

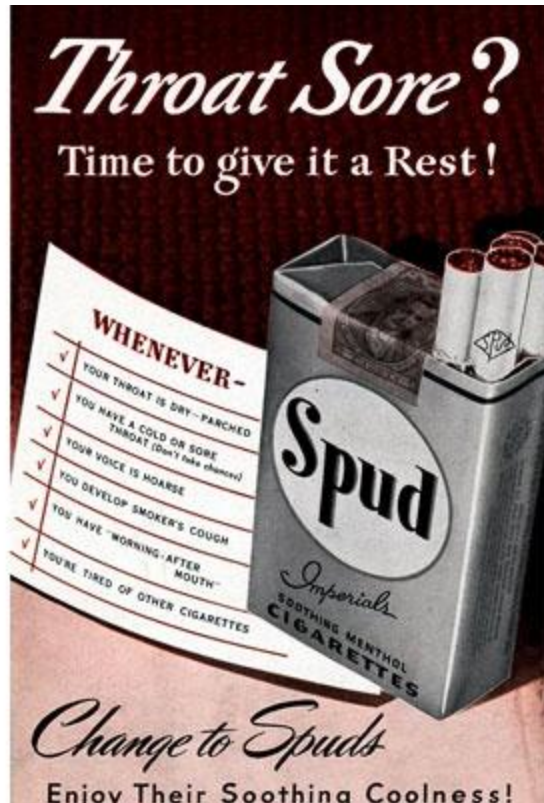
Informing FDA Policy: Menthol Journal Supplement

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Scientist, Pinney Associates

TReND “Making the Difference in Tobacco-Related Health
Disparities Science: TReND Progress, Process,
and Opportunities for Future Investment”

Rockville, MD October 2010

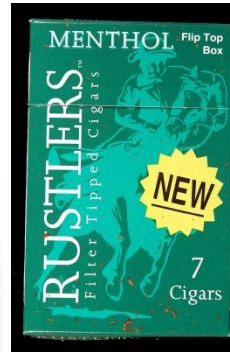
General Facts about Menthol



- An organic compound naturally found in mint plants like peppermint and spearmint
- Acts as a coolant, stimulates cold receptors, and is frequently used to relieve minor pain, irritation and to prevent infection.
- Menthol was first added to cigarettes in the 1920s.

Menthol and Tobacco

- About 90% of cigarettes marketed in the U.S. contain menthol (natural & synthetic)
 - “mentholated” cigarettes: 0.1%-0.45%
 - “non-mentholated” cigarettes: 0.01%-0.03%
- Menthol is also found in cigars, little cigars, smokeless tobacco products, and tobacco rolling paper.
- Some new tobacco products allow the user to adjust the intensity of menthol flavor through devices that contain concentrated amounts of menthol.



Actively marketed to consumers based on its physiological effects: Anti-irritant, cooling agent, refreshing

Salem refreshes naturally!

Natural Menthol is why.

Don't settle for a halfway menthol.

Come all the way up to KOOL. Pure menthol and the taste of extra coolness have made KOOL America's #1 selling menthol.

Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health.

13 mg. tar, 0.9 mg. nicotine. Now, lowered for KOOL Milds.

Heavy Date... Heavy Smoking

Mouth fresh and cool... thanks to SPUD

What causes the fresh, cool taste? Is it menthol? Yes... but only indirectly. Spud's smoke contains hardly a trace of menthol. The menthol does its work in the cigarette, it simply lowers the temperature of the smoke. Therefore, what Spud gives you is just pure tobacco goodness with the heat taken out. That's what causes the fresh, cool taste. Try a pack.

NEWPORT FILTER CIGARETTES

KING SIZE

Refreshing Hint of Mint

Pall Mall Menthol 100's. Extra cool...extra mild.

It's extra long at both ends.

Ordinary Menthol Filter

Pall Mall Menthol 100's

More cool history

More than to smoke colder

Enjoy Pall Mall quality with menthol. Puff for puff, milder than ever.

