Testimony before the U.S. Senate Committee on Health, Education, Labor and Pensions
The Need for FDA Regulation of Tobacco Products
(Family Smoking Prevention and Tobacco Control Act - S.625)

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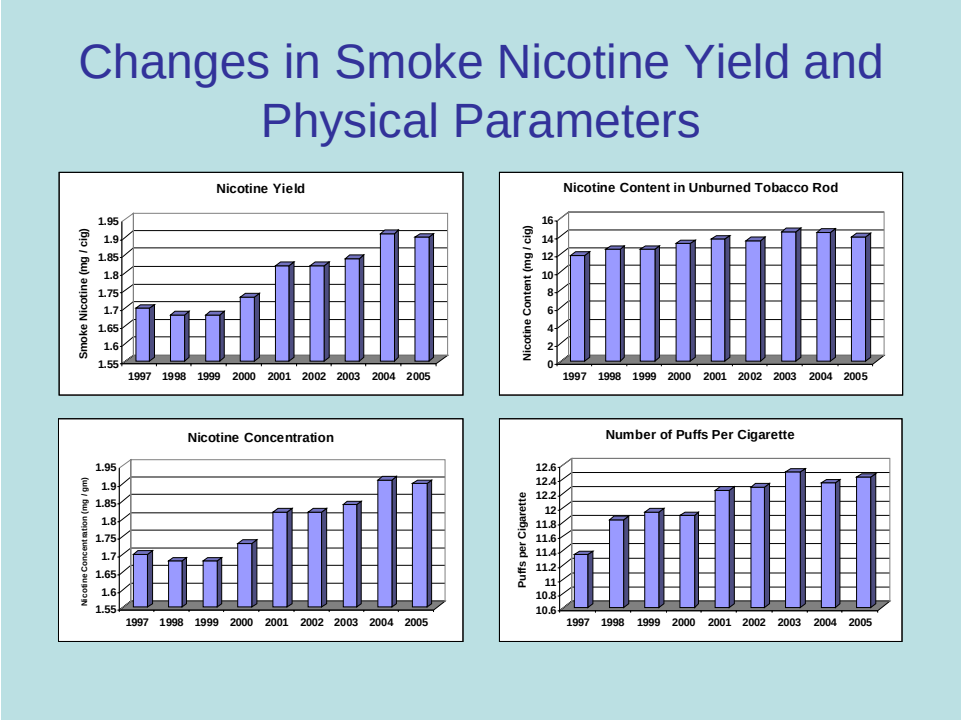
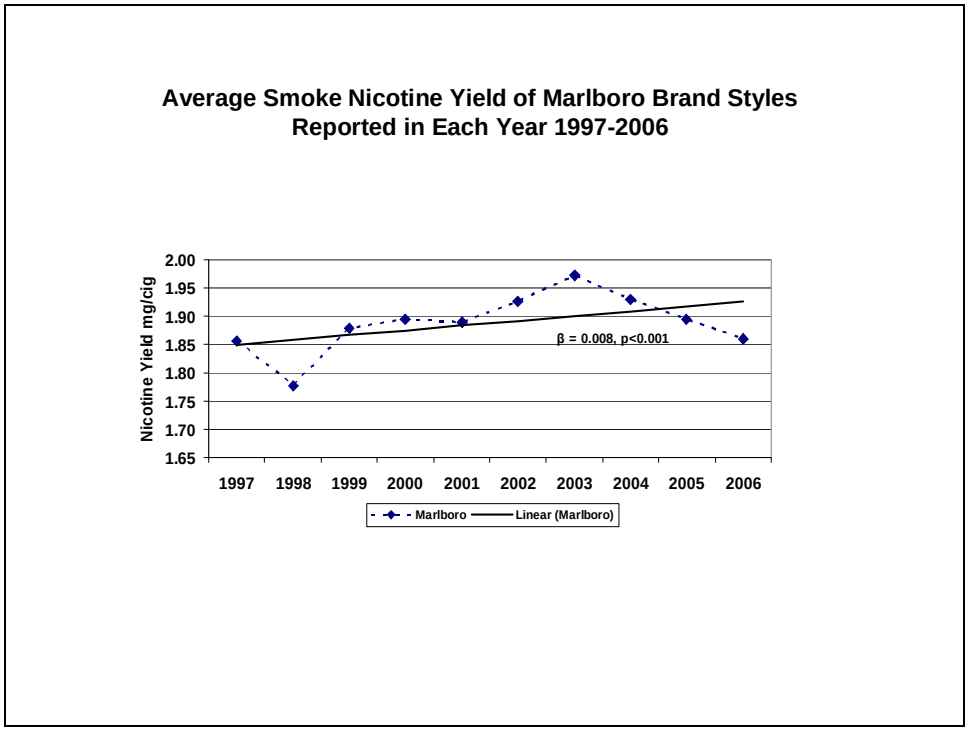
My name is Gregory N. Connolly. I am a professor at the Harvard School of Public Health (HSPH) and direct the Tobacco Control Research Program. Prior to coming to Harvard, I served as the director of the Massachusetts Department of Public Health's Tobacco Control Program and in that capacity, oversaw one of the largest public health programs to curb tobacco use in the United States achieving a 50% decline in cigarette consumption from 1993 to 2003. Massachusetts was the first state to require warning labels on smokeless tobacco, the second warnings on cigars and the first to require public disclosure of tobacco product additives and nicotine yield. Massachusetts has led all states in attempting to fill the federal void in regulating tobacco products and marketing. We clearly found that states lack the resources and legal authority to effectively do so. FDA regulation is urgently needed today. My opinion is based on the following:

1. Despite the Tobacco Industry's Admission that Nicotine is Addictive, Following the MSA Manufacturers have Increased Nicotine Content in Cigarettes and Cigarette Smoke

Our research has found a significant increase in nicotine to cigarette tobacco and smoke from 1997 to 2005 (12%). Industry manipulation of nicotine is nothing new, what is new it is still occurring post the MSA. A statistically significant trend confirmed an increased in smoke nicotine yield of 0.019 mg per cigarette (1.1%) per year over the period 1997-2005 for an 11.7% increase. The increasing trend was observed within all major market categories (mentholated vs. non-mentholated and full flavor vs. light, medium (mild), or ultralight).



Increasing smoke nicotine yield was associated with increasing nicotine concentration in the tobacco and number of puffs per cigarette, and decreasing percent filter ventilation of the cigarette. Such changes increased the elasticity of the cigarette making it potentially more addictive.



In her August 2006 decision, Judge Kessler devoted 140 pages to describing the tobacco industry's long history of nicotine manipulation. She concluded that tobacco manufacturers:

- "…have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction."
- "…have extensively studied smoking intake and inhalation, compensation, addiction physiology, smoker psychology, the pharmacological aspects of nicotine, the effects of nicotine on brain waves, and related subjects."
- "…intentionally developed and marketed cigarettes which, in actuality, delivered higher levels of nicotine than those measured by the FTC method."

These studies consisted not only of consumer smoking panels but also large-scale human clinical trials, electrophysiological studies of brain waves, chemical and physical brand analyses, and other sophisticated techniques. Factors such as use of blends, genetic modification of tobacco, and in particular, ammonia or other chemical agents are used to alter the chemical form of nicotine delivered to the smoker. Detailed evidence shows that manufacturers could and did manipulate free nicotine delivery through product changes and that even "small" increases in free nicotine delivery could significantly increase their ability to deliver an "optimum" dose of nicotine capable of creating and sustaining addiction in cigarette smokers.

Our research is not new but only shows that this historical pattern of nicotine manipulation has not changed. We don't know why nicotine has increased. The tobacco industry regulatory oversight by the FDA is necessary to evaluate changes in product

delivery and their effects on smoker initiation and use; and possibly to make the product less addictive.

