Koury, M.A., Cortner, C., Olmstead, R.E., Hartman, N., Kleinman, L., Kim, D., Chaya, C., & Leaf, D. (2006). Comparative preferences among four combination nicotine treatments. *Psychopharmacology*, 187, 476-485.
- Schneider, N.G., Lunell, E., Olmstead, R.E., & Fagerstrom, K.O. (1996). Clinical pharmacokinetics of nasal nicotine delivery: a review and comparison to other nicotine delivery systems. *Clinical Pharmacokinetics*, 31(1): 65-80.
- Schneider, N.G., Olmstead, R.E, Franzon, M.A. et al (2001). The nicotine inhaler: clinical pharmacokinetics and comparison with other nicotine treatments. *Clinical Pharmacokinetics*, 40(9): 661-684.
- Schneider, N.G., Olmstead, R.E., Nides, M. et al (2004). Comparative testing of 5 nicotine systems: initial use and preferences. *American Journal of Health Behavior*, 28(1): 72-86.

- Schneider, N.G., Terrace, S., Koury, M., Patel, S. Vaghaiwalla, B., Pendergrass, R., Olmstead, R.E., & Cortner, C. (2005). Comparison of three nicotine treatments: initial reactions and preferences with guided use. *Psychopharmacology*, 182: 545-550.
- Schuh, K.J. & Stitzer, M.L. (1995). Desire to smoke during spaced smoking intervals. *Psychopharmacology*, 120(3): 289-295.
- Shiffman, S., Gitchell, J.G., Warner, K.E., Slade, J., Henningfield, J.E., & Pinney, J.M. (2002). Tobacco harm reduction: Conceptual structure and nomenclature for analysis and research. *Nicotine & Tobacco Research*, 4(Suppl 2), S113-S129.
- Shiffman, S. Mason, K.M. & Henningfield, J.E. (1998). Tobacco dependence treatments: Review and prospectus. *Annual. Reviews in Public Health*, 19:335-58.
- Silagy C, Lancaster T, Stead L, Mant D, & Fowler G. (2004). Nicotine replacement therapy for smoking cessation (Cochrane Review). *The Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD000146. DOI:10.1002/14651858.CD000146.
- Stark E, Borgida E, Kim A, and Pickens B (in submission). Understanding public attitudes toward tobacco harm reduction: The role of attitude structure.
- Stratton, K., Shetty, P., Wallace, R., & Bondurant, S., eds. (2001). *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*. Washington, DC: Institute of Medicine, National Academy Press.
- Stepanov, I., Jensen, J., Hatsukami, D., & Hecht, S.S. (2006). Tobacco-specific nitrosamines in new tobacco products. *Nicotine & Tobacco Research*, 8(2):309-313.
- Sutton, S.R., Feyerabend, C., Cole, P.V., & Russell, M.A. (1978). Adjustment of smokers to dilution of tobacco smoke by ventilated cigarette holders. *Clinical Pharmacology & Therapeutics*, 24(4):395-405.
- Sutton, S.R, Russell, M.A., Iyer, R., Feyerabend, C., & Saloojee, Y. (1982). Relationship between cigarette yields, puffing patterns, and smoke intake: evidence for tar compensation? *British Medical Journal*, 285:600-603.
- Tiffany, S.T. & , Drobes, D.J. (1991). The development and initial validation of a questionnaire on smoking urges. *Addiction*, 86(11): 1467-1476.
- United States Department of Health and Human Services (1983). *The Health Consequences of Smoking: Cardiovascular Disease. A Report of the Surgeon General*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Office on Smoking and Health, DHHS Publication No. (PHS) 84-5204.
- United States Department of Health and Human Services. (1990). *The Health Benefits of Smoking Cessation. Surgeon General's Report on Smoking and Health*. Atlanta: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. DHHS Publication No. (CDC) 90-8416.
- U.S. Department of Health and Human Services (2006). *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Executive Summary*. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion,



- National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.
- U.S. Dept. of Health and Human Services, Centers for Disease, (2004). *The health consequences of smoking: a report of the Surgeon General*. [Atlanta, Ga.]:Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; Washington, D.C.
- U.S. Department of Health and Human Services. (2000). Healthy People 2010: Understanding and Improving Health. 2nd ed. Washington, DC: U.S. Government Printing Office.
- United States Department of Health, Education, and Welfare. (1979). *Smoking and Health: A Report of the Surgeon General*. Washington: U.S. Department of Health, Education, and Welfare, Public Health Service, Office of the Assistant Secretary for Health, Office on Smoking and Health. DHEW Publication No. (PHS) 79-50066.
- Warner, K.E. (2002). Tobacco harm reduction: Promise and perils. *Nicotine & Tobacco Research*, 4(Suppl 2), S61-S71.
- West, R. (2004). ABC of smoking cessation: Assessment of dependence and motivation to stop smoking. *British Medical Journal*, 328, 338-339.
- West, R. (2005). Time for a change: Putting the Transtheoretical (Stages of Change) Model to rest. *Addiction*, 100, 1036-1039.
- West, R., Hajek, P., Nilsson, F., et al (2001). Individual preferences for and responses to four nicotine replacement products. *Psychopharmacology*, 153: 225-230.
- Williams, J.M. & Ziedonis, D.(2004). Addressing tobacco among individuals with a mental illness or an addiction. *Addictive Behaviors*, 29(6):1067-1083.
- Witte, K., Meyer, G., & Martell, D. (2001). *Effective health risk messages: A step-by-step guide*. Thousand Oaks, CA: Sage Publications.



## **APPENDICES**

**Appendix A. Consent Form Study 1**

## INFORMED CONSENT FORM FOR CLINICAL RESEARCH STUDY

**Title of Project:** Smokers' Attitudes and Reactions to a Consumer Tobacco Product Message and Trial (Dissertation Development)

Principal Investigator: Beth Edwards

315 East Health and Human Development

Penn State University

University Park, PA 16802

Voicemail: (814) 865-0089

Email: [baq102@psu.edu](mailto:baq102@psu.edu)

ORP USE ONLY: IRB# 22611 Doc. # 1

The Pennsylvania State University

Office for Research Protections

Approval Date: 03/13/06 M. Becker

Expiration Date: 02/15/07 M. Becker

Biomedical Institutional Review Board

Student Adviser:

Lynn T. Kozlowski, Ph.D.

315 East Health and Human Development

Penn State University

University Park, PA 16802

Voicemail: (814) 865-0089

Email: [ltk1@psu.edu](mailto:ltk1@psu.edu)

This is to certify that you have been given the following information regarding your participation as a volunteer in a program of investigation under the supervision of Dr. Kozlowski.

### **Purpose of the study:**

The purpose of this study is to understand how smokers evaluate information about tobacco products and a sample of a tobacco product. The investigator will use the information you provide to develop effective ways of explaining the health risks of tobacco use to smokers.

Signing this form verifies that you understand that you are being asked to participate in this study because you are an adult, age 18 or older, who currently smokes at least 10 cigarettes per day, is not pregnant or lactating, and has no mouth sores or cuts.

### **Procedures to be followed:**

If you agree to participate in this study, you will be asked to do the following things:

1. Abstain from cigarette smoking for 1 hour before coming to the Behavioral Pharmacology Lab on the Penn State University Park Campus in 301 East Health and Development Building for a 2 hour lab session.
2. During the laboratory visit, you will be asked to do the following:
  - a. Give an expired air carbon monoxide breath sample by exhaling into a disposable cardboard mouthpiece for 15 s.
  - b. Complete a survey about your smoking and tobacco use. It will take about 10 minutes to complete the survey.

- c. After completing the survey, you will read a message about smoking and tobacco. It will take less than 5 minutes to read the message.
- d. Next, you will be asked to complete another series of questionnaires, including a writing exercise to evaluate what you heard in the message. This series of questionnaires will include closed-ended and open-ended questions. It may take up to 20 minutes to complete this series of questionnaires and the writing exercise.
- e. After you complete the questionnaires, you will be asked to sample a compressed powdered tobacco product. You understand that you can end your sample of the product at any time. It could take up to 20 minutes for the product to dissolve completely. You understand that the product is a tobacco product that contains nicotine. The amount of nicotine in the tobacco product is similar to or less than the amount of nicotine in one cigarette.
- f. About 10 minutes after you sample the product, you will be asked to complete a questionnaire and a short interview with the investigator. It will take about 10 minutes to complete the questionnaire and interview.
- g. If you have any questions, you may ask them at any time, and you may stop at any time during the session.
- h. After completing activities in the lab session, you will be offered a sample of the product to take home with you. If you accept a take home sample, you will also be asked to respond to a follow-up survey in 3 days by email or phone, depending on your preference.

**Discomforts and risks:**

1. Compressed Powdered Tobacco Sample. The tobacco product sample contains nicotine and you are eligible to participate in this study because you are an adult smoker (aged 18 years or older) of 10 or more cigarettes per day, are not pregnant or breast-feeding, and have no sores or cuts in your mouth. The amount of nicotine you will consume from the tobacco product will be approximately equal to or less than the amount of nicotine you consume from smoking a cigarette. Nicotine is a naturally occurring substance in tobacco and it is addictive. There may be some discomfort from the nicotine including an increased heart rate and blood pressure. In addition, some people who use oral tobacco products may experience temporary dizziness, heartburn, hiccups, or nausea. To reduce potential discomfort, you have been asked to abstain from smoking for 1 hour prior to your lab session. You may remove the product from your mouth at any time.

Medical care is available in the event of an injury resulting from research but neither financial compensation nor free medical treatment is provided. You are not waiving any rights that you might have against the University for injury resulting from negligence of the University or investigators. You can contact the Office for Research Protections, 201 Kern Graduate Building, University Park, PA 16802 (814-865-1775) if you have additional questions concerning your rights as a participant.

*In the event that you experience adverse psychological reactions, you understand that you can call one of the following phone numbers for counseling: Penn State Center for Counseling & Psychological Services (221 Ritenour Building, University Park, PA 16802; 814-863-0395) or Penn State Psychological Clinic (314 Moore Building, University Park, PA 16802; 814-865-2191).*

**Potential Benefits:**

There may be benefits to society from the research being conducted. It is hoped that results from this study will increase understanding of how to present useful and educational health information about smoking. There may be a benefit to you from the research being conducted as you may learn about how to protect your health and reduce the health risks you face from smoking.

**Statement of confidentiality:**

Your participation in this research is confidential. Only the investigators and their assistants will have access to your identity and to information that can be associated with your identity. No personally identifying information will be disclosed in publication of this research. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

The Office of Human Research Protections in the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration (FDA), the Office for Research Protections at Penn State and the Biomedical Institutional Review Board may review records related to this project.

**Right to ask questions:**

You have been given an opportunity to ask any questions you may have, and all such questions or inquiries have been answered to your satisfaction.

Dr. Kozlowski and Ms. Edwards, the investigators, are available to answer any questions that you may have at the time of your participation in this study or if you have questions in the future.

**Compensation:**

You will receive \$20.00 for completing the laboratory session. Circumstances may arise that may cause the investigator to terminate your participation before completion of the study. In the event that your participation in the study is terminated by the investigator, or you choose to discontinue the session, you will be entitled to payment of \$10.00 per

hour for the hours that you have participated on a pro-rated basis, up to the maximum amount of \$20.00 for the laboratory session.

**Voluntary participation:**

Your participation in this study is voluntary, and you may withdraw from this study at any time by notifying the investigator. Your withdrawal from this study or refusal to participate will in no way affect your care or access to medical services. You can refuse to answer any specific question during your participation in this study.

This is to certify that

- 1) You are at least 18 years of age.
- 2) You consent to and give permission for participation as a volunteer in this program of investigation.
- 3) You will receive a signed copy of this consent form.
- 4) You have read this form, and understand the content of this consent form.

---

**Participant's signature**

---

**Date**

I, the undersigned, have defined and explained the studies involved to the above volunteer.

---

**Investigator's signature**

---

**Date**

**Appendix B. History Questionnaire Study 1**

Thank you for agreeing to take part in the study today. First, you take a breath test that will measure your level of carbon monoxide (CO). I will measure your CO level by having you blow into this machine

Reading 1: \_\_\_\_\_ Reading 2: \_\_\_\_\_

**Next, please take a few minutes to complete this questionnaire about your current smoking habits, smoking history, thoughts about quitting smoking, and health.**

**1. How long has it been since your last cigarette?** \_\_\_\_\_

**2. To what extent do you agree with the following statement: “I have a desire for a cigarette right now”? Mark one answer.**

|  |   |   |                                    |                                    |                                      |   |
|--|---|---|------------------------------------|------------------------------------|--------------------------------------|---|
| <b>Very<br/>Definitely<br/>Do Not<br/>Agree</b><br>_____ | <b>Definitely<br/>Do Not<br/>Agree</b><br>_____ | <b>Probably<br/>Do Not<br/>Agree</b><br>_____ | <b>Possibly<br/>Agree</b><br>_____ | <b>Probably<br/>Agree</b><br>_____ | <b>Definitely<br/>Agree</b><br>_____ | <b>Very<br/>Definitely<br/>Agree</b><br>_____ |
|--|---|---|------------------------------------|------------------------------------|--------------------------------------|---|

**3. How old were you when you smoked your first cigarette?**

Age in years: \_\_\_\_\_ OR \_\_\_\_\_ Don't know

**4. How old were you when you started smoking everyday?**

Age in years: \_\_\_\_\_ OR \_\_\_\_\_ Don't know

**5. Do you NOW smoke cigarettes every day or just some days?**

**Mark one answer:** \_\_\_\_ Every day \_\_\_\_ Some days \_\_\_\_ Not at all  
\_\_\_\_ Don't know

**6. To what extent do you agree with the following statement: “I crave a cigarette right now.”? Mark one answer.**

|  |   |   |                                    |                                    |                                      |   |
|--|---|---|------------------------------------|------------------------------------|--------------------------------------|---|
| <b>Very<br/>Definitely<br/>Do Not<br/>Agree</b><br>_____ | <b>Definitely<br/>Do Not<br/>Agree</b><br>_____ | <b>Probably<br/>Do Not<br/>Agree</b><br>_____ | <b>Possibly<br/>Agree</b><br>_____ | <b>Probably<br/>Agree</b><br>_____ | <b>Definitely<br/>Agree</b><br>_____ | <b>Very<br/>Definitely<br/>Agree</b><br>_____ |
|--|---|---|------------------------------------|------------------------------------|--------------------------------------|---|



7. To what extent do you agree with the following statement: "I will smoke as soon as I get the chance"? Mark one answer.

|  |  |                                      |                            |                            |                              |                                      |
|--|--|--------------------------------------|----------------------------|----------------------------|------------------------------|--------------------------------------|
| Very<br>Definitely<br>Do Not<br>Agree<br>_____ | Definitely<br>Do Not<br>Agree<br>_____ | Probably<br>Do Not<br>Agree<br>_____ | Possibly<br>Agree<br>_____ | Probably<br>Agree<br>_____ | Definitely<br>Agree<br>_____ | Very<br>Definitely<br>Agree<br>_____ |
|--|--|--------------------------------------|----------------------------|----------------------------|------------------------------|--------------------------------------|

8. On the average day, how many cigarettes do you usually smoke? \_\_\_\_\_

**OR** mark the appropriate response:

\_\_\_\_\_ Less than one cigarette per day \_\_\_\_\_ None \_\_\_\_\_ Don't know

9. How soon after you wake up do you usually smoke your first cigarette of the day? \_\_\_\_\_ hours **OR** \_\_\_\_\_ minutes

**OR** mark the appropriate response: \_\_\_\_\_ It depends \_\_\_\_\_ Don't Know

10. To what extent do you agree with the following statement: "I do want to smoke right now"? Mark one answer.

|  |  |                                      |                            |                            |                              |                                      |
|--|--|--------------------------------------|----------------------------|----------------------------|------------------------------|--------------------------------------|
| Very<br>Definitely<br>Do Not<br>Agree<br>_____ | Definitely<br>Do Not<br>Agree<br>_____ | Probably<br>Do Not<br>Agree<br>_____ | Possibly<br>Agree<br>_____ | Probably<br>Agree<br>_____ | Definitely<br>Agree<br>_____ | Very<br>Definitely<br>Agree<br>_____ |
|--|--|--------------------------------------|----------------------------|----------------------------|------------------------------|--------------------------------------|

11. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g. in church, at the library, in the cinema? Mark one answer.