SNOW FRESH KOOL

AMERICA'S MOST REFRESHING CIGARETTE

SWITCH FROM HOTS... TO

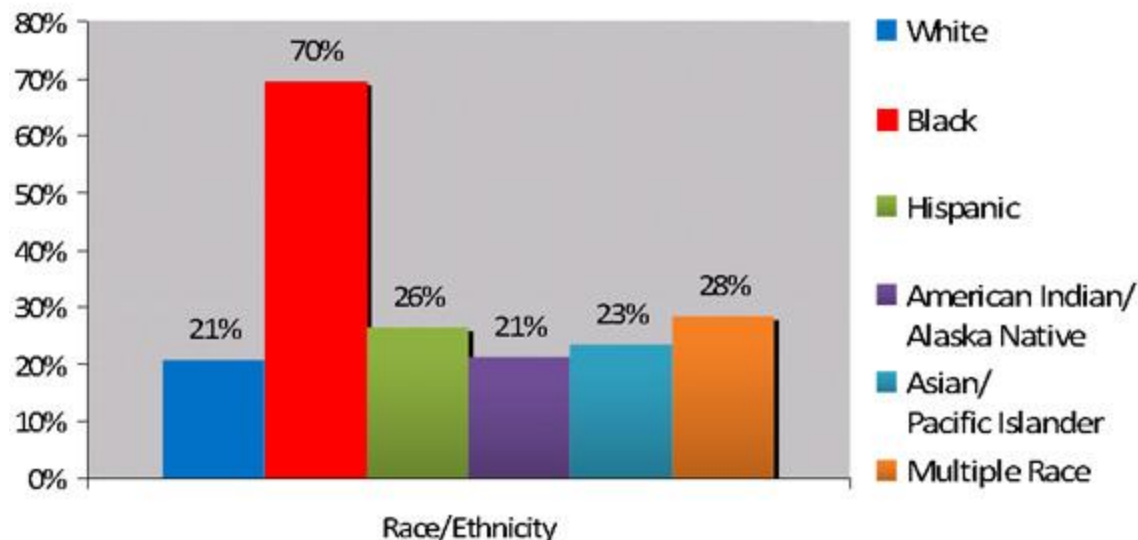
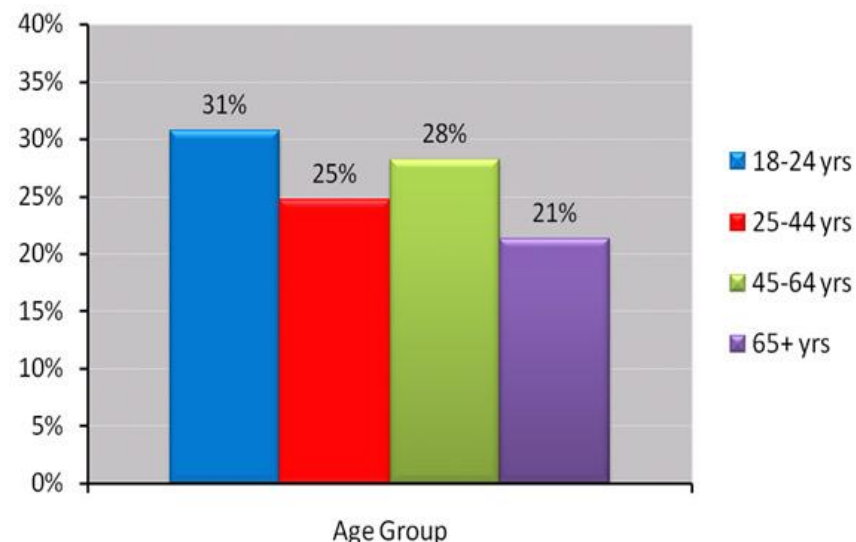
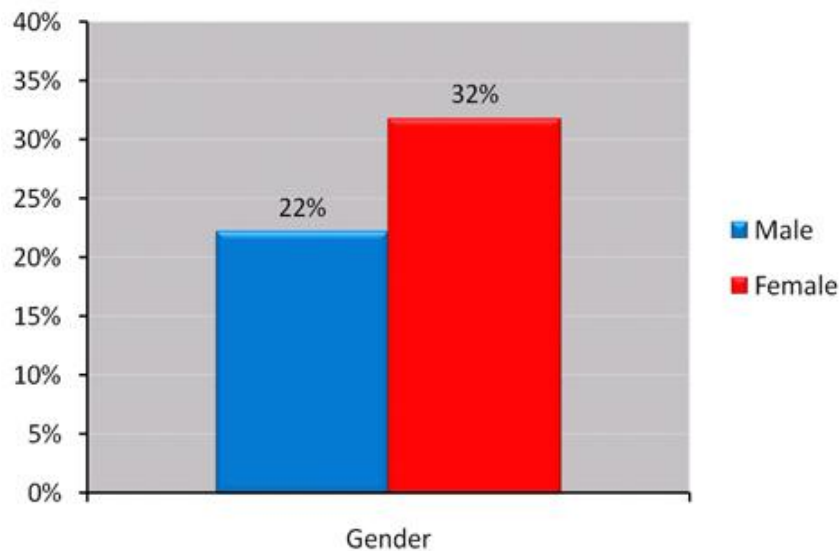
What a wonderful difference when you switch to Snow Fresh KOOL! In your own words, how often and how... your throat feels cooler, relaxed! Enjoy the most refreshing experience in smoking. Smoke KOOL... with taste, with menthol... for a reason. Smoke them all through the day!