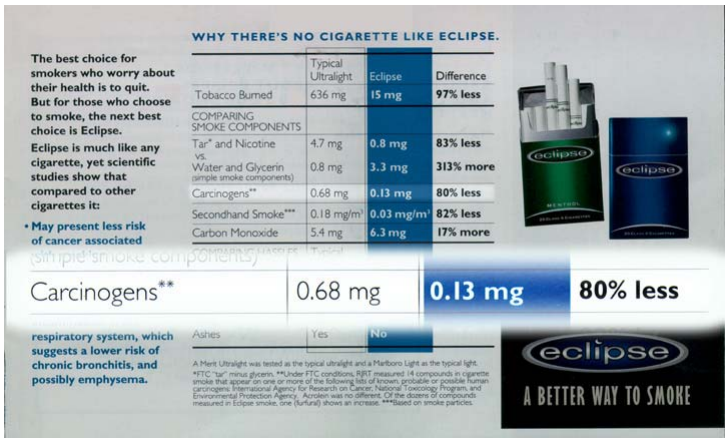
2. Since the MSA Tobacco Manufacturers have Greatly Increased the Marketing of "Safer" Cigarettes to Health Conscious Smokers in the Absence of Independent Scientific Evidence They are Actually "Safer"

This nation has already suffered immensely from the failed history of light cigarettes when they were presented in the 1970s as a "safer" alternative to regular brands. The Harvard School of Public Health's Nurses Study found that smokes of "lights" had the same risk of cardiovascular diseases as smokers of regular brands. The National Cancer Institute concluded in 2001 that smoking "lights" did not reduce the risk of lung cancer. In the absence of FDA regulation, the failed history of "lights" will only be repeated with the promotion of cigarettes today as being safe.

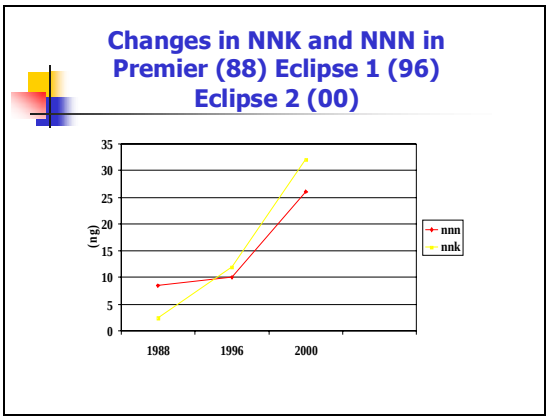
Potentially Reduced (tobacco) Exposure Products (PREPS) are being marketed with explicit and implicit claims that they reduce health risks in the absence of scientific evidence to show they actually do. Over 35 PREPS have been marketed over the past few years (see Appendix A).

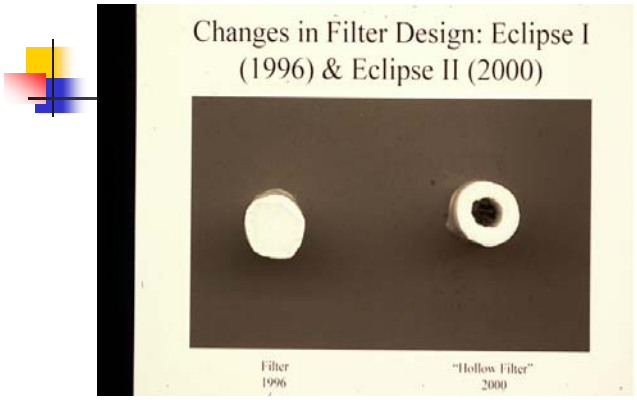
In 1998, RJR claimed that there is "No Cigarette Like Eclipse" based on a comparison of its smoke chemistry to a typical ultralight cigarette (Merit) and also claimed that Eclipse may reduce cancer risk. We analyzed the smoke chemistry of Eclipse versus two conventional ultralight cigarettes (NOW and Carlton) and found that Eclipse had up to five times the levels of cancer causing agents than the existing Now or Carlton brands. There are "Cigarettes like Eclipse" in the marketplace. A careful review of other

research conducted by RJR on Eclipse found serious problems with the methodology that supported the lung cancer reduction claim.



When sales for Eclipse faltered in the late 1990s, RJR altered the filter design by drilling a hole in it but not alerting consumers to the change. The new design resulted in an increase of 300% in two cancer causing agents called NNN and NNK. Consumers were not informed of the design change on increase in toxins.