\_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_ Don't know

12. Do you smoke more frequently during the first hours after waking than during the rest of the day? Mark one answer.

\_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_ Don't know

13. Do you smoke if you are so ill that you are in bed most of the day? Mark one answer.

\_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_ Don't know

14. Please rate your addiction to cigarettes on a scale of 0 – 100, where '0' means "I am NOT addicted to cigarettes at all" and 100 means "I am extremely addicted to cigarettes." \_\_\_\_\_

15. For you, quitting smoking would be: Mark one answer.

\_\_\_\_\_ Very easy \_\_\_\_\_ Fairly easy \_\_\_\_\_ Fairly difficult \_\_\_\_\_ Very difficult  
\_\_\_\_\_ Impossible

16. To what extent do you agree with the following statement: "After a few hours without smoking, I feel an irresistible urge to smoke."? Mark one answer.

|  |  |                                      |                            |                            |                              |                                      |
|--|--|--------------------------------------|----------------------------|----------------------------|------------------------------|--------------------------------------|
| Very<br>Definitely<br>Do Not<br>Agree<br>_____ | Definitely<br>Do Not<br>Agree<br>_____ | Probably<br>Do Not<br>Agree<br>_____ | Possibly<br>Agree<br>_____ | Probably<br>Agree<br>_____ | Definitely<br>Agree<br>_____ | Very<br>Definitely<br>Agree<br>_____ |
|--|--|--------------------------------------|----------------------------|----------------------------|------------------------------|--------------------------------------|

17. Mark the brand of cigarettes you usually smoke:

\_\_\_\_\_ Marlboro    \_\_\_\_\_ Newport    \_\_\_\_\_ Doral    \_\_\_\_\_ Camel    \_\_\_\_\_ Basic  
 \_\_\_\_\_ Winston  
 \_\_\_\_\_ GPC    \_\_\_\_\_ Kool    \_\_\_\_\_ Salem    \_\_\_\_\_ Virginia Slims  
 \_\_\_\_\_ Other Brand: \_\_\_\_\_

18. What is your usual brand? Mark one answer:

\_\_\_\_\_ ULTRA-LIGHT    \_\_\_\_\_ LIGHT    \_\_\_\_\_ REGULAR    \_\_\_\_\_ Don't Know

**For questions 19 – 22, mark one answer in the list below the statement.**

19. Do you think that using nicotine gum is:

\_\_\_\_\_ Much safer than smoking  
 \_\_\_\_\_ A little safer than smoking  
 \_\_\_\_\_ About the same as smoking  
 \_\_\_\_\_ A little more dangerous than smoking  
 \_\_\_\_\_ Much more dangerous than smoking  
 \_\_\_\_\_ Don't know

20. Do you think that using a nicotine patch is:

\_\_\_\_\_ Much safer than smoking  
 \_\_\_\_\_ A little safer than smoking  
 \_\_\_\_\_ About the same as smoking  
 \_\_\_\_\_ A little more dangerous than smoking  
 \_\_\_\_\_ Much more dangerous than smoking  
 \_\_\_\_\_ Don't know

21. Do you think that using the nicotine lozenge is:

\_\_\_\_\_ Much safer than smoking  
 \_\_\_\_\_ A little safer than smoking  
 \_\_\_\_\_ About the same as smoking  
 \_\_\_\_\_ A little more dangerous than smoking  
 \_\_\_\_\_ Much more dangerous than smoking  
 \_\_\_\_\_ Don't know

**22. Do you think that using smokeless tobacco (snuff, chew, or dip) is:**

- ☐ Much safer than smoking  
☐ A little safer than smoking  
☐ About the same as smoking  
☐ A little more dangerous than smoking  
☐ Much more dangerous than smoking  
☐ Don't know

**23. How likely it is that each of the following will cause health problems?**

Mark one answer in the list under each product.

- |  |  |  |
|--|--|--|
| <b>~Nicotine gum~</b>                  | <b>~Cigarettes~</b>                    | <b>~Nicotine lozenge~</b>              |
| <input type="checkbox"/> Not at all    | <input type="checkbox"/> Not at all    | <input type="checkbox"/> Not at all    |
| <input type="checkbox"/> Only a little | <input type="checkbox"/> Only a little | <input type="checkbox"/> Only a little |
| <input type="checkbox"/> Somewhat      | <input type="checkbox"/> Somewhat      | <input type="checkbox"/> Somewhat      |
| <input type="checkbox"/> Very likely   | <input type="checkbox"/> Very likely   | <input type="checkbox"/> Very likely   |
| <input type="checkbox"/> Don't know    | <input type="checkbox"/> Don't know    | <input type="checkbox"/> Don't know    |
| <b>~Chew, snuff, or dip~</b>           | <b>~Nicotine Patch~</b>                |  |
| <input type="checkbox"/> Not at all    | <input type="checkbox"/> Not at all    |  |
| <input type="checkbox"/> Only a little | <input type="checkbox"/> Only a little |  |
| <input type="checkbox"/> Somewhat      | <input type="checkbox"/> Somewhat      |  |
| <input type="checkbox"/> Very likely   | <input type="checkbox"/> Very likely   |  |
| <input type="checkbox"/> Don't know    | <input type="checkbox"/> Don't know    |  |

**24. How likely is it that most of the people who are important to you think you should quit smoking in the next 6 months? Mark one answer.**

- ☐ Not at all likely   ☐ Only a little likely   ☐ Somewhat likely   ☐ Very likely  
☐ Don't know

**25. How likely is it that people whose opinions you value would approve of your quitting smoking in the next 6 months? Mark one answer.**

- ☐ Not at all likely   ☐ Only a little likely   ☐ Somewhat likely   ☐ Very likely  
☐ Don't know

**26. How much do you WANT to give up smoking cigarettes in the next 6 months? Mark one answer.**

- ☐ Not at all   ☐ Only a little   ☐ Somewhat   ☐ Very much  
☐ Don't know

**27. How likely is it that you will try to quit smoking in the next 6 months? Mark one answer.**

- ☐ Not at all likely   ☐ Only a little likely   ☐ Somewhat likely   ☐ Very likely  
☐ Don't know

**28. Are you seriously thinking of quitting smoking? Mark one answer.**

- \_\_\_\_\_ Yes, within the next **30 days** (GO TO question 29)  
 \_\_\_\_\_ Yes, within the next **6 months** (GO TO question 30)  
 \_\_\_\_\_ No, I am not thinking of quitting (GO TO question 31)

**29. On a scale of 1 to 10 where 1 means “I have absolutely no intention of quitting smoking” and 10 means “I have made a firm decision to quit smoking in the next 30 days” rate how strongly you intend to quit smoking: \_\_\_\_\_**

**30. On a scale of 1 to 10 where 1 means “I have absolutely no intention of quitting smoking” and 10 means “I have made a firm decision to quit smoking in the next 6 months” rate how strongly you intend to quit smoking: \_\_\_\_\_**

**31. What is the possibility that you will be smoking five years from now? Mark one answer. Will you . . .**

- \_\_\_ Definitely be smoking    \_\_\_ Probably be smoking    \_\_\_ Probably not be smoking  
 \_\_\_ Definitely not be smoking    \_\_\_ Don't know

**32. How likely is it that you would be able to quit smoking if you tried to in the next 6 months? Mark one answer.**

- \_\_\_ Not at all likely    \_\_\_ Only a little likely    \_\_\_ Somewhat likely    \_\_\_ Very likely  
 \_\_\_ Don't know

**33. To what extent do you agree with the following statement: “I believe that it is mostly up to me whether or not I quit smoking in the next 6 months”? Mark one answer.**

|  |   |   |                                    |                                    |                                      |   |
|--|---|---|------------------------------------|------------------------------------|--------------------------------------|---|
| <b>Very<br/>Definitely<br/>Do Not<br/>Agree</b><br>_____ | <b>Definitely<br/>Do Not<br/>Agree</b><br>_____ | <b>Probably<br/>Do Not<br/>Agree</b><br>_____ | <b>Possibly<br/>Agree</b><br>_____ | <b>Probably<br/>Agree</b><br>_____ | <b>Definitely<br/>Agree</b><br>_____ | <b>Very<br/>Definitely<br/>Agree</b><br>_____ |
|--|---|---|------------------------------------|------------------------------------|--------------------------------------|---|

**34. If you were going to quit smoking, how likely is it that you would use each of the following? Mark one answer in the list under each product.**

| <b>~Nicotine gum~</b>                  | <b>~Nicotine Patch~</b>                | <b>~Nicotine lozenge~</b>              |
|--|--|--|
| <input type="checkbox"/> Not at all    | <input type="checkbox"/> Not at all    | <input type="checkbox"/> Not at all    |
| <input type="checkbox"/> Only a little | <input type="checkbox"/> Only a little | <input type="checkbox"/> Only a little |
| <input type="checkbox"/> Somewhat      | <input type="checkbox"/> Somewhat      | <input type="checkbox"/> Somewhat      |
| <input type="checkbox"/> Very likely   | <input type="checkbox"/> Very likely   | <input type="checkbox"/> Very likely   |
| <input type="checkbox"/> Don't know    | <input type="checkbox"/> Don't know    | <input type="checkbox"/> Don't know    |

**35. Have you ever made a serious attempt to stop smoking cigarettes entirely?**  
☐ Yes                      OR                      ☐ No (Go to question 42)

**36. How many times have you tried to quit smoking AND succeeded for at least 24 hours in the past 12 months?** \_\_\_\_\_

**37. How many times have you tried to quit smoking AND succeeded for at least 24 hours in the past 30 days?** \_\_\_\_\_

**38. How many times have you tried to quit smoking AND succeeded for at least 24 hours in the past 7 days?** \_\_\_\_\_

**39. About how many times IN THE PAST FIVE YEARS have you made a serious attempt to stop smoking?** \_\_\_\_\_

**40. Put a mark next to any method you have tried to quit smoking. A 'method' could mean things like using the patch, going cold turkey, going to a support group, etc. – any strategy you tried to help you not smoke.**

- ☐ Nicotine gum
- ☐ Nicotine patch
- ☐ Nicotine lozenge
- ☐ Cold Turkey
- ☐ Other (please describe): \_\_\_\_\_

**41. Thinking about the very last time you tried quitting (the most recent time), mark any methods you used.**

- ☐ Nicotine gum
- ☐ Nicotine patch
- ☐ Nicotine lozenge
- ☐ Cold Turkey
- ☐ Other (please describe): \_\_\_\_\_

The next few questions ask about your use of smokeless tobacco products. "Smokeless tobacco" means snuff (sometimes called 'dip') and/or chewing tobacco (sometimes called 'chew').

**42. Have you ever used smokeless tobacco? Mark one answer.**

\_\_\_\_\_ Yes OR \_\_\_\_\_ No (Go to question 61 on page 8)

**43. How old were you the first time you used smokeless tobacco?**

\_\_\_\_\_ Years OR \_\_\_\_\_ Don't know

**44. How old were you when you started using smokeless tobacco everyday? Mark one answer.**

\_\_\_\_\_ Years OR \_\_\_\_\_ Never used daily OR \_\_\_\_\_ Don't know

**45. Do you currently use snuff or chewing tobacco? Mark one answer.**

\_\_\_\_\_ Yes, BOTH \_\_\_\_\_ Yes, only chewing tobacco \_\_\_\_\_ Yes, only dip/snuff

\_\_\_\_\_ No, neither [go to question 51] \_\_\_\_\_ Don't know [go to question 51]

**46. How many days do you use smokeless tobacco in a typical week? \_\_\_\_\_**

**47. How many days does a tin or pouch last you? \_\_\_\_\_**

**48. How many minutes after you wake up do you use smokeless tobacco? \_\_\_\_\_**

**49. How many minutes do you keep a dip or chew in before putting in a fresh one? \_\_\_\_\_**

**50. How many minutes do you usually go between dips or chews? \_\_\_\_\_ (GO TO QUESTION 58 on page 8).**

~Questions 51 – 57 are for FORMER smokeless tobacco users only.~

**51. What smokeless tobacco product did you formerly use? Mark one answer.**

\_\_\_\_\_ BOTH chew and snuff \_\_\_\_\_ Only chewing tobacco \_\_\_\_\_ Only dip/snuff  
\_\_\_\_\_ Don't know

**52. About how long ago did you stop using smokeless tobacco? Put your answer in the category that fits best.**

\_\_\_\_\_ Days \_\_\_\_\_ Weeks \_\_\_\_\_ Months \_\_\_\_\_ Years  
\_\_\_\_\_ Don't know

**53. Before you quit, how many days did you use smokeless tobacco in a typical week? \_\_\_\_\_**

54. Before you quit, how many days did a tin or pouch last you? \_\_\_\_\_
55. Before you quit, how many minutes after you wake up did you use smokeless tobacco? \_\_\_\_\_
56. Before you quit, how many minutes did you keep a dip or chew in before putting in a fresh one? \_\_\_\_\_
57. Before you quit, how many minutes did you usually go between dips or chews? \_\_\_\_\_
58. Have you ever used smokeless tobacco as a substitute for cigarettes when you could not smoke? Mark one answer.  
       \_\_\_\_\_ Yes                \_\_\_\_\_ No                \_\_\_\_\_ Don't Know
59. Have you ever used cigarettes as a substitute for smokeless tobacco when you could not dip or chew? Mark one answer.  
       \_\_\_\_\_ Yes                \_\_\_\_\_ No                \_\_\_\_\_ Don't Know
60. Which product do/did you find more enjoyable to use? Mark one answer.  
       \_\_\_\_\_ Dip/snuff/chew    \_\_\_\_\_ Cigarettes    \_\_\_\_\_ Equally enjoyable/no difference  
       \_\_\_\_\_ Don't Know
61. In general, how would you rate your physical health? Mark one answer.  
       \_\_\_\_\_ Excellent    \_\_\_\_\_ Good    \_\_\_\_\_ Fair    \_\_\_\_\_ Poor    \_\_\_\_\_ Don't know
62. In the past month, have you often been bothered by feeling down, depressed, or hopeless? Mark one answer.  
       \_\_\_\_\_ Yes                \_\_\_\_\_ No                \_\_\_\_\_ Don't Know
63. Do you know anyone else taking part in this study? Mark one answer.  
       \_\_\_\_\_ Yes                \_\_\_\_\_ No (GO TO QUESTION 65)
64. What did they tell you about what happens in this study?  
       \_\_\_\_\_  
       \_\_\_\_\_
65. Besides yourself, how many people live in your household? \_\_\_\_\_
66. Besides yourself, how many members of your household smoke? \_\_\_\_\_

**67. If you decided to quit smoking, how likely is it that you could get a member of your household to quit with you? Mark one answer.**

☐ Not at all likely   ☐ Only a little likely   ☐ Somewhat likely   ☐ Very likely  
☐ Don't know

**68. What is the highest grade or year of regular school or college/professional schooling that you completed? Mark one answer:**

|   |  |
|---|--|
| <input type="checkbox"/> 1st grade            | <input type="checkbox"/> 1 year College/Professional School  |
| <input type="checkbox"/> 2nd grade            | <input type="checkbox"/> 2 years College/Professional School |
| <input type="checkbox"/> 3rd grade            | <input type="checkbox"/> 3 years College/Professional School |
| <input type="checkbox"/> 4th grade            | <input type="checkbox"/> 4 years College/Professional School |
| <input type="checkbox"/> 5th grade            | <input type="checkbox"/> 5 years College/Professional School |
| <input type="checkbox"/> 6th grade            | <input type="checkbox"/> 6 years or more College             |
| <input type="checkbox"/> 7th grade            | <input type="checkbox"/> No Formal Schooling                 |
| <input type="checkbox"/> 8th grade            | <input type="checkbox"/> Don't Know                          |
| <input type="checkbox"/> 1st year high school |  |
| <input type="checkbox"/> 2nd year high school |  |
| <input type="checkbox"/> 3rd year high school |  |
| <input type="checkbox"/> 4th year high school |  |

**69. How would you describe your racial background?**

☐ White  
☐ Black  
☐ Native American/Alaskan  
☐ Asian  
☐ Other – please describe:  
☐ Don't know  
☐ Refused

**70. Do you consider yourself to be of Hispanic origin?**

☐ Yes  
☐ No  
☐ Don't Know  
☐ Refused

**71. Are you:**

|   |  |
|---|--|
| <input type="checkbox"/> Married            | <input type="checkbox"/> Divorced                        |
| <input type="checkbox"/> Widowed            | <input type="checkbox"/> Separated                       |
| <input type="checkbox"/> Never been married | <input type="checkbox"/> A member of an unmarried couple |

**Thank you for completing this survey. Please return it to the investigator and wait for instructions on the next exercise.**



### **Appendix C. Harm Reduction Message Study 1**

**Instructions:** Please read the following argument carefully and evaluate it closely. After you read the argument, you will be asked to list your thoughts and evaluations.

These days, there is a lot of information in the news, the media, and even in ads from cigarette companies about the risks of smoking and why smokers should quit. But, there hasn't been much information in the news or media about tobacco products that are actually less dangerous than cigarettes and some health experts have begun to argue that smokers be told about these products. One example of a tobacco product that is less dangerous than cigarettes is a hard tobacco called Ariva. The main arguments of experts who support making this information more widely available are described below:

1) Not a smokey tobacco: What are Ariva cigarett pieces?

Ariva cigarett pieces are small hard pieces of compressed tobacco that dissolve in one's mouth. They aren't smoked and they don't burn and that is good news for smokers' health.

Many of the health risks from smoking are due to tobacco smoke and burning tobacco. Breathing tobacco smoke into the lungs can cause lung cancer, chronic lung disease, and breathing problems. These diseases alone are responsible for over 50% of smokers' deaths. Cigarette smoking is also a major cause of heart disease. In fact, 1 out of 2

smokers die from a smoking-related illness. If a smoker used a piece of Ariva instead of a cigarette, they wouldn't be breathing in any smoke or exposing themselves to the health risks of breathing tobacco smoke into their lungs.

—► Not breathing in tobacco smoke is a major reason why Ariva is less harmful to health than smoking.