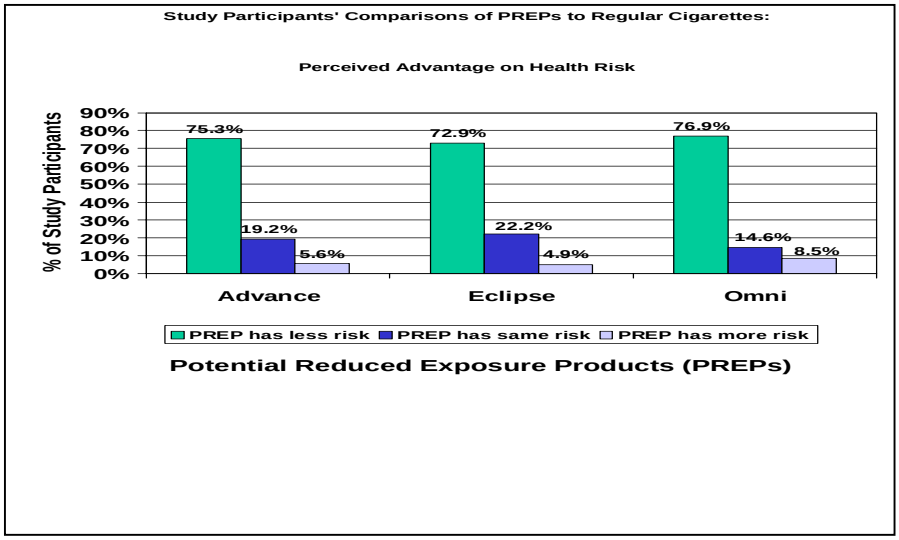


We tested two prototypes of the new carbon filtered PREP, Marlboro UltraSmooth (MUS), test marketed in the U.S. beginning in 2005, using both standard (FTC/ISO) and intensive (Health Canada) machine methods to measure gas/vapor and particulate phase smoke constituents. When tested under the standard regimen, gas phase constituents of MUS prototypes were reduced compared with a conventional low yield cigarette. However, far smaller reductions in gas phase constituents were observed under the intensive regimen, suggesting that the carbon technology employed in MUS is less effective when smoked under more intense conditions. Particulate phase constituents were not reduced by the carbon filter under either machine smoking regimen. Studies of human smoking show that MUS is likely to be smoked intensively, thus negating its potential for toxic constituent reductions.

PREPS have been marketed include nicotine hand gel, nicotine chewing gum, modified cigarettes (Omni, Advance and Marlboro UltraSmooth) and electrically heated nicotine inhalers (Accord) (see Appendix). All of these products have been sold with implied or

explicit claims of reduced risk without review or approval of independent scientific agencies such as the FDA.

Other research we conducted showed that consumers perceive implied claims for reduced levels of toxins in smoke as explicit claims for reduced health risks when in fact there is no science to support the claims. We studied 600 adult smokers who reviewed advertisement for regular and PREP cigarettes. Smokers perceived PREP products as having lower health risks (mean=5.4 on a scale of 1-10) and carcinogens (6.6) than light cigarettes (5.8 and 6.9, respectively, $p < .001$), and lights as having lower health risks and carcinogen levels than regular cigarettes (8.2 and 8.8, respectively, $p < .001$). Although no advertisements explicitly said that the products were healthy or safe, advertisements for PREP products and light cigarettes were interpreted as conveying positive messages about health and safety. Most smokers believed that claims made in cigarette advertisements must be approved by a government agency. The results indicate that advertisements can and do leave consumers with perceptions of the health and safety of tobacco products that are contrary to the scientific evidence. This supports regulating the promotion, advertising, and labeling of PREP tobacco products and light cigarettes. Effective FDA regulation should focus on consumer perceptions resulting from advertisements not just the explicit content of advertising text. This is needed to prevent a repeat of the failed history and disease burden by the marketing of "lights." The unintended consequences of PREP marketing by youth initiation and deterrence of quitting can also be monitored by the FDA



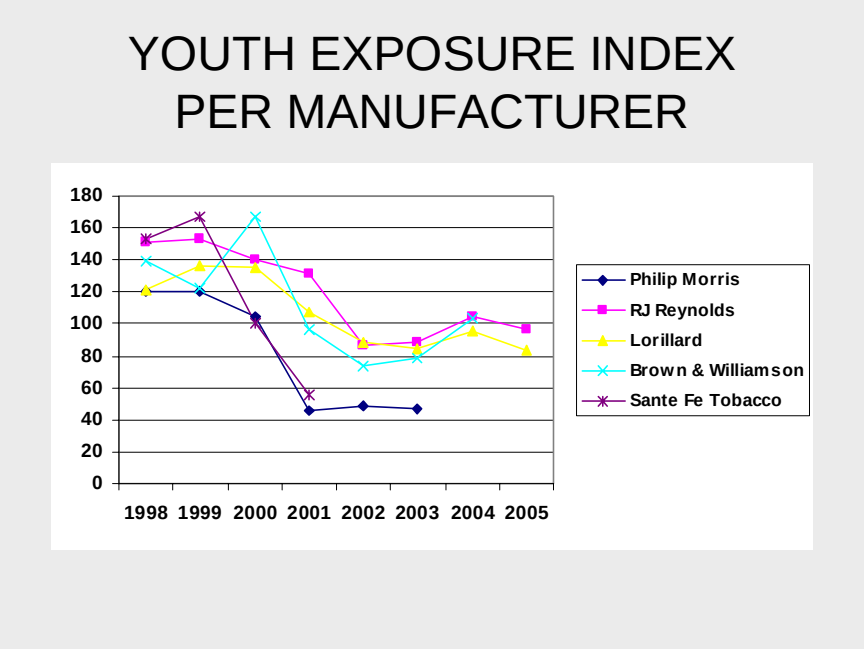
The Bill will give the FDA authority to prevent such unsubstantiated claims from being made. FDA will require scientific support and closely examine the real world performance of PREPs such as Eclipse and MUS. Regulation of PREPS by independent health agencies such as the Food and Drug Administration is needed to protect the public health and validate both the industry science and its claims.

3. <u>Advertising After the Master Settlement Agreement has Become More Targeted to Youth, Minorities and Other High-Risk Groups</u>

Following the Master Settlement Agreement (MSA), youth and other high-risk groups, including low income women and African Americans, have been targeted with disproportionate levels of magazine advertising for tobacco products. Our analysis of tobacco magazine advertising post the MSA found, from 1998-2005 on average, every youth in the United States was exposed to 559 tobacco ads, every adult female 617 advertisements, every African American adult 892 ads, and every Hispanic adult 605 ads.

Exposure to a magazine advertisement is measured as the percentage of a population group that reads the magazines that runs the advertisement in the studied time period.

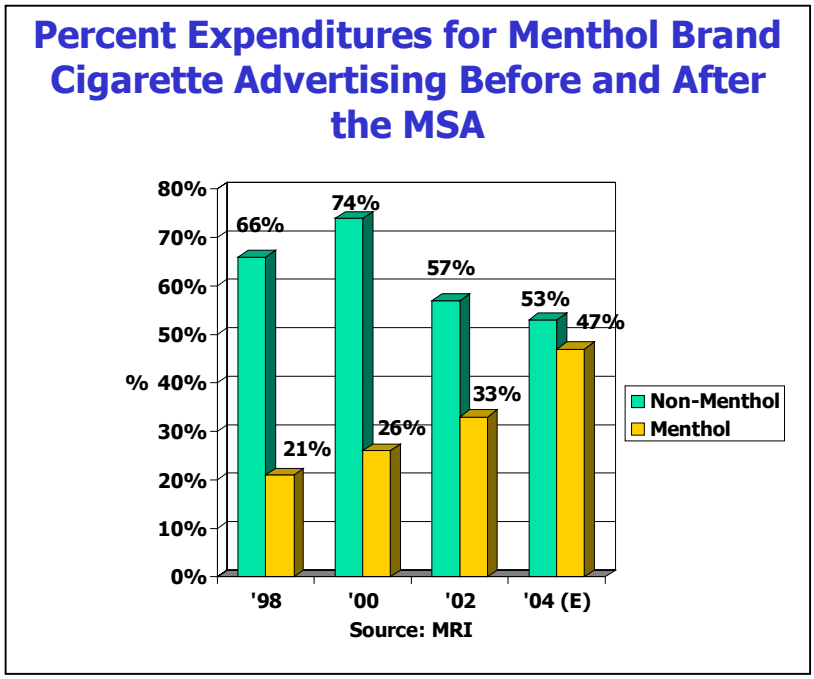
Compared to adults, youth had greater exposure to magazine advertising for cigarettes or major manufacturers including R.J. Reynolds, Brown & Williamson and Lorillard and were disproportionately exposed to magazine advertising for brands and varieties preferred more by youth including Newport and Camel, and mentholated and full flavor cigarettes. Philip Morris ended magazine advertising in 2003 but the other companies have more than made up for PM's absence. Despite the MSA, cigarettes were advertised in magazines with 15% or greater youth readership and in magazines with 2 million or more youth readers in every year from 1998 to 2005, criteria used in the 1994 FDA rule to define a youth magazine.