## 2) Less cancer causing toxins: What are Nitrosamines?

Besides not burning and causing lung cancer, lung disease, and breathing problems, there is something else that makes Ariva less harmful than cigarettes – the tobacco it's made from is cured in a special way that reduces the cancer causing toxins in it called nitrosamines. Nitrosamines are one of the main cancer causing toxins found in tobacco and tobacco smoke.

So, when smokers breathe in tobacco smoke, they also breathe in cancer-causing nitrosamines, and a lot of them. But the tobacco that Ariva is made from has very low levels of cancer causing nitrosamines, especially compared to cigarette smoke – and the research to demonstrate this has been done by academic (not tobacco industry) scientists.

- ▶ Ariva has far fewer nitrosamines than cigarettes. For example, the amount of nitrosamines in a Marlboro light cigarette is almost 25 times more than the amount in a piece of Ariva. One light cigarette has 25 times more cancer causing nitrosamines than a piece of Ariva.

Think about how many cigarettes a smoker has each day and how much exposure to nitrosamines could be reduced by replacing some, or better yet, all of those cigarettes with Ariva.

### 3) “But can a piece of Ariva still give smokers a ‘kick’?”

Using Ariva instead of cigarettes can reduce smokers’ health risks and relieve some or all of the cravings smokers might have for cigarettes because Ariva contains nicotine.

- ▶ Nicotine is the drug that makes all tobacco addictive, BUT, **and this is important, nicotine is not the most harmful or toxic substance in cigarettes and tobacco.**

Nicotine is addictive and it may seem to go against logic that nicotine, the substance that keeps smokers hooked on cigarettes, isn’t the substance that makes cigarettes so harmful to health – but this is the case. The bottom line is, most of the disease risks from smoking are due to thousands of toxic compounds in tobacco smoke and burning tobacco.

Smokers could significantly reduce their health risks by using Ariva instead of cigarettes.

4) Does this mean Ariva is good for me?

No. It is important that smokers understand that Ariva is a tobacco product and no tobacco is good for health and the best choice for smokers' health is to stop smoking as soon as possible and not use any tobacco.

—► But, compared to smoking, Ariva is much less harmful to health. For smokers, using a less harmful product, like Ariva, could greatly reduce their health risk if they don't quit.

**Appendix D. Consumer Benefit Message Study 1**

**Instructions:** Please read the following argument carefully and evaluate it closely. After you read the argument, you will be asked to list your thoughts and evaluations.

These days, there is a lot of information in the news, the media, and even in ads from cigarette companies about the risks of smoking and why smokers should quit. But, there hasn't been much information in the news or media about tobacco products that are actually less dangerous than cigarettes and some health experts have begun to argue that smokers be told about these products. One example of a tobacco product that is less dangerous than cigarettes is a hard tobacco called Ariva. The main arguments of experts who support making this information more widely available are described below:

**1) Not a smokey tobacco: What are Ariva cigalett pieces?**

**Ariva cigalett pieces are small, hard pieces of compressed tobacco, about the size of a tic tac, that dissolve against the inside of the cheek. They aren't smoked and they don't burn and that is good news for smokers' health.** Many of the health risks from smoking are due to tobacco smoke and burning tobacco – breathing tobacco smoke into the lungs can cause lung cancer, chronic lung disease, and breathing problems.

—► Not breathing in tobacco smoke is a major reason why Ariva is less harmful to health than smoking.

2) “If there is no smoke, can a piece of Ariva still give smokers a ‘kick’?”

For smokers who can’t quit or aren’t ready to, there are a lot of good reasons to use Ariva instead of smoking a cigarette. There is the reduction in health risks which is a great reason by itself, but Ariva can still give a smoker some of the pleasant sensations they enjoy when they smoke, like feeling more alert or less stressed out, for example, because it is a tobacco product that contains nicotine. Nicotine also relieves *withdrawal symptoms*, or the unpleasant sensations a smoker feels after going a long time without smoking, like feeling irritable or on edge.

—► Nicotine in Ariva gives smokers many of the sensations they enjoy from smoking.

3) No smoke . . . no more dirty looks? Is using a piece of Ariva obvious to others?

Ariva pieces are small enough that they can be used without anyone seeing they are in someone’s mouth – they don’t make smokers need to spit, they don’t need to be chewed, or sucked on, and they don’t create any second-hand smoke. That is a good thing for smokers and the people they care about.



Smokers can face a lot of criticism – from the people who love them and worry about their health, from their friends and co-workers who might not like to be around their smoke or cover for them on smoke breaks, maybe even from themselves. A lot of smokers have tried to quit but couldn't or are putting off quitting until they feel more ready.

Using a piece of Ariva instead of smoking a cigarette could help smokers in a lot of these situations. For example, smokers' friends, family, and co-workers won't be able to see it in their mouth, smell it on their clothes or in their car. It won't give them smokers' breath or a cough, either. And, if smokers do talk to their friends and family about using Ariva, they can tell them about the ways that this product has much lower health risks than smoking. With more places going smoke-free everyday (restaurants, malls, even bars), using a piece of Ariva could also help a smoker feel more comfortable in places that they usually have to go without a cigarette or around friends or family members where smoking is off-limits.

—► **Ariva doesn't give off smoke, so a smoker can use it almost anywhere, any time.**

4) Can using a piece of Ariva instead of a cigarette really make a difference in a smokers' life?

If smokers can use a piece of Ariva sometimes instead of smoking a cigarette, they may soon find that they can use a piece of Ariva most of the time, maybe even all the time. And, this could help a smoker thinking of quitting to know what to expect when they aren't smoking anymore.

There are also a lot of things that smokers enjoy about smoking, besides the nicotine, that can make it hard to give up – like the way it feels to hold a cigarette or looking forward to taking a little break from work or studying, to go out for a smoke. But, slowly replacing cigarettes with pieces of Ariva could also help smokers break some of the habits that make cigarettes so hard to give up.

—► Slowly replacing a cigarette here and there with pieces of Ariva could also help smokers break some of the habits that make cigarettes so hard to give up.

5) Does this mean Ariva is good for me?

No. The best choice for smokers' health is to stop smoking as soon as possible and abstain from any tobacco use. But smokers who can't quit or aren't ready to give up tobacco completely should seriously think about switching to a product like Ariva.

## **Appendix E. Thought Listing Exercise**

### Thought Listing Exercise

**You have just read an argument about why smokers should consider using a tobacco product, called Ariva.**

**I would like you to write down all the thoughts and ideas you had while you were reading the argument.**

**You might have had ideas that are favorable, unfavorable, irrelevant, or a mixture of all of these, and any case is fine. Below these instructions there is a form that has been prepared for you to record your thoughts and ideas. Simply write the first idea that comes to mind in the first box, the second idea in the second box, and so on.**

**Don't censor yourself – just write as many thoughts you had that you can remember. Please state your thoughts and ideas as concisely as possible – a phrase is sufficient. Don't worry about grammar, spelling, or punctuation. You will have 2 1/2 minutes to write down your thoughts. I will tell you when the time is up. There is more space provided than should be needed, so don't worry about trying to fill every space. Please be completely honest and list all the thoughts you had.**

**Write one thought in each large box below. Leave the small box on the right blank.**

|  |  |
|--|--|
|  |  |
|  |  |
|  |  |

[illegible]

Ok – the time for this part of the exercise is complete. Please take a moment if you need it to finish up.

Now that you have listed all your thoughts, I would like you to go back and read over each one and decide if you think it is a thought that is mostly favorable, unfavorable, or neutral. There is a small box on the right hand side of each thought-listing space. In that box, use the following scale to rate how favorable or unfavorable you think the thought is:

1 . . . 2 . . . 3 . . . 4 . . . 5 . . . 6 . . . 7

Totally Unfavorable                      Neutral                      Totally Favorable

## **Appendix F. Argument Evaluation Exercise**



### Argument Evaluation Exercise

In this questionnaire, you will rank the quality of the argument that you read about the tobacco product.

For each statement below, fill in the number from 1 to 7 that best represents your **agreement**. Use this scale.

| 1                                     | 2                             | 3                           | 4                 | 5                 | 6                   | 7                           |
|---------------------------------------|-------------------------------|-----------------------------|-------------------|-------------------|---------------------|-----------------------------|
| Very<br>Definitely<br>Do Not<br>Agree | Definitely<br>Do Not<br>Agree | Probably<br>Do Not<br>Agree | Possibly<br>Agree | Probably<br>Agree | Definitely<br>Agree | Very<br>Definitely<br>Agree |

1. The information in the argument was mostly new to me. \_\_\_\_\_
2. The information in the argument was easy to understand. \_\_\_\_\_
3. The information in the argument was important to me. \_\_\_\_\_
4. I already knew most of the information in the argument. \_\_\_\_\_
5. The information in the argument was convincing. \_\_\_\_\_
6. The information in the argument is important for smokers to know. \_\_\_\_\_
7. The information in the argument made sense. \_\_\_\_\_
8. I will share the information in the argument with other smokers I know. \_\_\_\_\_
9. The information in the argument is easy to remember. \_\_\_\_\_
10. The information in the argument was helpful to me. \_\_\_\_\_
11. The information in the argument was believable. \_\_\_\_\_
12. The argument informed that Ariva tobacco pieces are much less harmful to health than smoking cigarettes. \_\_\_\_\_
13. The argument informed that Ariva tobacco pieces are not addictive. \_\_\_\_\_
14. The argument informed that most of the health harm from smoking is due to tobacco smoke. \_\_\_\_\_
15. The argument informed that nicotine is the main cancer causing compound in tobacco. \_\_\_\_\_

**WHEN YOU ARE FINISHED, RETURN THIS FORM TO THE INVESTIGATOR AND WAIT FOR INSTRUCTIOSN ON THE NEXT EXERCISE.**

## **Appendix G. Product Evaluation Exercise**

Product Evaluation Exercise

On this questionnaire, you will be asked to share your reactions to the tobacco product.

For the first set of statements, please rate each aspect of the product using the scale of 1 to 7 described below:

|                                    |                           |                         |                 |                 |                   |                            |
|------------------------------------|---------------------------|-------------------------|-----------------|-----------------|-------------------|----------------------------|
| <b>1</b>                           | <b>2</b>                  | <b>3</b>                | <b>4</b>        | <b>5</b>        | <b>6</b>          | <b>7</b>                   |
| <b>Very<br/>Definitely<br/>Not</b> | <b>Definitely<br/>Not</b> | <b>Probably<br/>Not</b> | <b>Possibly</b> | <b>Probably</b> | <b>Definitely</b> | <b>Very<br/>Definitely</b> |

1. \_\_\_\_\_ The product is an excellent product overall.
2. \_\_\_\_\_ The product provided relief of nicotine withdrawal.
3. \_\_\_\_\_ The product provided relief of urges to smoke.
4. \_\_\_\_\_ I did not need cigarettes while using the product.
5. \_\_\_\_\_ The product is easy to use.
6. \_\_\_\_\_ The product provides enough nicotine.
7. \_\_\_\_\_ The product provides too much nicotine.
8. \_\_\_\_\_ I believe I might become dependent on the product if I used it regularly.
9. \_\_\_\_\_ I believe I would still crave cigarettes if I used the product regularly.
10. \_\_\_\_\_ The product had bothersome side effects.
11. \_\_\_\_\_ I would be uncomfortable using the product in public.
12. \_\_\_\_\_ I would use the product again.
13. \_\_\_\_\_ I would be comfortable using the product for a long period of time.
14. \_\_\_\_\_ I would tell my friends who smoke to try the product.

15. Where **1 means the least satisfaction possible and 10 means the most satisfaction possible.** rate your level of satisfaction with the product. \_\_\_\_\_

In this set of statements, please think about how the product you sampled compares to cigarettes and rate each statement with a number from 1 to 7 based on the scale below.

|                   |                   |                 |                 |                 |                   |                   |
|-------------------|-------------------|-----------------|-----------------|-----------------|-------------------|-------------------|
| <b>1</b>          | <b>2</b>          | <b>3</b>        | <b>4</b>        | <b>5</b>        | <b>6</b>          | <b>7</b>          |
| <b>Very</b>       | <b>Definitely</b> | <b>Probably</b> | <b>Possibly</b> | <b>Probably</b> | <b>Definitely</b> | <b>Very</b>       |
| <b>Definitely</b> | <b>Not</b>        | <b>Not</b>      |                 |                 |                   | <b>Definitely</b> |
| <b>Not</b>        |                   |                 |                 |                 |                   |                   |

16. \_\_\_\_\_ Compared to cigarettes, this is an excellent product overall.
17. \_\_\_\_\_ Compared to cigarettes, the product is easy to use.
18. \_\_\_\_\_ Compared to cigarettes, I liked how the product tasted.
19. \_\_\_\_\_ Compared to cigarettes, the product is less harmful to my \_\_\_\_\_ health.
20. \_\_\_\_\_ Compared to cigarettes, the product provides enough nicotine.
21. \_\_\_\_\_ Compared to cigarettes, the product provides too much nicotine.
22. \_\_\_\_\_ I believe the product is as addictive as cigarettes.
23. \_\_\_\_\_ Compared to cigarettes, I would be uncomfortable using the product in public.
24. \_\_\_\_\_ Compared to cigarettes, the product had bothersome side effects.
25. On a scale of **1 (is the least satisfaction possible) to 10 (is the most satisfaction possible)**, rate your satisfaction with the product *compared to cigarettes*: \_\_\_\_\_

**WHEN YOU ARE DONE, PLEASE RETURN THIS FORM TO THE INVESTIGATOR AND WAIT FOR INSTRUCTIONS ON THE NEXT EXERCISE.**

## **Appendix H. Open Ended Interview Study 1**

## Interview

Over the course of our session today, I have asked you to think and write quite a bit about the product, but I would also like to talk to you about what you thought about your experience today.

1. I am especially interested in what your first reactions to the product were. What can you tell me about what your first reactions when you tried it?

[OK – is there anything else – up to 5 prompts]

2. Was the product as you expected it to be from hearing the message?
3. Was there anything you really liked about it?
4. Was there anything you really disliked about it?
5. On a scale of 1 to 7, where 1 means “very definitely not” and 7 means “very definitely” how likely do you think you would be to try the product again? \_\_\_\_\_
  - a. Why do you feel that way?
6. On a scale of 1 to 7, where 1 means “very definitely not” and 7 means “very definitely” how likely would you be to use this product as a substitute for cigarettes when you cannot smoke? \_\_\_\_\_
  - a. Why do you feel that way?

7. On a scale of 1 to 7, where 1 means “very definitely not” and 7 means “very definitely”, how likely is it that you would use this product if you wanted to try to quit smoking?
  - a. Why do you feel that way?
8. Would you be interested in taking a pack of the product with you?
9. Is there anything else you want to tell me about our session today?

Thank you very much for your time and assistance today. The information you have provided will be very valuable in learning about how smokers think about strategies to reduce their risks from smoking.

There is also an optional follow-up to this study. If you’d like, you can take a pack of the product with you to try over the next few days. If you agree, we would contact you with a short email or telephone survey in 3 days. The survey is brief and takes about 5 minutes to complete. Whether you participate in this follow-up is completely voluntary and will not affect your compensation today. If you do choose to participate by taking a pack home with you, your participation in the follow-up survey is also voluntary. You could choose not to answer any part of the survey.

Would you like a pack to take with you?      \_\_\_\_\_ yes      \_\_\_\_\_ no thanks

Great. Do I have your permission to contact you with a short follow-up survey in about 3 days?

\_\_\_\_\_ Yes, my email is: \_\_\_\_\_

\_\_\_\_\_ Yes, I would rather be contacted by phone.

○ My phone number is: \_\_\_\_\_

○ A good time to reach me is: \_\_\_\_\_

\_\_\_\_\_ No, please do not contact me

**Appendix I. Follow-Up Interview Study 1**



### Follow Up Survey

Dear \_\_\_\_\_

This is Beth Edwards emailing you about the study you participated in on (date) at the Behavioral Pharmacology Lab at Penn State. I just had a few questions to follow-up with you about your visit. If you agree to this short survey, please hit reply to this email and answer the questions below. You may refuse to answer questions. If you have questions about this survey, you may contact the investigator at [baq102@psu.edu](mailto:baq102@psu.edu) or 856-0089 or Dr. Lynn Kozlowski at [ltk1@psu.edu](mailto:ltk1@psu.edu) or 863-7256.

Thank you in advance for your help!

1. Since your lab session, how many pieces of the tobacco product have you used?
2. Would you say that you have smoked:
  - a. Much more than usual
  - b. More than usual
  - c. About the same as usual
  - d. Less than usual
  - e. Much less than usual

For the first set of statements, please rate each aspect of the tobacco product on a scale of 1 to 7 where 1 means "VERY DEFINITELY NOT" and 7 means "VERY DEFINITELY".