Regulation by the FDA can eliminate cigarette advertising to youth.

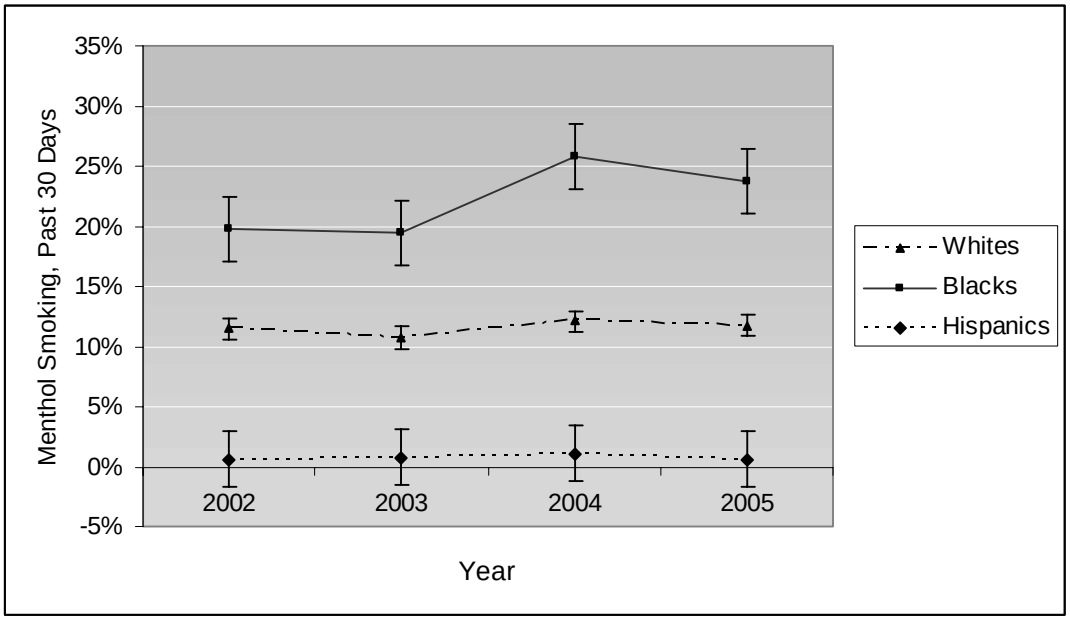
Among young, Black smokers, Newport has traditionally been the most popular menthol brand. Newport has the lowest menthol levels (0.24% weight of tobacco filler among King-size, full flavor) compared to its major competitor (Kool, 0.36%). Between 1993 and 2005, Newport's market share doubled, from 4% of market to 8%, while Kool and Salem's share of market has remained relatively steady.

Reynolds American Tobacco aggressively competed against Lorillard and recently redesigned Kool under the name Kool XL and heavily advertised it to compete against Newport's dominance among young Blacks. Kool Smooth Fusions is a candy-flavored menthol brand, promoted through dance clubs and hip hop music venues beginning in 2004. Philip Morris has followed Reynolds American promotion of Kool with Marlboro Smooth, a new menthol product, available in March 2007. Both brands employed the selling message "smoother" a possible connation of a reduction in menthol levels to target young Black smokers. Expenditures for magazine advertising of mentholated cigarettes has increased from 13% of total ad expenditures in 1998 to 49% by 2005.



Among Black young adults (age 18 to 25) menthol smoking rates increased significantly by 30% between 2002 and 2005 from 19.8% (95% CI: 17.7-21.9%) to 25.8% (95% CI: 23.5-28.1%), but did not increase significantly among same-aged Whites and Hispanics during that time. Non-menthol cigarette use decreased by 39% among African-American young adults, although this change was not significant (from 7.9% in 2002 to 4.8% in 2005). In 2002, 19.8% (95% CI: 17.7-21.9%) of African-Americans age 18-25 smoked menthol cigarettes (an additional **7**.8% smoked non-menthols). In 2004, 25.8% (95% CI: 23.5-28.1%) of African-American young adults smoked menthol (while an additional 4.0% smoked non-menthols). In 2005, this proportion decreased slightly, but remained above pre-2004 levels.