3. Overall, this is an excellent overall. \_\_\_\_\_
4. The product provided relief of nicotine withdrawal. \_\_\_\_\_
5. The product provided relief of urges to smoke. \_\_\_\_\_
6. I did not need cigarettes while using the product. \_\_\_\_\_
7. The product was easy to use. \_\_\_\_\_
8. The product provided enough nicotine. \_\_\_\_\_
9. The product provided too much nicotine. \_\_\_\_\_
10. I believe I might become dependent on the product if I used it regularly. \_\_\_\_\_
11. I believe I would still crave cigarettes if I used the product regularly. \_\_\_\_\_
12. The product had bothersome side effects. \_\_\_\_\_
13. I was uncomfortable using the product in public. \_\_\_\_\_
14. I would use the tobacco product again. \_\_\_\_\_
15. I would be comfortable using the product for a long period of time. \_\_\_\_\_
16. I would tell my friends who smoke to try the product. \_\_\_\_\_

On a scale of 1 (least) to 10 (most), rate your satisfaction with the tobacco product: \_\_\_\_\_

In the next set of statements, please think about how the tobacco product compares to cigarettes and respond to each statement using the 1 (VERY DEFINITELY NOT) to 7 (VERY DEFINITELY) scale.

17. Compared to cigarettes, the tobacco product is an excellent product overall. \_\_\_\_\_
18. Compared to cigarettes, the tobacco product is easy to use. \_\_\_\_\_

19. Compared to cigarettes, I liked the sensory aspects of using the tobacco product \_\_\_\_\_
20. Compared to cigarettes, I liked how the tobacco product tasted. \_\_\_\_\_
21. Compared to cigarettes, the tobacco product is less harmful to my health. \_\_\_\_\_
22. Compared to cigarettes, the product provides enough nicotine. \_\_\_\_\_
23. Compared to cigarettes, the product provides too much nicotine. \_\_\_\_\_
24. I believe the product is as addictive as cigarettes. \_\_\_\_\_

**25. How likely is it that you will try to quit smoking in the next 6 months?**

- < \_\_\_\_\_ > Not at all
- < \_\_\_\_\_ > Only a little
- < \_\_\_\_\_ > Somewhat
- < \_\_\_\_\_ > Very much
- < \_\_\_\_\_ > Don't Know
- < \_\_\_\_\_ > Refused Self Efficacy

**26. How likely is it that you would be able to quit smoking if you tried to in the next 6 months?**

- < \_\_\_\_\_ > Not at all likely
- < \_\_\_\_\_ > Only a little likely
- < \_\_\_\_\_ > Somewhat likely
- < \_\_\_\_\_ > Very likely
- < \_\_\_\_\_ > Don't Know
- < \_\_\_\_\_ > Refused

**27. What is the possibility that you will be smoking five years from now? Will you . . .**

- < \_\_\_\_\_ > Definitely be smoking
- < \_\_\_\_\_ > Probably be smoking
- < \_\_\_\_\_ > Probably not be smoking
- < \_\_\_\_\_ > Definitely not be smoking
- < \_\_\_\_\_ > Don't Know
- < \_\_\_\_\_ > Refused

If you were going to tell another smoker about the tobacco product, what would you tell them about it?

Please use this space to record any other reactions or thoughts you had about using the product:

**Appendix J. Telephone Pre-Screener Study 2**

**Title of Project:** Smokers' Evaluations of a Reduced Exposure Tobacco Product (IRB# 22611)

Modified Telephone Pre-Screener: Statements in **BOLD** will be read aloud.

Participant ID

Number: \_\_\_\_\_

Screening Date: \_\_\_\_\_ Screening

Time: \_\_\_\_\_

Interviewer

name: \_\_\_\_\_

Note caller sex: \_\_\_\_\_ male \_\_\_\_\_ female

**Hi, this is \_\_\_\_\_ calling from the Biobehavioral Health Studies Lab at Penn State University. I am calling because you expressed interest in our ongoing research study of smokers' attitudes about smoking and tobacco and evaluations of a sample of a tobacco product. Do you have about 10 minutes for me to tell you about the study and see if you are eligible to participate?**

If no, **"OK, what would be a good time to call you back?"**

Day: \_\_\_\_\_ Time: \_\_\_\_\_ or \_\_\_\_\_ no longer interested

**To help maintain confidentiality of this conversation, you may wish to use a hard wired telephone (in other words, not a cordless or cell phone) if it is available.**

**The purpose of this study is to learn about smokers' attitudes and beliefs about smoking and tobacco use and how smokers evaluate a sample of a tobacco product both in a laboratory trial and in daily life. The investigators will use the attitude and belief measures and evaluations to develop effective risk communications that incorporate an understanding of how people think about their smoking and tobacco use and how they use these products in daily life. This study is independent academic research and is not sponsored or funded by the tobacco industry.**

**This study requires attending 3 lab sessions over the course of 2 consecutive weeks in the Health Studies laboratory located on the University Park campus. Participants will need to provide their own transportation to each lab session. Each lab session will last between 120 and 150 minutes (or 2 to 2 ½ hours) and will be scheduled during normal working hours Monday through Friday. Between the lab sessions, participants will be asked to make brief daily diary entries about their tobacco use.**

**Participants will be compensated \$20 at the end of each lab session and may earn an additional \$15 for complying with study instructions and procedures between lab sessions. The total possible compensation for participating in this study is \$90.**

**Do you have any questions?**

**If you are eligible and choose to participate, when you arrive at the first lab session, the investigator will go over an informed consent for your participation. If you agree to participate, you will be asked to provide an expired air breath sample to verify that you are a smoker and a urine sample to measure the amount nicotine in your body. If you are a woman, the urine sample will also be tested to rule out pregnancy. The urine sample will not be tested for any substances other than tobacco use.**

**Next, you will fill out several questionnaires about your tobacco use, read and evaluate information about the novel tobacco product being sampled in the study, sample and evaluate the tobacco product by completing several questionnaires and a complete a brief interview with the investigator.**

**Next, if you agree to sample the product outside of the lab for the following 5 days, you will receive additional instructions for how and when to sample the product in your daily life. You will be asked to make brief daily diary entries about your use of the sample product and smoking and to collect your cigarette butts over the next 5 days and return to the lab for a second visit.**

**Do you have any questions?**

**At the second lab session, you will return your diary and collected cigarette butts and any unused sample product. Participants who comply with the use instructions, diary entries, and collection of butts and unused product will receive a \$15 compliance bonus at the end of the session. Then you will provide another expired air and urine sample which will be tested as described, complete several questionnaires, sample the tobacco product again, and evaluate it again. You will then receive a sample of the product and may use it as you choose over the next 7 days. You will be asked to make dairy entries and collect your cigarette butts as described and to return for a third and final lab visit. You will receive another \$20 compensation (plus a possible \$15 compliance bonus) at the end of the 2<sup>nd</sup> lab session.**

**Do you have any questions?**

You will be asked to return to the lab for a final visit 7 days after your 2<sup>nd</sup> lab session. At this last lab session, you will return your diary and collected cigarette butts and any unused sample product. Those participants who comply with the instructions for diary entries, and collection of butts and unused product will receive another \$15 compensation bonus at the end of the session. Then you will provide another expired air and urine sample which will be tested as described, complete several questionnaires, sample the tobacco product again, and evaluate it again. You will receive a sample of the product and may use it as you choose over the next 7 days. You will be asked to make dairy entries and collect your cigarette butts as described and to return for a third and final lab visit. You will receive \$20 compensation (plus a possible \$15 compliance bonus) at the end of the 2<sup>nd</sup> lab session. The total possible compensation for participating in all the lab sessions and compliance bonuses is \$90.

Do you think that you would like to participate in this study?

“NO” – OK, thank you for your time.

“YES” – continue:

Before we go any further, I need to ask you some questions to see if you are eligible to participate. Is that OK? \_\_\_\_\_

1. What is your birth date?

a. Day \_\_\_\_\_ Month \_\_\_\_\_ Year \_\_\_\_\_

\_\_\_\_\_ check here if response is NOT between the day of the current date of 1988 and 1941 – or age must be between 18-65 years

2. Have you smoked at least 100 cigarettes (about 5 packs) in your entire life?

a. \_\_\_\_\_ Yes

b. \_\_\_\_\_ No

\_\_\_\_\_ check here if response was NO

3. Are you currently a daily smoker?

a. \_\_\_\_\_ Yes

b. \_\_\_\_\_ No

\_\_\_\_\_ check here if response was NO

4. How soon after waking do you usually smoke your first cigarette? \_\_\_\_\_

a. convert answer to minutes: \_\_\_\_\_

b. Circle score:

i. After 60 minutes = 0

ii. 31-60 minutes = 1

iii. 6-30 minutes = 2



iv. Within 5 minutes = 3

**5. About how many cigarettes do you smoke each day? \_\_\_\_\_**

a. Circle score:

- i. 10 or less = 0
- ii. 11-20 = 1
- iii. 21-30 = 2
- iv. 31 or more = 3

SUM=\_\_\_\_

\_\_\_\_\_ Check here if the sum of 4b and 5a is less than 4

**6. Are you currently making an attempt to quit smoking?**

a. Yes

b. No

\_\_\_\_\_ Check here if response is YES

**7. How much would you say that you want to quit smoking in the next 6 months?**

a. Not at all

b. Only a little

c. Somewhat

d. Very much

\_\_\_\_\_ Check here if response is a – “not at all”

**8. Have you used any tobacco products other than cigarettes (such as cigar or chewing tobacco) in the last 7 days?**

a. Yes

b. No

\_\_\_\_\_ Check here if response is YES

**9. Do you have any sores or cuts in your mouth?**

a. Yes

b. No

c. Don't Know

\_\_\_\_\_ Check here if response is YES

**10. Do you wear dentures?**

a. Yes

b. No

c. Don't Know

\_\_\_\_\_ Check here if response is YES

11. (Ask female callers only) **Are you currently pregnant or trying to become pregnant?**

- a. Yes
- b. No
- c. Don't Know

☐ Check here if response is YES or Don't Know

12. (Ask female callers only) **Are you nursing (breast feeding)?**

- a. Yes
- b. No
- c. Don't Know

☐ Check here if response is YES or Don't Know

13. **Now I am going to read you a list of health conditions. Please let me know if a doctor has ever told you you have any of them. It is not necessary for you to indicate which diagnosis you have received.**

- a. Untreated hypertension/high blood pressure
- b. Diabetes
- c. Stroke
- d. Heart attack
- e. Heart surgery
- f. Congestive heart failure
- g. Peptic/stomach ulcer
- h. Mood disorder or schizophrenia

☐ Check here if caller responded YES to any items

**Thank you. Please wait a moment while I review your answers to determine your eligibility to participate.**

Are there check marks in any boxes?

- 1. YES = Not Eligible
- 2. NO = ELIGIBLE

1. Not Eligible **"Based on your responses, you are not eligible to participate in this study, however the health studies lab may be conducting other studies you qualify for now or in the future. Would you like to be invited to participate in other studies?"**

- 1. Yes = record contact info on separate form
- 2. No = **"OK, thank you for your time today."**

2. ELIGIBLE **Based on your answers to this pre-screener, you are eligible to participate in this study. Would you like to schedule an appointment now?**



Eligible Participant Schedule Form

Participant name:

LAB session 1 date:

LAB session 1 time:

May I have your email address or phone number to remind you of your appointment:

Email Address:

Phone number:

---

**Ineligible Participant Future Study Contact Form**

First Name:

Contact phone number:

Contact email address:

Preferred contact method:

1. phone
2. email
3. both
4. no preference

**Appendix K. Consent Form Study 2**

## INFORMED CONSENT FORM FOR CLINICAL RESEARCH STUDY

**Title of Project:** Smokers' Evaluations of a reduced exposure tobacco product

Principal Investigator: Beth Edwards  
315 East Health and Human Development  
Penn State University  
University Park, PA 16802  
Voicemail: (814) 863-5845  
Email: [baq102@psu.edu](mailto:baq102@psu.edu)

Student Adviser: Laura Cousino Klein, Ph.D.  
311 East Health and Human Development  
Penn State University  
University Park, PA 16802  
Office Line: (814) 863-5845  
Email: [lc Klein@psu.edu](mailto:lc Klein@psu.edu)

---

This is to certify that you have been given the following information regarding your participation as a volunteer in a program of investigation under the supervision of Dr. Laura Klein.

**Purpose of the study:**

The purpose of this study is to learn about how smokers evaluate information about tobacco products and a sample of a tobacco product in the lab and outside of the lab. The investigator will use the information you provide to develop effective ways of explaining the health risks of tobacco use to smokers.

Signing this form verifies that you understand that you are being asked to participate in this study because you are a healthy adult, age 18 or older, who currently smokes every day, are not currently making an attempt to quit smoking, are not pregnant or nursing an infant (if you are a woman), and you have no mouth sores or cuts and do not wear dentures and are willing to: 1) provide expired air breath samples and urine samples, 2) be randomly assigned to an instructed use of the sample product outside of the lab, 3) make daily diary recording of your smoking and use of the sample product during the periods between lab sessions, and 4) return to the lab for two additional sessions, each lasting approximately 2 hours.

**Procedures to be followed:**

If you agree to participate in this study, you will be asked to do the following things:

1. During the laboratory visit(s), you will be asked to do the following:
  - a. Give an expired air carbon monoxide breath sample by exhaling into a disposable cardboard mouthpiece for 15 seconds. You will be asked to provide 3 expired air samples, one at each of your 3 lab visits.

- b. Provide a urine sample at each of the 3 lab visits that will be used to measure the level of nicotine in your body and, if you are female, to verify that you are not pregnant. Facilities and instructions will be provided to you. These samples will not be tested for the use of any substance other than tobacco and pregnancy.
- c. Complete a survey about your smoking and tobacco use. It will take about 10 minutes to complete the survey. You will complete this survey at the first lab visit and a shortened form of this survey at both follow-up visits.
- d. After completing the survey, you will read a message about smoking and tobacco. It will take less than 5 minutes to read the message. You will read this message and complete a survey questionnaire to evaluate it during the first lab session only.
- e. Next, you will be asked to complete a brief writing exercise (2 minutes) and complete a series of questionnaires about the information you read. The writing exercise and questionnaire will take 15 minutes or less to complete.
- f. After you complete the information evaluation exercises, you will be asked to sample a compressed powdered tobacco product. You understand that you can end your sample of the product at any time. It could take up to 20 minutes for the product to dissolve completely. You understand that the product is a tobacco product that contains nicotine. The amount of nicotine in the tobacco product is similar to or less than the amount of nicotine in one cigarette. The investigator will provide instructions on the placement of this product in your mouth and use of the sample product, as well as the possible sensations you can expect to experience during your sample.
- g. About 10 minutes after you begin your sample of the product, you will be asked to complete another series of questionnaires and a short interview with the investigator. It will take about 20 minutes to complete the questionnaire and interview.
- h. You will be asked to sample the product and complete the evaluation exercises at each of the 3 lab visits.
- i. You will be asked to confirm that you are willing to participate in the remainder of the study that may require you to sample additional pieces of the tobacco product outside of the lab and will require you to sample the product again at the 2<sup>nd</sup> lab session. If you are not willing to do so you may choose to end your participation in the study at this time without consequences.
- j. Next, you will be informed of your random assignment to an assigned protocol of use of the sample product for the 5-day period between the first and second lab sessions. Your assignment to the protocol is determined by chance, meaning that neither you nor the investigator will decide which set of use instructions you receive. If you are not willing to

be assigned to a set of follow-up period instructions by chance, you should choose not to continue participation in this study.

- k. You will be asked to make brief, daily diary entries about your smoking and tobacco use, collect your cigarette butts and/or partially used sample product in provided containers, and to save any unused sample product to return at the second lab session. Diary entries and collections will be made for the periods between lab sessions 1 and 2 as well as sessions 2 and 3.
- l. You will be asked to return to the lab approximately 5 days after your first visit to 1) return your diary and samples and 2) repeat the activities conducted in the first lab session (except reading and evaluating written information). At the end of the second lab visit, all participants will receive package of the sample product, daily diary materials, tobacco product collection materials and will schedule their final lab session 7 days after the 2<sup>nd</sup> lab session. You will be instructed on the proper use of the sample product, procedures for diary entries, and procedures for collecting used tobacco products.
- m. You will have the opportunity to ask questions at any time, and you will have the opportunity to withdrawal from the study if you are not willing to adhere to the study procedures. Participants who withdrawal will be compensated at a prorated amount of \$10 per hour.

**Discomforts and risks:**

1. Compressed Powdered Tobacco Sample. The tobacco product sample contains nicotine and you are eligible to participate in this study because you are a healthy, adult smoker (aged 18 years or older) of 15 or more cigarettes per day for the last 3 year, are not pregnant or breast-feeding, and have no sores or cuts in your mouth and do not wear dentures. The amount of nicotine you will consume from the tobacco product will be approximately equal to or less than the amount of nicotine you consume from smoking a cigarette. Nicotine is a naturally occurring substance in tobacco and it is addictive. There may be some discomfort from the nicotine including an increased heart rate and blood pressure. In addition, some people who use oral tobacco products may experience temporary dizziness, heartburn, hiccups, or nausea. You are advised not to use the sample product during vigorous physical activity or exercise. If you experience discomfort, you may remove the product from your mouth at any time.

Medical care is available in the event of an injury resulting from research but neither financial compensation nor free medical treatment is provided. You are not waiving any rights that you might have against the University for injury resulting from negligence of the University or investigators. You can contact the Office for Research Protections, 201 Kern Graduate Building, University Park, PA 16802 (814-865-1775) if you have additional questions concerning your rights as a participant.

***In the event that you experience adverse psychological reactions, you understand that you can call one of the following phone numbers for counseling: Penn State Center***

*for Counseling & Psychological Services (221 Ritenour Building, University Park, PA 16802; 814-863-0395) or Penn State Psychological Clinic (314 Moore Building, University Park, PA 16802; 814-865-2191).*

**Potential Benefits:**

There may be benefits to society from the research being conducted. It is hoped that results from this study will increase understanding of how to present useful and educational health information about smoking. There may be a benefit to you from the research being conducted as you may learn about how to protect your health and reduce the health risks you face from smoking.

**Statement of confidentiality:**

Your participation in this research is confidential. Only the investigators and their assistants will have access to your identity and to information that can be associated with your identity. No personally identifying information will be disclosed in publication of this research. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

The Office of Human Research Protections in the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration (FDA), the Office for Research Protections at Penn State and the Biomedical Institutional Review Board may review records related to this project.

**Right to ask questions:**

You have been given an opportunity to ask any questions you may have, and all such questions or inquiries have been answered to your satisfaction.

Ms. Edwards and Dr. Klein, the investigators, are available to answer any questions that you may have at the time of your participation in this study or if you have questions in the future.

**Compensation:**

You will receive \$20.00 for completing each laboratory session. You will also receive a \$15 dollar bonus for complying with the study protocol outside of the lab, including following product use instructions, making brief diary entries, and collecting used tobacco products, at each follow-up visit. The total possible compensation for participation in this study is \$90. Circumstances may arise that may cause the investigator to terminate your participation before completion of the study. In the event that your participation in the study is terminated by the investigator, or you choose to withdraw from the study, you will be entitled to payment of \$10.00 per hour for the hours

that you have participated in the lab on a pro-rated basis, up to the maximum amount of \$20.00 for the laboratory session.

**Voluntary participation:**

Your participation in this study is voluntary, and you may withdraw from this study at any time by notifying the investigator. Your withdrawal from this study or refusal to participate will in no way affect your care or access to medical services. You can refuse to answer any specific question during your participation in this study.

This is to certify that

- 1) You are at least 18 years of age.
- 2) You consent to and give permission for participation as a volunteer in this program of investigation.
- 3) You will receive a signed copy of this consent form.
- 4) You have read this form, and understand the content of this consent form.

---

**Participant's signature**

---

**Date**

I, the undersigned, have defined and explained the studies involved to the above volunteer.

---

**Investigator's signature**

---

**Date**



**Appendix L. Product Information Study 2**

**Instructions:** Please read the following argument carefully and evaluate it closely. Scrutinize the information as you read it because when you are through, you will be asked to write your thoughts about and reactions to this message.

These days, there is a lot of information in the news, the media, and even in ads from cigarette companies about the risks of smoking and why smokers should quit. There are even advertisements from tobacco companies that suggest some cigarettes, light or low tar, for example, are less harmful to health than others. While this isn't the case, these ads can be misleading and confusing. On the other hand, there hasn't been much information in the news or media about other tobacco products that actually are less harmful to health than cigarettes. Some health experts have begun to advocate that smokers be informed about tobacco products available now that are less harmful to health than cigarettes. One example of a tobacco product that is less dangerous than cigarettes is a hard tobacco called Ariva™. The main arguments of experts who support making information about the risks of different tobacco products and cigarettes more widely known are described below:

### **1) Not a smokey tobacco: What are Ariva cigarett pieces?**

**Ariva cigarett pieces are small hard pieces of compressed tobacco that dissolve in one's mouth. They aren't smoked and they don't burn and that is good news for smokers' health.**

Many of the health risks from smoking are due to tobacco smoke and burning tobacco. Breathing tobacco smoke into the lungs can cause lung cancer, chronic lung disease, and breathing problems. These diseases alone are responsible for over 50% of smokers' deaths. Cigarette smoking is also a major cause of heart disease. In fact, 1 out of 2 smokers die from a smoking-related illness. If a smoker used a piece of Ariva instead of a cigarette, they wouldn't be breathing in any smoke or exposing themselves to the health risks of breathing tobacco smoke into their lungs.

—► **Not breathing in tobacco smoke is a major reason why Ariva is less harmful to health than smoking.**

## 2) Less cancer causing toxins: What are Nitrosamines?

Besides not burning and causing lung cancer, lung disease, and breathing problems, there is something else that makes Ariva less harmful than cigarettes – the tobacco it's made from is cured in a special way that reduces the cancer causing toxins in it called nitrosamines. Nitrosamines are one of the main cancer causing toxins found in tobacco and tobacco smoke.

So, when smokers breathe in tobacco smoke, they also breathe in cancer-causing nitrosamines, and a lot of them. But the tobacco that Ariva is made from has very low levels of cancer causing nitrosamines, especially compared to cigarette smoke – and the research to demonstrate this has been done by academic (not tobacco industry) scientists.

—► **Ariva has far fewer nitrosamines than cigarettes. For example, the amount of nitrosamines in a Marlboro light cigarette is almost 25 times more than the amount in a piece of Ariva. One light cigarette has 25 times more cancer causing nitrosamines than a piece of Ariva.**

Think about how many cigarettes a smoker has each day and how much exposure to nitrosamines could be reduced by replacing some, or better yet, all of those cigarettes with Ariva.

## 3) “If there is no smoke, can a piece of Ariva still give smokers a ‘kick’?”

For smokers who can't quit or aren't ready to, there are a lot of good reasons to use Ariva instead of smoking a cigarette. There is the reduction in health risks which is a great reason by itself, but Ariva can still give a smoker some of the pleasant sensations they enjoy when they smoke, like feeling more alert or less stressed out, for example, because it is a tobacco product that contains nicotine. Nicotine also relieves *withdrawal symptoms*, or the unpleasant sensations a smoker feels after going a long time without smoking, like feeling irritable or on edge.

—► **Nicotine in Ariva gives smokers many of the sensations they enjoy from smoking.**

#### **4) No smoke . . . no more dirty looks? Is using a piece of Ariva obvious to others?**

Ariva pieces are small enough that they can be used without anyone seeing they are in someone's mouth - they don't make smokers need to spit, they don't need to be chewed, or sucked on, and they don't create any second-hand smoke. That is a good thing for smokers and the people they care about.

Smokers can face a lot of criticism – from the people who love them and worry about their health, from their friends and co-workers who might not like to be around their smoke or cover for them on smoke breaks, maybe even from themselves. A lot of smokers have tried to quit but couldn't or are putting off quitting until they feel more ready.

Using a piece of Ariva instead of smoking a cigarette could help smokers in a lot of these situations. For example, smokers' friends, family, and co-workers won't be able to see it in their mouth, smell it on their clothes or in their car. It won't give them smokers' breath or a cough, either. And, if smokers do talk to their friends and family about using Ariva, they can tell them about the ways that this product has much lower health risks than smoking. With more places going smoke-free everyday (restaurants, malls, even bars), using a piece of Ariva could also help a smoker feel more comfortable in places that they usually have to go without a cigarette or around friends or family members where smoking is off-limits.

—► **Ariva doesn't give off smoke, so a smoker can use it almost anywhere, any time.**

#### **5) Can using a piece of Ariva instead of a cigarette really make a difference in a smokers' life?**

If smokers can use a piece of Ariva sometimes instead of smoking a cigarette, they may soon find that they can use a piece of Ariva most of the time, maybe even all the time. And, this could help a smoker thinking of quitting to know what to expect when they aren't smoking anymore.

There are also a lot of things that smokers enjoy about smoking, besides the nicotine, that can make it hard to give up – like the way it feels to hold a cigarette or looking forward to taking a little break from work or studying, to go out for a

smoke. But, slowly replacing cigarettes with pieces of Ariva could also help smokers break some of the habits that make cigarettes so hard to give up.

—► **Slowly replacing a cigarette here and there with pieces of Ariva could also help smokers break some of the habits that make cigarettes so hard to give up.**

**6) Does this mean Ariva is good for me?**

No. The best choice for smokers' health is to stop smoking as soon as possible and abstain from any tobacco use. But smokers who can't quit or aren't ready to give up tobacco completely should seriously think about switching to a product like Ariva as a less dangerous form of tobacco use.

**Appendix M. Social Climate Survey**

**Title of Project:** Smokers' Evaluations of a Reduced Exposure Tobacco Product  
(IRB# 22611)

**Participant ID number:** \_\_\_\_\_

**Instruction Set:** E N

**US Social Climate Survey**

**Instructions:** Circle the number of the best response for each question on this survey or fill in the answer as noted.

Question q1

Which of the following best describes your household's rules about smoking:

1. Smoking is allowed in all parts of the home,
2. Smoking is allowed in some parts of the home, or
3. Smoking is not allowed in any part of the home?

Question Q2

In your home, is smoking in the presence of children always allowed, sometimes allowed or never allowed?

1. always allowed
2. sometimes allowed
3. never allowed

Question Q3

Do you have a car or do you travel in a car regularly?

1. Yes
2. No

Here are four different ways people handle smoking in their cars.

Please tell me which best describes how cigarette smoking is handled in your car:

1. No one is allowed to smoke in my car,
2. Only special guests are allowed to smoke in my car,
3. People are allowed to smoke in my car only if the windows are open, or
4. People are allowed to smoke in my car at any time

Question Q5

Please tell me which best describes how cigarette smoking is handled in your car when children are present:

1. No one is allowed to smoke in my car,
2. Only special guests are allowed to smoke in my car,
3. People are allowed to smoke in my car only if the windows are open, or
4. People are allowed to smoke in my car at any time

## Question q6

In your opinion, how much does smoking in a car affect the health of children?

Would you say:

1. Not at All,
2. A Little Bit,
3. Somewhat,
4. A Lot, or
5. A Great Extent

## Question Q10

How many children under 18 years of age currently live in your household? \_\_\_\_\_

## Question Q11

How old are each of your children?

---



---



---



---

## Question Q12

NOT including yourself, which of the following ADULTS living in your household currently smoke cigarettes?

1. Your spouse or significant other
2. Your children
3. Adult children living in house
4. Other adults in your household
5. None or not applicable

## Question Q13

In your home, are children under the age of 18 always allowed, sometimes allowed, or never allowed to smoke cigarettes?

1. Always allowed
2. Sometimes allowed
3. Never allowed

Please note your agreement with the following statements:

## Question Q14

Parents have a responsibility to prevent their children's exposure to second hand smoke?

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree



## Question Q15

It is acceptable for parents to smoke in front of children.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

## Question Q16

Parents should not allow children under the age of eighteen to smoke cigarettes.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

## Question Q17

Inhaling smoke from a parent's cigarette harms the health of babies and children.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

## Question Q17a

Babies and children should be tested for exposure to second hand smoke when they go to their doctor.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

## Question Q42.1

Breathing air in a room today where people smoked yesterday can harm the health of babies and children.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

## Question Q42.2

Breathing air in a car today where people smoked yesterday can harm the health of babies and children.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

## Question Q18

Children are more likely to smoke if their parents are smokers.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

## Question Q19

In social settings where there are smokers and non-smokers, do you tend to:

1. Always refrain from smoking,
2. Sometimes refrain from smoking, or
3. Never refrain from smoking?
4. All of my friends smoke

## Question q45

How much does it bother you when you are exposed to other people's cigarette smoke?

1. Not at all
2. A little
3. Moderately
4. Very much

## Question q62

When dining out, do you request a table in the non-smoking section, smoking section, or the first available table?

1. Non-smoking section
2. Smoking section
3. First available table

## Question q63

If you travel and stay in a hotel or motel, do you usually request a non-smoking room?

1. Yes
2. No
3. I do not travel

## Question Q21

In schools, do you think that students should be allowed to smoke:

1. in all areas,
2. some, designated areas, or
3. not allowed at all?

## Question Q22

In schools, do you think that faculty and staff should be allow to smoke:

1. in all areas,
2. some, designated areas, or
3. not allowed at all?

For each statement below, indicate whether you strongly agree, agree, disagree, or strongly disagree.

## Question Q27

Stores should be penalized for the sale of tobacco products to persons under the age of 18.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

## Question q28

Persons under the age of 18 should be penalized for the possession and use of tobacco products?

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

The following questions are about the work place and tobacco.

## Question Q30

In indoor work areas, do you think that smoking should be allowed in all areas, some areas or not allowed at all?

1. in all areas
2. in some areas
3. not allowed at all

## Question q31

Are you currently:

1. employed for wages,
2. self-employed,
3. out of work for more than 1 year,
4. out of work for less than 1 year,
5. homemaker,
6. student,
7. retired, or
8. unable to work

## Question q33

Which of the following best describes your place of work's official smoking policy for indoor areas:

1. smoking is not allowed in any area,
2. it is allowed in some areas,
3. it is allowed in all areas, or
4. there is no official policy.
5. Not applicable

## Question q34

Would you say that this smoking policy is not enforced at all, poorly enforced, somewhat enforced or strictly enforced?

1. not enforced at all
2. poorly enforced
3. somewhat enforced
4. strictly enforced
5. Not applicable

## Question q37

Within the past 12 months, has your employer offered any stop smoking program or other help to employees who want to quit smoking?

1. Yes
2. No
3. Not applicable

Please read this list of activities, for each activity indicate if you think it is very dangerous, somewhat dangerous, or not very dangerous.

## Question Q38

Is breathing second hand smoke:

1. Very dangerous,
2. Somewhat dangerous, or
3. Not very dangerous
4. Don't Know/Not Sure

## Question q39

Chewing tobacco.

1. Very dangerous
2. Somewhat dangerous
3. Not very dangerous
4. Don't Know/Not Sure

## Question q40

Smoking cigarettes

1. Very dangerous
2. Somewhat dangerous
3. Not very dangerous
4. Don't Know/Not Sure

## Question q41

Using snuff

1. Very dangerous
2. Somewhat dangerous
3. Not very dangerous
4. Don't Know/Not Sure

## Question q42

Smoking cigars

1. Very dangerous
2. Somewhat dangerous
3. Not very dangerous
4. Don't Know/Not Sure

Next, please indicate which of the following places in your community are currently smoke free, have designated smoking areas, or permit smoking anywhere.

## Question q49

Fast food restaurants

1. Completely smoke free
2. Have designated smoking and non-smoking areas
3. Permit smoking anywhere
4. Don't Know
5. DOESN'T APPLY (none in community)

## Question q50

Restaurants

1. Completely smoke free
2. Have designated smoking and non-smoking areas
3. Permit smoking anywhere
4. Don't Know
5. DOESN'T APPLY (none in community)

## Question q51

## Bars and taverns

1. Completely smoke free
2. Have designated smoking and non-smoking areas
3. Permit smoking anywhere
4. Don't Know
5. DOESN'T APPLY (none in community)

## Question q52

## Indoor sporting events

1. Completely smoke free
2. Have designated smoking and non-smoking areas
3. Permit smoking anywhere
4. Don't Know
5. DOESN'T APPLY (none in community)

## Question q53

## Outdoor parks

1. Completely smoke free
2. Have designated smoking and non-smoking areas
3. Permit smoking anywhere
4. Don't Know
5. DOESN'T APPLY (none in community)

In the following places, do you think that smoking should be allowed in all areas, some areas, or not allowed at all?

## Question q54

In hospitals, do you think that smoking should be allowed in:

1. All areas,
2. Some areas, or
3. Not at all

## Question q54.1

Outside of hospitals, on hospital property, do you think that smoking should be allowed in:

1. All areas,
2. Some areas, or
3. Not at all

## Question q57

## In fast food restaurants

1. All areas
2. Some areas
3. Not at all

Question q58

In restaurants

1. All areas
2. Some areas
3. Not at all

Question q59

In bars and taverns

1. All areas
2. Some areas
3. Not at all

Question q60

At indoor sporting events

1. All areas
2. Some areas
3. Not at all

Question q61

In outdoor parks

1. All areas
2. Some areas
3. Not at all

Please indicate your agreement with the following statements:

Question q66

Tobacco advertising is acceptable in grocery and convenient stores.