Menthol Use in Past 30 Days Among Young Adults, by Race, 2002-2005



- The rates of menthol smoking among African Americans ages 18-25 years have increased by 10% per year since 2002 (OR=1.10, 95% CI = 1.04-1.18).
- No statistically significant trends over time since 2002 are seen in the rates of menthol smoking among Whites and Hispanics ages 18-25 years or among Blacks or Hispanics ages 12-17 years.
- The rates of menthol smoking among Whites ages 12-17 years have decreased since 2002 (OR = 0.95, 95% CI = 0.90 – 0.99).

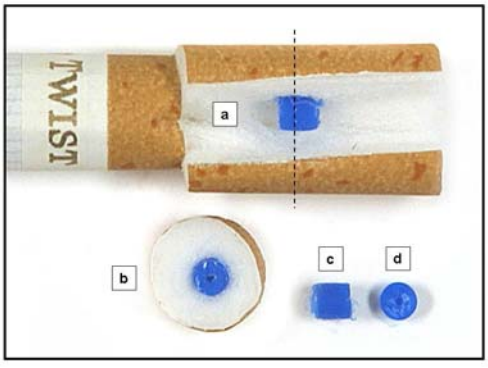
Following the MSA, R.J. Reynolds acquired the second largest smokeless company Conwood for $ 4.8 billion and introduced its own smokeless brand called Camel Snuss. Philip Morris introduced its new smokeless tobacco brand in Indianapolis called Taboka and acquired a Swedish smokeless company the same year. Lorillard has entered into an agreement with Swedish Match North America to produce its smokeless brand in 2007. The cigarette companies rather than offering smokeless products as an alternative to

cigarettes have only produced and sold smokeless products as a temporary way to receive nicotine through smokeless tobacco in places where smoking is banned thus perpetuating smoking.

FDA regulation is needed to prevent cigarette companies from marketing smokeless tobacco to perpetuate smoking. FDA authority is needed to require manufacturers to adopt new technologies to reduce toxins in all smokeless products not just the ones they make "safer" claims for

In 2002, RJR introduced Camel "Exotic" Blends and Brown and Williamson "Kool Fusion" brands all with candy-like flavors in the product. The Exalt Camel brand used a plastic pellet in the filter to delivered flavors to smokers. No public health agency knew it was present, its toxicity or how it contributed to youth initiation. Candy-like flavorants mask the natural toxicity of smoke and could enhance initiation and addiction.

Examples of recent candy flavored cigarettes and flavor delivery systems



Camel Twist: Emission of This the Blue Flavor Pellet

- Laboratory test of compounds released by the blue pellet
  - Flavors on 599 list (linalool, citronellol, citral, cubeb oil, caryophyllene)
  - Flavors not on 599 list (elemene, copaene, muurolene,candinene, p-menth-1-en-8-ol)
  - Hydrocarbons (tetradecane, pentadecane, dodecane, hexadecane, heptadecane, octadecane)

The use of flavorants to appeal to young non-smokers is consistent with other research on the reformulation of Camel cigarettes in the 1980s, a brand then popular with older men. The newly designed Camel was targeted to first time young smokers by using additives that masked the harshness, making it smoother and easier to inhale. Market share for Camels rose among adolescent males three fold post the reformulation from 3 to 10%.

Conclusion

Post the MSA manufacturers have become more aggressive in targeting high risk groups including minorities and youth with aggressive advertising, redesigned products with more not less nicotine, introducing candy-like flavored product and aggressively marketing brands popular with young African Americans.

Forty years ago, a Senator from New York gave the opening address at the First World Conference on Smoking and Health and prophetically warned that 28 million Americans

would be killed prematurely by smoking unless urgent action was taken at that time. None was taken. The same Senator urged the attendees to "be equal to the task. For the stakes are nothing less than the lives and health of millions all over the world. I know it is a battle which will be won." (Robert Kennedy, First World Conference on Smoking or Health) Our battle will be won and that vision fulfilled when the Congress passes this historic legislation.