1. Strongly agree,
2. Agree,
3. Disagree, or
4. Strongly disagree

Question q67

Tobacco advertising is acceptable in magazines.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

Question q68

Tobacco advertising is acceptable in direct mailers.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

Question q69

Tobacco advertising is acceptable on Internet sites.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

Question Q77

Tobacco companies have been unfairly criticized in the media.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

Question Q78

Tobacco companies target teens to replace smokers who die.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

**THANK YOU. PLEASE RETURN THIS FORM TO THE INVESTIGATOR AND  
AIT FOR THE NEXT INSTRUCTIONS.**



**Appendix N. MNWS**

**Title of Project:** Smokers' Evaluations of a Novel Tobacco Product (IRB# 22611)

**Participant ID number:** \_\_\_\_\_

**Lab Session:** 1 2 3

**Instruction Set:** E N

**MNWS**

**Instructions:** For each of the items below, rate yourself on how you have been feeling over the past twenty-four hours. Circle the number that applies to you.

|  | Not at all | Slight | Moderate | Quite a bit | Extreme |
|--|------------|--------|----------|-------------|---------|
| 1. Urge to smoke                       | 0          | 1      | 2        | 3           | 4       |
| 2. Depressed mood                      | 0          | 1      | 2        | 3           | 4       |
| 3. Irritability, frustration, or anger | 0          | 1      | 2        | 3           | 4       |
| 4. Anxiety                             | 0          | 1      | 2        | 3           | 4       |
| 5. Difficulty concentrating            | 0          | 1      | 2        | 3           | 4       |
| 6. Restlessness                        | 0          | 1      | 2        | 3           | 4       |
| 7. Increased appetite                  | 0          | 1      | 2        | 3           | 4       |
| 8. Difficulty going to sleep           | 0          | 1      | 2        | 3           | 4       |
| 9. Difficulty staying asleep           | 0          | 1      | 2        | 3           | 4       |

**Appendix O. QSU-Brief**

**Title of Project:** Smokers' Evaluations of a Reduced Exposure Tobacco Product  
(IRB# 22611)

**Participant ID number:** \_\_\_\_\_

**Lab Session:** 1 2 3

**Instruction Set:** E N

**QSU-Brief**

**Instructions:** Respond to each of the statements below using a 100-point scale ranging from strongly disagree (1) to strongly agree (100).

|  |       |
|--|-------|
| 1. I have a desire for a cigarette right now.                  | _____ |
| 2. Nothing would be better than smoking a cigarette right now. | _____ |
| 3. If it were possible, I probably would smoke right now.      | _____ |
| 4. I could control things better right now if I could smoke.   | _____ |
| 5. All I want right now is a cigarette.                        | _____ |
| 6. I have an urge for a cigarette.                             | _____ |
| 7. A cigarette would taste good right now.                     | _____ |
| 8. I would do almost anything for a cigarette right now.       | _____ |
| 9. Smoking would make me less depressed.                       | _____ |
| 10. I am going to smoke as soon as possible.                   | _____ |

**Appendix P. WISDM-68**

Title of Project: Smokers' Evaluations of a Reduced Exposure Tobacco Product (IRB# 22611)

Participant ID number: \_\_\_\_\_

Lab Session: 1 2 3

Instruction Set: E N

WISDM-68

**Instructions:** Below are a series of statements about cigarette smoking. Please rate your level of agreement for each using the following scale:

| 1  | 2 | 3 | 4 | 5 | 6 | 7                       |
|--|---|---|---|---|---|-------------------------|
| Not at all<br>true of me   |   |   |   |   |   | Extremely<br>true of me |
| 1. I enjoy the taste of cigarettes most of the time.                               | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 2. Smoking keeps me from gaining weight.   | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 3. Smoking makes a good mood better.   | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 4. If I always smoke in a certain place it is hard to be<br>there and not to smoke | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 5. I often smoke without thinking about it.  | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 6. Cigarettes control me.  | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 7. Smoking a cigarette improves my mood.   | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 8. Smoking makes me feel content.  | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 9. I usually want to smoke right after I wake up.                                  | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 10. Very few things give me pleasure each day like cigarettes.                     | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 11. It's hard to ignore an urge to smoke.  | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 12. The flavor of a cigarette is pleasing.   | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 13. I smoke when I really need to concentrate.                                     | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 14. I can only go a couple hours between cigarettes.                               | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 15. I frequently smoke to keep my mind focused.                                    | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 16. I rely upon smoking to control my hunger and eating.                           | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 17. My life is full of reminders to smoke.   | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 18. Smoking helps me feel better in seconds.                                       | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 19. I smoke without deciding to.   | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 20. Cigarettes keep me company, like a close friend.                               | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 21. Few things would be able to replace smoking in my life.                        | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 22. I'm around smokers much of the time.   | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 23. There are particular sights and smells that trigger strong<br>urges to smoke.  | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 24. Smoking helps me stay focused.   | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 25. Smoking helps me deal with stress.   | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 26. I frequently light cigarettes without thinking about it.                       | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 27. Most of my daily cigarettes taste good.  | 1 | 2 | 3 | 4 | 5 | 6 7                     |
| 28. Sometimes I feel like cigarettes rule my life.                                 | 1 | 2 | 3 | 4 | 5 | 6 7                     |

- |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|
| 29. I frequently crave cigarettes.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 30. Most of the people I spend time with are smokers.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 31. Weight control is a major reason that I smoke.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 32. I usually feel much better after a cigarette.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 33. Some of the cigarettes I smoke taste great.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 34. I'm really hooked on cigarettes.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 35. Smoking is the fastest way to reward myself.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 36. Sometimes I feel like cigarettes are my best friends.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 37. My urges to smoke keep getting stronger if I don't smoke.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 38. I would continue smoking, even if it meant I could spend less time on my hobbies and other interests. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 39. My concentration is improved after smoking a cigarette.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 40. Seeing someone smoke makes me really want a cigarette.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 41. I find myself reaching for cigarettes without thinking about it.                                      | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 42. I crave cigarettes at certain times of day.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 43. I would feel alone without my cigarettes.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 44. A lot of my friends or family smoke.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 45. Smoking brings me a lot of pleasure.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 46. Cigarettes are about the only things that can give me a lift when I need it.                          | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 47. Other smokers would consider me a heavy smoker.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 48. I feel a strong bond with my cigarettes.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 49. It would take a pretty serious medical problem to make me quit smoking.                               | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 50. When I haven't been able to smoke for a few hours, the craving gets intolerable.                      | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 51. When I do certain things I know I'm going to smoke.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 52. Most of my friends and acquaintances smoke.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 53. I love the feel of inhaling the smoke into my mouth.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 54. I smoke within the first 30 minutes of awakening in the morning.                                      | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 55. Sometimes I'm not aware that I'm smoking.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 56. I'm worried that if I quit smoking I'll gain weight.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 57. Smoking helps me think better.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 58. Smoking really helps me feel better if I've been feeling down.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 59. Some things are very hard to do without smoking.  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 60. Smoking makes me feel good.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 61. Smoking keeps me from overeating.   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

- |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|
| 62. My smoking is out of control.                               | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 63. I consider myself a heavy smoker.                           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 64. Even when I feel good, smoking helps me feel better.        | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 65. I reach for cigarettes when I feel irritable.               | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|   |   |   |   |   |   |   |   |
| 66. I enjoy the sensations of a long, slow exhalation of smoke. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 67. Giving up cigarettes would be like losing a good friend.    | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 68. Smoking is the easiest way to give myself a lift.           | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**THANK YOU. PLEASE RETURN THIS FORM TO THE INVESTIGATOR AND WAIT FOR INSTRUCTIONS.**



**Appendix Q. Product Evaluation – VAS**

**Title of Project:** Smokers' Evaluations of a Reduced Exposure Tobacco Product  
(IRB# 22611)

**Participant ID number:** \_\_\_\_\_

**Lab Session:** 1 2 3

**Instruction Set:** E N

### Product Evaluation –VAS

**Directions:** Please rate the following characteristics of the tobacco product you just sampled by placing a vertical line ( ) at the point you feel best indicates your rating.

1. How pleasant would a cigarette be right now?  
Not at all \_\_\_\_\_ Extremely

2. How much of an urge or desire do you have to smoke right now?  
Not at all \_\_\_\_\_ Extremely

3. How much do you need to smoke right now, just for relief?  
Not at all \_\_\_\_\_ Extremely

4. How much do you want to smoke right now?  
Not at all \_\_\_\_\_ Extremely

5. Do you feel any drug effect?  
Not at all \_\_\_\_\_ Extremely

6. How strong is the drug effect?  
Not at all \_\_\_\_\_ Extremely

7. Does the drug have any good effects?  
Not at all \_\_\_\_\_ Extremely

8. Does the drug have any bad effects?  
Not at all \_\_\_\_\_ Extremely

9. Do you like the drug effect?  
Not at all \_\_\_\_\_ Extremely

10. Do you dislike the drug effect?  
Not at all \_\_\_\_\_ Extremely

11. Do you like the product's taste?  
Not at all \_\_\_\_\_ Extremely

12. Do you like the feel of the product in your mouth?  
Not at all \_\_\_\_\_ Extremely

13. Does the product taste good?  
Not at all \_\_\_\_\_ Extremely

14. Does the product taste bad?  
Not at all \_\_\_\_\_ Extremely

15. Would you use this product just for its taste?  
Not at all \_\_\_\_\_ Extremely

16. Would you use this product just to get the drug effect?  
Not at all \_\_\_\_\_ Extremely

17. Does the product have a strong taste?  
Not at all \_\_\_\_\_ Extremely

18. How sweet is the product?  
Not at all \_\_\_\_\_ Extremely

19. How bitter is the product?  
Not at all \_\_\_\_\_ Extremely

20. How much do you like the product overall (taste plus drug effect)?  
Not at all \_\_\_\_\_ Extremely

21. How much do you dislike the product overall(taste plus drug effect)?  
Not at all \_\_\_\_\_ Extremely

**THANK YOU. PLEASE RETURN THIS FORM TO THE INVESTIGATOR AND  
WAIT FOR THE NEXT INSTRUCTIONS.**

**Appendix R. Interview Study 2**

Interview

Over the course of our session today, I have asked you to think and write quite a bit about the product, but I would also like to talk to you about what you thought about your experience today.

1. I am especially interested in what your first reactions to the product were. What can you tell me about what your first reactions when you tried it?
2. Was the product as you expected it to be from reading the message?
3. Now I am going to ask you how likely it is that you would use this product again in a variety of different situations. After I read each one, please tell me how likely you would be to use the product in each situation on a scale of 1 to 7 where 1 is very definitely would not and 7 is very definitely would. How likely is it that you would:
  - a. Ever use this product again? \_\_\_\_\_
  - b. Use this product in situations where you could not smoke? \_\_\_\_\_
  - c. Use this product in situations where you did not want to smoke? \_\_\_\_\_
  - d. Use this product to try to cut down on smoking? \_\_\_\_\_
  - e. Use this product to try to quit smoking? \_\_\_\_\_
4. Are there any other situations where you might consider using this product?
5. What are the most important factors in your decisions about how likely you would be to use this product again?

6. If you were going to tell another smoker about this tobacco product, what would you tell them?

7. Are you willing to use this product again outside of the lab as part of this study?

f. Yes

g. No

8. Are you willing to be assigned by chance to a specific schedule of use of this product over the next 5 days?

h. Yes

i. No

Thank you. I will review the instructions for the next part of the study now. [or, that concludes your participant in this study – if unwilling to continue].

**Appendix S. Diary Instruction**

# Daily Diary Entries



Penn State University Study IRB #22611  
 "Smokers' Evaluations of a Novel Tobacco Product"

## Thank You For Recording!

### ~~~~~Diary Instructions ~~~~~

Each time you use tobacco, make an entry. Record:

- \_\_\_ Your ID #, the date, the time - remember to circle AM or PM!
- \_\_\_ Mark Cigarette or Ariva, as appropriate
- \_\_\_ Codes for PLACE, WHO, MOOD
- \_\_\_ For Ariva only, codes for COULD SMOKE and USE
- \_\_\_ Circle the correct follow-up day (1, 2, 3, etc.)

- ⇒ Diary entries should describe the situation when you started the cigarette or Ariva.
- ⇒ If you have an emergency during your participation, call 911.
- ⇒ If you need to reach the investigator, you may call the pager number: 814-567-7499.  
 Pages will be answered between 7 am and 10 pm. You can also call the lab during  
 working hours and leave a message at 865-3319.
- ⇒ SAVE YOUR BUTTS & BACKING IN THE BAGGIES PROVIDED



## ~~~~~REMINDER CARD~~~~~

Remember to return for your follow-up appointment(s) on \_\_\_\_\_.

If you need to reschedule this important appointment, please call 865-8780.

It is VERY important to the success of the study for you to return for the follow-up sessions.

*Even if you don't use any sample product, please return for the next lab session.*

You will be compensated for your participation in each session and may earn another \$CASH\$ bonus for good compliance with the study protocol.

When you return, bring the following items with you:

- ☐ Your daily diary
- ☐ Your blue baggies with cigarette butts and Ariva backing.
- ☐ Any unused Ariva

THANK YOU FOR PARTICIPATING!

## DIARY CODES

Codes for PLACES you might be when you smoke:

1. At home-indoors
2. At home-outdoors
3. At home-in a designated smoking place
4. Working
5. Working but on break
6. School
7. In your car
8. In someone else's car
9. Public transportation (bus)
10. Walking
11. Public social situation (restaurant, movie, bar, mall, sports event)
12. Private social situation (at another person's home)
13. Other (please describe)

Codes for what kind of MOOD you are in:

- |                          |                       |                      |
|--------------------------|-----------------------|----------------------|
| M1 = Nervous/worried     | M6 = Impatient        | M11 = Hungry         |
| M2 = Happy               | M7 = Tired/low energy | M12 = Restless/bored |
| M3 = Thirsty             | M8 = Angry            | M13 = Focused        |
| M4 = Frustrated          | M9 = Sad              | M14 = Irritable      |
| M5 = Curious, interested | M10 = Disorganized    | M15 = Stressed       |

Codes for WHO might be with you:

- A. Alone
- B. With non-smoking person(s)
- C. With smoking person(s)
- D. Mixed company- smokers and non smokers
- E. Children present
- F. In public
- G. Other (describe)

Could you have smoked: Y or N

ID \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_ AM / PM  
 \_\_\_\_\_ Cigarette \_\_\_\_\_ Ariva

PLACE: \_\_\_\_\_ COULD SMOKE: \_\_\_\_\_

WHO: \_\_\_\_\_ USE: \_\_\_\_\_

MOOD: \_\_\_\_\_

Follow-up Day: 1 2 3 4 5 6 7



**Did you leave your diary & collection message today???**

It's easy & required for your compliance bonus \$. Call 814-865-8780 – state your ID number, the date & confirm that you will make entries/collections today. Done \_\_\_\_\_

**Appendix T: Closing Interview Study 2**

**Title of Project:** Smokers' Evaluations of a Reduced Exposure Tobacco Product (IRB# 22611)

**Participant ID number:** \_\_\_\_\_

**Lab Session:** 1 2 3

**Instruction Set:** E N

### Follow-Up Survey

1. CO Reading \_\_\_\_\_

2. **How long it has been since your last cigarette?**

(Note: 1hr=60 min, 2=120, 3=180, 4=240, 5=300, 6=360, 7=420, 8=480)

Number of minutes: \_\_\_\_\_

3. **Please rate your addiction to cigarettes on a scale of 0-100. 0 means "I am NOT addicted to cigarettes at all." 100 means "I am extremely addicted to cigarettes."**

\_\_\_\_\_

4. **For you, quitting smoking would be:**

- a. \_\_\_\_\_ Very Easy
- b. \_\_\_\_\_ Fairly Easy
- c. \_\_\_\_\_ Fairly Difficult
- d. \_\_\_\_\_ Very Difficult
- e. \_\_\_\_\_ Impossible

5. **How likely is it that most of the people who are important to you think you should quit smoking in the next 6 months?**

- a. \_\_\_\_\_ Not at all likely
- b. \_\_\_\_\_ Only a little likely
- c. \_\_\_\_\_ Somewhat likely
- d. \_\_\_\_\_ Very likely

6. **How likely is it that people whose opinions you value would approve of your quitting smoking in the next 6 months?**

- a. \_\_\_\_\_ Not at all likely
- b. \_\_\_\_\_ Only a little likely
- c. \_\_\_\_\_ Somewhat likely
- d. \_\_\_\_\_ Very likely

7. **How much do you WANT to give up smoking cigarettes in the next 6 months?**

- a. \_\_\_\_\_ Not at all
- b. \_\_\_\_\_ Only a little
- c. \_\_\_\_\_ Somewhat
- d. \_\_\_\_\_ Very much

8. **How much would you LIKE to give up smoking in the next 6 months?**
- a.  Not at all
  - b.  Only a little
  - c.  Somewhat
  - d.  Very much
9. **How likely is it that you will try to quit smoking in the next 6 months?**
- a.  Not at all
  - b.  Only a little
  - c.  Somewhat
  - d.  Very much
10. **Are you seriously thinking of quitting smoking?**
- a.  Yes, within the next 30 days (GO TO 11)
  - b.  Yes, within the next 6 months (GO TO 12)
  - c.  No, not thinking of quitting
11. **On a scale of 1 to 10 where 1 means "I have absolutely no intention of quitting smoking" and 10 means "I have made a firm decision to quit smoking in the next 30 days" please rate how strongly you intend to quit smoking.**  
<  > 1-10
12. **On a scale of 1 to 10 where 1 means "I have absolutely no intention of quitting smoking" and 10 means "I have made a firm decision to quit smoking in the next 6 months" please rate how strongly you intend to quit smoking.**  
<  > 1-10
13. **What is the possibility that you will be smoking five years from now? Will you . . .**
- a.  Definitely be smoking
  - b.  Probably be smoking
  - c.  Probably not be smoking
  - d.  Definitely not be smoking
14. **How likely is it that you would be able to quit smoking if you tried to in the next 6 months?**
- a.  Not at all likely
  - b.  Only a little likely
  - c.  Somewhat likely
  - d.  Very likely
15. **Do you agree with the following statement: I believe that it is mostly up to me whether or not I quit smoking in the next 6 months.**
- a.  Not at all
  - b.  Only a little
  - c.  Somewhat
  - d.  Very much

## **Appendix U. Symptom Report Questionnaire**

Date

|  |  |   |  |  |   |  |  |
|--|--|---|--|--|---|--|--|
|  |  | / |  |  | / |  |  |
|--|--|---|--|--|---|--|--|

IDNUM

|  |  |  |  |  |  |
|--|--|--|--|--|--|
|  |  |  |  |  |  |
|--|--|--|--|--|--|

## Symptom Report Questionnaire

For each of the following statements, please circle the number that indicates to what degree you feel these symptoms at this moment.

|   | Not at<br>all | A little<br>bit | Moderately | Quite<br>a bit | Extremely |
|---|---------------|-----------------|------------|----------------|-----------|
| 1. My heart is pounding -----               | 0             | 1               | 2          | 3              | 4         |
| 2. I feel drowsy or sleepy -----            | 0             | 1               | 2          | 3              | 4         |
| 3. I feel restless -----                    | 0             | 1               | 2          | 3              | 4         |
| 4. I feel lethargic -----                   | 0             | 1               | 2          | 3              | 4         |
| 5. I feel hungry -----                      | 0             | 1               | 2          | 3              | 4         |
| 6. I feel tense or edgy -----               | 0             | 1               | 2          | 3              | 4         |
| 7. I feel dizzy -----                       | 0             | 1               | 2          | 3              | 4         |
| 8. My skin feels itchy or irritated -----   | 0             | 1               | 2          | 3              | 4         |
| 9. My fingers or hands feel numb -----      | 0             | 1               | 2          | 3              | 4         |
| 10. I feel anxious -----                    | 0             | 1               | 2          | 3              | 4         |
| 11. My head aches -----                     | 0             | 1               | 2          | 3              | 4         |
| 12. I feel nauseous/my stomach is upset --- | 0             | 1               | 2          | 3              | 4         |
| 13. I am thirsty -----                      | 0             | 1               | 2          | 3              | 4         |
| 14. I feel faint -----                      | 0             | 1               | 2          | 3              | 4         |
| 15. I am having trouble concentrating ----- | 0             | 1               | 2          | 3              | 4         |

## **Appendix V. Mood Assessment**



**Appendix W. Self-Evaluation Trait Questionnaire**

DATE

|  |  |   |  |  |   |  |  |
|--|--|---|--|--|---|--|--|
|  |  | / |  |  | / |  |  |
|--|--|---|--|--|---|--|--|

IDNUM

|  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|

**Self-Evaluation TRAIT Questionnaire**
 Developed by Charles D. Spielberger  
 STAI Form Y-2

**Directions:** A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you *generally* feel.

1 = NOT AT ALL

2 = SOMEWHAT

3 = MODERATELY SO

4 = VERY MUCH SO

- |  |   |   |   |   |
|--|---|---|---|---|
| 1. I feel pleasant -----   | 1 | 2 | 3 | 4 |
| 2. I feel nervous and restless-----  | 1 | 2 | 3 | 4 |
| 3. I feel satisfied with myself-----   | 1 | 2 | 3 | 4 |
| 4. I wish I could be as happy as others seem to be-----  | 1 | 2 | 3 | 4 |
| 5. I feel like a failure-----  | 1 | 2 | 3 | 4 |
| 6. I feel rested-----  | 1 | 2 | 3 | 4 |
| 7. I am "calm, cool, and collected"-----   | 1 | 2 | 3 | 4 |
| 8. I feel that difficulties are piling up so that I cannot<br>overcome them -----                    | 1 | 2 | 3 | 4 |
| 9. I worry too much over something that really<br>doesn't matter-----                                | 1 | 2 | 3 | 4 |
| 10. I am happy -----   | 1 | 2 | 3 | 4 |
| 11. I have disturbing thoughts-----  | 1 | 2 | 3 | 4 |
| 12. I lack self-confidence -----   | 1 | 2 | 3 | 4 |
| 13. I feel secure -----  | 1 | 2 | 3 | 4 |
| 14. I make decisions easily -----  | 1 | 2 | 3 | 4 |
| 15. I feel inadequate -----  | 1 | 2 | 3 | 4 |
| 16. I am content -----   | 1 | 2 | 3 | 4 |
| 17. Some unimportant thought runs through my<br>mind and bothers me -----                            | 1 | 2 | 3 | 4 |
| 18. I take disappointments so keenly that I can't put them out of my mind                            | 1 | 2 | 3 | 4 |
| 19. I am a steady person-----  | 1 | 2 | 3 | 4 |
| 20. I get in a state of tension or turmoil as I think over my<br>recent concerns and interests ----- | 1 | 2 | 3 | 4 |

## **Appendix X. Risk Perception Questionnaire**



## **Appendix Y. Menstrual Cycle Questionnaire**

### Questions for Women Only

The following questions are personal. You are not required to answer them and you may choose which ones you would like to answer. This information is being sought because research has shown that the level of estrogen can affect the metabolism of nicotine in women. Because estrogen levels change across a women's menstrual cycle and if they are pregnant or breast-feeding, the information you are willing to provide will help us understand how nicotine is being metabolized in your body as measured through the urine.

This information is confidential and only will be used to understand your metabolic responses to nicotine.

1. Are you using Estrogen/birth control/hormone replacement therapy?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO                      \_\_\_\_\_ Prefer Not to Answer

2. Are you taking Depo-Provera?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO                      \_\_\_\_\_ Prefer Not to Answer

3. Are you currently pregnant or have you been pregnant within the last year?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO                      \_\_\_\_\_ Prefer Not to Answer

4. Are you currently breast feeding or have you breast-fed within the last year?

\_\_\_\_\_ YES                      \_\_\_\_\_ NO                      \_\_\_\_\_ Prefer Not to Answer

5. What was the first date of your last menstrual period?

Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_                      \_\_\_\_\_ Prefer Not to Answer

Typically, how many days are there between your periods?    21    28    30    32    Other: \_\_\_\_\_

**PLEASE PLACE THIS QUESTIONNAIRE IN YOUR PARTICIPANT FOLDER.**

*Thank You!!*

**Appendix Z. Tobacco History Questionnaire Study 2**

Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3

Study Condition: E C  
Experimenter: \_\_\_\_\_

1

Initial Session\_History Survey

This questionnaire is about your smoking and tobacco use. Please complete the survey and proceed to the next questionnaire in your packet. Alert the investigator if you have any questions about how to answer.

1. Use an 'x' to mark how much you agree with the statement: **"I have a desire for a cigarette right now"**

\_\_\_\_\_ Totally disagree  
\_\_\_\_\_ Somewhat disagree  
\_\_\_\_\_ Neither agree nor disagree  
\_\_\_\_\_ Somewhat agree  
\_\_\_\_\_ Fully agree

2. How old were you when you smoked your first cigarette?

Age in years: \_\_\_\_\_  
\_\_\_\_\_ Don't know

3. How old were you when you started smoking everyday?

Age in years: \_\_\_\_\_

-OR-

\_\_\_\_\_ Never smoked everyday \_\_\_\_\_ Don't know

4. Do you NOW smoke cigarettes every day or just some days?

Mark one response below:

\_\_\_\_\_ Every day \_\_\_\_\_ Some days \_\_\_\_\_ Not at all \_\_\_\_\_ Don't know

5. Use an 'x' to mark how much you agree with the statement: **"I crave a cigarette right now"**

\_\_\_\_\_ Totally disagree  
\_\_\_\_\_ Somewhat disagree  
\_\_\_\_\_ Neither agree nor disagree  
\_\_\_\_\_ Somewhat agree  
\_\_\_\_\_ Fully agree

6. Use an 'x' to mark how much you agree with the statement: **"I will smoke as soon as I get the chance"**:

\_\_\_\_\_ Totally disagree  
\_\_\_\_\_ Somewhat disagree  
\_\_\_\_\_ Neither agree nor disagree  
\_\_\_\_\_ Somewhat agree  
\_\_\_\_\_ Fully agree

7. On the average day, how many cigarettes do you usually smoke?

Enter Number of cigarettes per day: \_\_\_\_\_

**OR** mark the appropriate response in the list below:

\_\_\_\_\_ Less than one cigarette per day  
\_\_\_\_\_ None



Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3

Study Condition: E C  
Experimenter: \_\_\_\_\_

2

History\_addothertobacco\_030107

\_\_\_\_\_ Don't know

**8. How soon after you wake up do you usually smoke your first cigarette of the day?**

Please answer in MINUTES - Note: 1hour=60 min, 2 hours=120, 3=180, 4=240, 5=300,  
6=360, 7=420, 8=480)

Number of minutes: \_\_\_\_\_

**OR** mark the appropriate response in the list below:

\_\_\_\_\_ It depends  
\_\_\_\_\_ Don't Know

**9. Use an 'x' to mark how much you agree with the statement: "I do want to smoke right now":**

\_\_\_\_\_ Totally disagree  
\_\_\_\_\_ Somewhat disagree  
\_\_\_\_\_ Neither agree nor disagree  
\_\_\_\_\_ Somewhat agree  
\_\_\_\_\_ Fully agree

**10. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g. in church, at the library, in the cinema? Mark one answer below.**

\_\_\_\_\_ Yes  
\_\_\_\_\_ No  
\_\_\_\_\_ Don't know

**11. Do you smoke more frequently during the first hours after waking than during the rest of the day? Mark one answer below.**

\_\_\_\_\_ Yes  
\_\_\_\_\_ No  
\_\_\_\_\_ Don't know

**12. Do you smoke if you are so ill that you are in bed most of the day? Mark one answer below.**

\_\_\_\_\_ Yes  
\_\_\_\_\_ No  
\_\_\_\_\_ Don't know

**13. Please rate your addiction to cigarettes on a scale of 0-100. 0 means "I am NOT addicted to cigarettes at all." 100 means "I am extremely addicted to cigarettes."**

\_\_\_\_\_

Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3

Study Condition: E C  
Experimenter: \_\_\_\_\_

3

History\_addothertobacco\_030107

**14. For you, quitting smoking would be:**

- \_\_\_\_\_ Very easy
- \_\_\_\_\_ Fairly easy
- \_\_\_\_\_ Fairly difficult
- \_\_\_\_\_ Very difficult
- \_\_\_\_\_ Impossible

**15. After a few hours without smoking, I feel an irresistible urge to smoke.**

- \_\_\_\_\_ Totally disagree
- \_\_\_\_\_ Somewhat disagree
- \_\_\_\_\_ Neither agree nor disagree
- \_\_\_\_\_ Somewhat agree
- \_\_\_\_\_ Fully agree

**16. Circle the brand of cigarettes you usually smoke:**

- |              |                     |
|--------------|---------------------|
| <1> Marlboro | <6> Winston         |
| <2> Newport  | <7> GPC             |
| <3> Doral    | <8> Kool            |
| <4> Camel.   | <9> Salem           |
| <5> Basic    | <10> Virginia Slims |

Other Brand: \_\_\_\_\_

**17. Is your usual brand:**

- \_\_\_\_\_ ULTRA-LIGHT
- \_\_\_\_\_ LIGHT
- \_\_\_\_\_ MEDIUM
- \_\_\_\_\_ REGULAR
- \_\_\_\_\_ OTHER: \_\_\_\_\_
- \_\_\_\_\_ Don't Know

**18. About how much does a pack of your usual cigarettes cost?** \_\_\_\_\_

**19. How many cigarettes are in a pack of your usual brand?** \_\_\_\_\_

The next section contains questions about Nicotine Replacement Therapies and oral tobacco. Answer to the best of your knowledge.

**20. Do you think that using nicotine gum is:**

- \_\_\_\_\_ Much safer than smoking
- \_\_\_\_\_ A little safer than smoking
- \_\_\_\_\_ About the same as smoking
- \_\_\_\_\_ A little more dangerous than smoking
- \_\_\_\_\_ Much more dangerous than smoking
- \_\_\_\_\_ Don't know

Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3

History\_addothertobacco\_030107

Study Condition: E C  
Experimenter: \_\_\_\_\_

4

**21. Do you think that using a nicotine patch is:**

- \_\_\_\_\_ Much safer than smoking
- \_\_\_\_\_ A little safer than smoking
- \_\_\_\_\_ About the same as smoking
- \_\_\_\_\_ A little more dangerous than smoking
- \_\_\_\_\_ Much more dangerous than smoking
- \_\_\_\_\_ Don't know

**22. Do you think that using the nicotine lozenge is:**

- \_\_\_\_\_ Much safer than smoking
- \_\_\_\_\_ A little safer than smoking
- \_\_\_\_\_ About the same as smoking
- \_\_\_\_\_ A little more dangerous than smoking
- \_\_\_\_\_ Much more dangerous than smoking
- \_\_\_\_\_ Don't know

**23. Do you think that using smokeless tobacco (snuff, chew, or dip) is:**

- \_\_\_\_\_ Much safer than smoking
- \_\_\_\_\_ A little safer than smoking
- \_\_\_\_\_ About the same as smoking
- \_\_\_\_\_ A little more dangerous than smoking
- \_\_\_\_\_ Much more dangerous than smoking
- \_\_\_\_\_ Don't know

**24. How likely it is that each of the following will cause health problems?**

**a. Nicotine gum**

- \_\_\_\_\_ Not at all
- \_\_\_\_\_ Only a little
- \_\_\_\_\_ Somewhat
- \_\_\_\_\_ Very likely
- \_\_\_\_\_ Don't know

**b. Cigarettes**

- \_\_\_\_\_ Not at all
- \_\_\_\_\_ Only a little
- \_\_\_\_\_ Somewhat
- \_\_\_\_\_ Very likely
- \_\_\_\_\_ Don't know

**c. Nicotine lozenge**

- \_\_\_\_\_ Not at all
- \_\_\_\_\_ Only a little
- \_\_\_\_\_ Somewhat
- \_\_\_\_\_ Very likely
- \_\_\_\_\_ Don't know

**d. Chew, snuff, or dip**

- \_\_\_\_\_ Not at all
- \_\_\_\_\_ Only a little
- \_\_\_\_\_ Somewhat
- \_\_\_\_\_ Very likely
- \_\_\_\_\_ Don't know

**e. Nicotine Patch**

- \_\_\_\_\_ Not at all
- \_\_\_\_\_ Only a little
- \_\_\_\_\_ Somewhat
- \_\_\_\_\_ Very likely
- \_\_\_\_\_ Don't know

**25. How likely is it that most of the people who are important to you think you should quit smoking in the next 6 months?**

\_\_\_\_\_ Not at all likely    \_\_\_\_\_ Only a little likely    \_\_\_\_\_ Somewhat likely    \_\_\_\_\_ Very likely

Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3

Study Condition: E C  
Experimenter: \_\_\_\_\_

5

History\_addothertobacco\_030107

**26. How likely is it that people whose opinions you value would approve of your quitting smoking in the next 6 months?**

\_\_\_\_\_ Not at all likely \_\_\_\_\_ Only a little likely \_\_\_\_\_ Somewhat likely \_\_\_\_\_ Very likely

**27. How much do you WANT to give up smoking cigarettes in the next 6 months?**

\_\_\_\_\_ Not at all \_\_\_\_\_ Only a little \_\_\_\_\_ Somewhat \_\_\_\_\_ Very much

**28. How much would you LIKE to give up smoking in the next 6 months?**

\_\_\_\_\_ Not at all \_\_\_\_\_ Only a little \_\_\_\_\_ Somewhat \_\_\_\_\_ Very much

**29. How likely is it that you will try to quit smoking in the next 6 months?**

\_\_\_\_\_ Not at all likely \_\_\_\_\_ Only a little likely \_\_\_\_\_ Somewhat likely \_\_\_\_\_ Very likely

**30. Are you seriously thinking of quitting smoking? Choose one response:**

\_\_\_\_\_ Yes, within the next 30 days (GO TO question 31)

\_\_\_\_\_ Yes, within the next 6 months (GO TO question 32)

\_\_\_\_\_ No, not thinking of quitting (GO TO question 33)

**31. On a scale of 1 to 10 where 1 means "I have absolutely no intention of quitting smoking" and 10 means "I have made a firm decision to quit smoking in the next 30 days" please rate how strongly you intend to quit smoking.**\_\_\_\_\_ (enter a number 1- 10)

**32. On a scale of 1 to 10 where 1 means "I have absolutely no intention of quitting smoking" and 10 means "I have made a firm decision to quit smoking in the next 6 months" please rate how strongly you intend to quit smoking.**\_\_\_\_\_ (enter a number 1- 10)

**33. What is the possibility that you will be smoking five years from now? Will you ...**

\_\_\_\_\_ Definitely be smoking

\_\_\_\_\_ Probably be smoking

\_\_\_\_\_ Probably not be smoking

\_\_\_\_\_ Definitely not be smoking

**34. How likely is it that you would be able to quit smoking if you tried to in the next 6 months?**

\_\_\_\_\_ Not at all likely \_\_\_\_\_ Only a little likely \_\_\_\_\_ Somewhat likely \_\_\_\_\_ Very likely

**35. Do you agree with the following statement: I believe that it is mostly up to me whether or not I quit smoking in the next 6 months.**

\_\_\_\_\_ Not at all \_\_\_\_\_ Only a little \_\_\_\_\_ Somewhat \_\_\_\_\_ Very much

Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3  
History\_addothertobacco\_030107

Study Condition: E C  
Experimenter: \_\_\_\_\_

6

36. If you were going to quit smoking, how likely is it that you would use each of the following:  
(circle one choice for each item).

- |                          |                          |                          |
|--------------------------|--------------------------|--------------------------|
| a. Nicotine gum          | b. Nicotine Patch        | c. Nicotine lozenge      |
| <1> Not at all likely    | <1> Not at all likely    | <1> Not at all likely    |
| <2> Only a little likely | <2> Only a little likely | <2> Only a little likely |
| <3> Somewhat likely      | <3> Somewhat likely      | <3> Somewhat likely      |
| <4> Very likely          | <4> Very likely          | <4> Very likely          |
| <8> Don't know           | <8> Don't know           | <8> Don't know           |
| <9> Refused              | <9> Refused              | <9> Refused              |

37. Have you ever made a serious attempt to stop smoking cigarettes entirely?

\_\_\_\_\_ Yes  
\_\_\_\_\_ No (Go to question 44)

38. How many times have you tried to quit smoking AND succeeded for at least 24 hours in the past 12 months?

Number of times: \_\_\_\_\_

39. How many times have you tried to quit smoking AND succeeded for at least 24 hours in the past 30 days?

Number of times: \_\_\_\_\_

40. How many times have you tried to quit smoking AND succeeded for at least 24 hours in the past 7 days?

Number of times: \_\_\_\_\_

41. About how many times IN THE PAST FIVE YEARS have you made a serious attempt to stop smoking?

Number of times: \_\_\_\_\_

42. Please check the methods you have tried to quit smoking. A 'method' could mean things like using the patch, going cold turkey, going to a support group, etc. – any strategy you tried to help you not smoke.

- \_\_\_\_\_ Nicotine gum  
\_\_\_\_\_ Nicotine patch  
\_\_\_\_\_ Nicotine lozenge  
\_\_\_\_\_ Cold Turkey  
\_\_\_\_\_ Other (please describe):

Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3

Study Condition: E C  
Experimenter: \_\_\_\_\_

7

History\_addothertobacco\_030107

43. Thinking about the very last time you tried quitting (the most recent time), what methods did you use? Remember, a 'method' could mean things like using the patch, going cold turkey, going to a support group, etc. – any strategy you tried to help you not smoke.

- \_\_\_\_ Nicotine gum  
\_\_\_\_ Nicotine patch  
\_\_\_\_ Nicotine lozenge  
\_\_\_\_ Cold Turkey  
\_\_\_\_ Other (please describe):

The next few questions ask about your use of other tobacco products. "Smokeless tobacco" refers to snuff (sometimes called 'dip'), chewing tobacco, or both.

44. Have you ever used smokeless tobacco?

\_\_\_\_ Yes \_\_\_\_ No (go to question 63 on page 9)

45. How old were you the first time you used smokeless tobacco?

\_\_\_\_ Years \_\_\_\_ Don't know

46. How old were you when you started using smokeless tobacco everyday?

\_\_\_\_ Years \_\_\_\_ Never used smokeless tobacco everyday \_\_\_\_ Don't know

47. Do you currently use snuff or chewing tobacco?

\_\_\_\_ Yes, dip/snuff \_\_\_\_ Yes, chewing tobacco \_\_\_\_ Yes, both \_\_\_\_ No [go to question 53]  
\_\_\_\_ Don't know

48. How many days do you use smokeless tobacco in a typical week?

\_\_\_\_ days \_\_\_\_ Don't use weekly

49. How many days does a tin or pouch last you?

\_\_\_\_ days

50. How many minutes after you wake up do you use smokeless tobacco?

\_\_\_\_ Number of minutes \_\_\_\_ N/A

51. How many minutes do you keep a rub or chew in before putting in a fresh one?

\_\_\_\_ Number of minutes

52. How many minutes do you usually go between dips or chews?

\_\_\_\_ Number of minutes \_\_\_\_ N/A

53. What smokeless tobacco product did you formerly use?

- \_\_\_\_ dip/snuff  
\_\_\_\_ chewing tobacco  
\_\_\_\_ both



Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3  
History\_addothertobacco\_030107

Study Condition: E C  
Experimenter: \_\_\_\_\_

8

54. About how long ago did you stop using smokeless tobacco? Enter your response in the category that fits best.

- <1> \_\_\_\_\_ days  
<2> \_\_\_\_\_ weeks  
<3> \_\_\_\_\_ months  
<4> \_\_\_\_\_ years

55. Before you quit, how many days did you use smokeless tobacco in a typical week?

\_\_\_\_\_ days      \_\_\_\_\_ Not a regular user

56. Before you quit, how many days did a tin or pouch last you?

\_\_\_\_\_ days      \_\_\_\_\_ N/A

57. Before you quit, how many minutes after you wake up did you use smokeless tobacco?

\_\_\_\_\_ Number of minutes

58. Before you quit, how many minutes did you keep a dip or chew in before putting in a fresh one?

\_\_\_\_\_ Number of minutes

59. Before you quit, how many minutes did you usually go between rubs or chews?

\_\_\_\_\_ Number of minutes

60. Have you ever used smokeless tobacco as a substitute for cigarettes when you could not smoke?

\_\_\_\_\_ Yes  
\_\_\_\_\_ No  
\_\_\_\_\_ Don't know

61. Have you ever used cigarettes as a substitute for smokeless tobacco when you could not dip or chew?

\_\_\_\_\_ Yes  
\_\_\_\_\_ No  
\_\_\_\_\_ Don't know

62. Which product do/did you find more enjoyable to use?

\_\_\_\_\_ Dip/snuff/chew  
\_\_\_\_\_ Cigarettes  
\_\_\_\_\_ Equally enjoyable / no difference / about the same

Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3

Study Condition: E C  
Experimenter: \_\_\_\_\_

9

History\_addothertobacco\_030107

63. Have you ever used cigars?

\_\_\_ Yes \_\_\_ No (go to 65)

64. Do you currently use cigars:

- A. Every day
- B. Some days
- C. Never

65. Have you ever used a tobacco pipe?

- A. Yes
- B. No (go to 67)

66. Do you currently use a pipe:

- A. Everyday
- B. Some days
- C. Never

67. Have you ever used a water pipe or hookah for tobacco?

- A. Yes
- B. No (go to 69)

68. Do you currently use a water pipe or hookah for tobacco:

- A. Everyday
- B. Some days
- C. Never

69. In general, how would you rate your physical health?

\_\_\_ Excellent \_\_\_ Good \_\_\_ Fair \_\_\_ Poor

70. In the past month, have you often been bothered by feeling down, depressed, or hopeless?

\_\_\_ Yes \_\_\_ No \_\_\_ Don't know

71. Do you know anyone else taking part in this study?

\_\_\_ Yes \_\_\_ No (go to question 73)

72. What did they tell you about what happens in this study?

---

73. Besides yourself, how many people live in your household?

\_\_\_\_\_

74. Besides yourself, how many members of your household smoke?

\_\_\_\_\_



Participant ID: \_\_\_\_\_  
Date: \_\_\_\_\_

Lab Session: 1 2 3

Study Condition: E C  
Experimenter: \_\_\_\_\_

10

History\_addothertobacco\_030107

**75. If you decided to quit smoking, how likely is it that you could get a member of your household to quit with you?**

- ☐ Not at all likely  
☐ Only a little likely  
☐ Moderately likely  
☐ Very likely  
☐ Don't know  
☐ Not applicable

**76. What is the highest grade or year of regular school or college that you completed? Check one choice:**

- |   |  |
|---|--|
| <input type="checkbox"/> 1st grade            | <input type="checkbox"/> 1 year College/Professional School  |
| <input type="checkbox"/> 2nd grade            | <input type="checkbox"/> 2 years College/Professional School |
| <input type="checkbox"/> 3rd grade            | <input type="checkbox"/> 3 years College/Professional School |
| <input type="checkbox"/> 4th grade            | <input type="checkbox"/> 4 years College/Professional School |
| <input type="checkbox"/> 5th grade            | <input type="checkbox"/> 5 years College/Professional School |
| <input type="checkbox"/> 6th grade            | <input type="checkbox"/> 6 years or more College             |
| <input type="checkbox"/> 7th grade            | <input type="checkbox"/> No Formal Schooling                 |
| <input type="checkbox"/> 8th grade            | <input type="checkbox"/> Don't Know                          |
| <input type="checkbox"/> 1st year high school | <input type="checkbox"/> Refused                             |
| <input type="checkbox"/> 2nd year high school | <input type="checkbox"/> Other schooling:                    |
| <input type="checkbox"/> 3rd year high school |  |
| <input type="checkbox"/> 4th year high school |  |

**77. How would you describe your racial background?**

- ☐ White  
☐ Black  
☐ Native American/Alaskan  
☐ Asian  
☐ Other – please describe:  
☐ Don't know  
☐ Refused

**78. Do you consider yourself to be of Hispanic origin?**

☐ Yes ☐ No ☐ Don't Know ☐ Refused

**79. Are you:**

- ☐ Married ☐ Never been married  
☐ Divorced ☐ A member of an unmarried couple  
☐ Widowed ☐ Refused  
☐ Separated

**Thank you for completing this survey. Please set it aside and proceed to the next questionnaire.**

**Appendix AA. Thought Listing Exercise Study 2**

Participant ID: \_\_\_\_\_

1

### Thought Listing Exercise

You have just read information about why smokers should consider using a tobacco product, called Ariva.

I would like you to write down all the thoughts and ideas you had while you were reading the argument.

You might have had ideas that are favorable, unfavorable, irrelevant, or a mixture of all of these, and any case is fine. Below these instructions there is a form that has been prepared for you to record your thoughts and ideas. Simply write the first idea that comes to mind in the first box, the second idea in the second box, and so on.

Don't censor yourself – just write as many thoughts you had that you can remember. Please state your thoughts and ideas as concisely as possible – a phrase is sufficient. Don't worry about grammar, spelling, or punctuation. You will have 2 1/2 minutes to write down your thoughts. I will tell you when the time is up. There is more space provided than should be needed, so don't worry about trying to fill every space. Please be completely honest and list all the thoughts you had.

Write one thought in each large box below.

Leave this box blank for now.

Example: thought thought thought ...

|  |  |
|--|--|
|  |  |
|  |  |
|  |  |

Participant ID: \_\_\_\_\_

3

Now that you have listed all your thoughts, I would like you to go back and read over each one and decide if you think it is a thought that is mostly favorable, unfavorable, or neutral. There is a small box on the right hand side of each thought-listing space. In that box, use the following scale to rate how favorable or unfavorable you think the thought is:

1 . . . . 2 . . . . 3 . . . . 4 . . . . 5 . . . . 6 . . . . 7  
Totally Unfavorable                      Neutral                      Totally Favorable

**Thank You**

**When you are finished, please return this form to the investigator and wait for your next instructions.**

**Appendix BB. Information Evaluation Exercise Study 2**

Message\_Evaluation 12/18/2006

Participant ID: \_\_\_\_\_

Condition: E C

Session: 1

### Information Evaluation Exercise

In this questionnaire, you will rate the quality of the information that you read about the novel tobacco product Ariva.

For each statement below, fill in the number from 1 to 7 that best represents your agreement. Use this scale.

|                                       |                               |                             |                   |                   |                     |                             |
|---------------------------------------|-------------------------------|-----------------------------|-------------------|-------------------|---------------------|-----------------------------|
| 1                                     | 2                             | 3                           | 4                 | 5                 | 6                   | 7                           |
| Very<br>Definitely<br>Do Not<br>Agree | Definitely<br>Do Not<br>Agree | Probably<br>Do Not<br>Agree | Possibly<br>Agree | Probably<br>Agree | Definitely<br>Agree | Very<br>Definitely<br>Agree |

1. The information was mostly new to me. \_\_\_\_\_
2. The information was easy to understand. \_\_\_\_\_
3. The information was important to me. \_\_\_\_\_
4. I already knew most of the information I read. \_\_\_\_\_
5. The information was convincing. \_\_\_\_\_
6. The information is important for smokers to know. \_\_\_\_\_
7. The information made sense. \_\_\_\_\_
8. I will share the information with other smokers I know. \_\_\_\_\_
9. The information is easy to remember. \_\_\_\_\_
10. The information was helpful to me. \_\_\_\_\_
11. The information was believable. \_\_\_\_\_
12. The informed stated that Ariva tobacco pieces are much less harmful to health than smoking cigarettes. \_\_\_\_\_
13. The information stated that Ariva tobacco pieces are not addictive. \_\_\_\_\_
14. The information stated that most of the health harm from smoking is due to tobacco smoke. \_\_\_\_\_
15. The information stated that nicotine is the main cancer causing compound in tobacco. \_\_\_\_\_

WHEN YOU ARE FINISHED, RETURN THIS FORM TO THE INVESTIGATOR AND WAIT FOR INSTRUCTIONS.

**Appendix CC. Diary and Tobacco Collection Compliance Tracking Sheet**

11/6/2006 BQE Diary and Collection Check

1

Title of Project: Smokers' Evaluations of a Novel Tobacco Product (IRB# 22611)

Participant ID number: \_\_\_\_\_

Lab Session: 2 3

Instruction Group: E C

|   |
|---|
| Diary & Collection Compliance Check List<br>Follow-up Visit One |
|---|

**Voice Message Compliance**

| <u>Expected Call Dates:</u> | <u>Message Left?</u> | <u>Confirmatory?</u> | <u>Other Notes</u> |
|-----------------------------|----------------------|----------------------|--------------------|
| Day 1:                      | _____                | _____                | _____              |
| Day 2:                      | _____                | _____                | _____              |
| Day 3:                      | _____                | _____                | _____              |
| Day 4:                      | _____                | _____                | _____              |
| Day 5:                      | _____                | _____                | _____              |

**Diary Recording Compliance**

| <u>Date of Diary Entries</u> | <u>Smoking Recorded?</u> | <u>***Ariva?</u> | <u>Questions?</u> |
|------------------------------|--------------------------|------------------|-------------------|
| Day 1:                       | _____                    | _____            | _____             |
| Day 2:                       | _____                    | _____            | _____             |
| Day 3:                       | _____                    | _____            | _____             |
| Day 4:                       | _____                    | _____            | _____             |
| Day 5:                       | _____                    | _____            | _____             |

\*\*\*For participants in experience group, are 2 pieces of Ariva recorded each day?\*\*\*

**Collection Compliance**

| <u>Date of Collection</u> | <u># Butts Collected?</u> | <u># Ariva/backing Collected</u> |
|---------------------------|---------------------------|----------------------------------|
| Day 1:                    | _____                     | _____                            |
| Day 2:                    | _____                     | _____                            |
| Day 3:                    | _____                     | _____                            |
| Day 4:                    | _____                     | _____                            |
| Day 5:                    | _____                     | _____                            |



Curriculum Vitae  
Beth Q. Edwards

**Work**

315 East Health and Human Development  
The Pennsylvania State University  
University Park, PA USA 16802  
4114  
Phone: (814) 863-2756  
Email: [baq102@psu.edu](mailto:baq102@psu.edu)

**Home**

1933 Princeton Ave.  
Camp Hill, PA 17011  
Phone: (814)769-

**Education**

Pennsylvania State University  
Pennsylvania State University

**Degree**

Ph.D. 2007 (expected)  
B.S. 1999

**Year**

**Field**

Biobehavioral Health  
Health Policy  
& Administration

**Professional and Research Experience**

|              |  |
|--------------|--|
| 2006-2007    | Graduate Teaching Assistant, Department of Biobehavioral Health, The Pennsylvania State University (PSU)   |
| 2002-2006    | Graduate Research Assistant, Department of Biobehavioral Health, PSU, Robert Wood Johnson Foundation, (PI: Dr. Lynn Kozlowski), Project Title: <u>Medicinal Nicotine for Harm Reduction.</u>     |
| 2002-present | Instructor of Biobehavioral Health; The Pennsylvania State University World Campus   |
| 2001-2002    | Graduate Research Assistant, Department of Biobehavioral Health & Women's Studies, PSU, (PI: Dr. Phyllis Mansfield ), Project Title: <u>The Tremin Trust Research Program on Women's Health.</u> |
| 2000-2001    | Graduate Teaching Assistant, Department of Biobehavioral Health, The Pennsylvania State University (PSU)   |
| 1999-2000    | Research Assistant & Analyst, The MEDSTAT Group, Washington, DC, (Co-I: Dr. Patricia Russo), Project Title: <u>Schizophrenia Care and Assessment Project.</u>                                    |
| 1999 – 2001  | Undergraduate Research Assistant, Women's Studies Department, The Pennsylvania State University, Tremin Trust Research Program on Women's Health (Advisor: Dr. Phyllis Mansfield)                |

**Awards and Honors**

|           |  |
|-----------|--|
| 2003-2006 | Graduate Research Assistantship, Robert Wood Johnson Foundation, (PI: Dr. Lynn Kozlowski)  |
| 1999      | Cum Laude, College of Health & Human Development, The Pennsylvania State University<br>Academic Achievement Award, College of Health and Human Development, Penn State University; |
| 1997-1999 | Schreyer's Scholar, Schreyer Honors College, The Pennsylvania State University   |

**Complete vita, including list of manuscripts, available upon request.**