KOOL, BIKER, YOU A CHOICE - REGULAR - OR - KING-SIZE WITH FILTER.

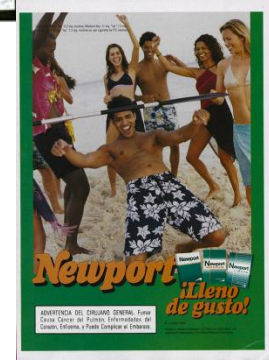
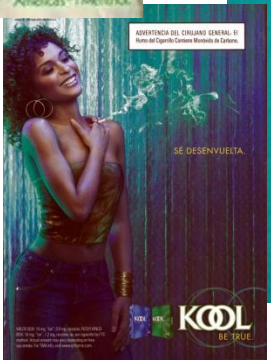
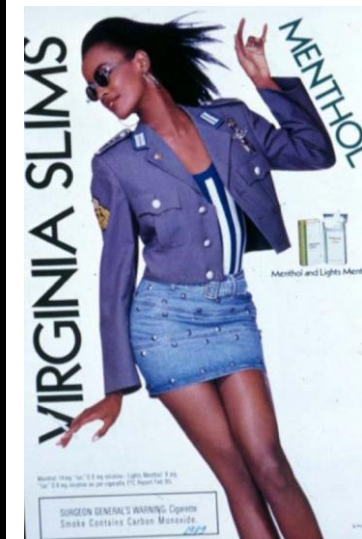
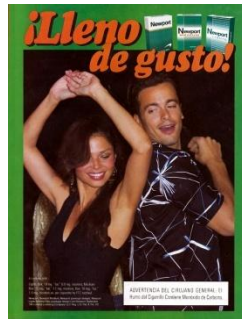
Source: <http://www.us-winston.com/70-years-of-menthol-cigarette-ads/>; http://tobaccodocuments.org/pollay_ads

Menthol Smoking among Adults (18+) Varies by gender, age and race/ethnicity

TUS-CPS 2006-07



Marketing to women, racial/ethnic minorities & youth



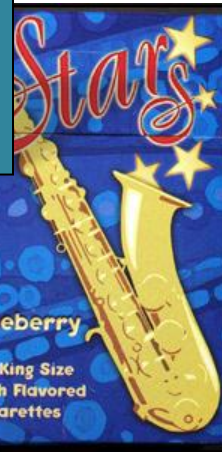


FDA Tobacco Legislation

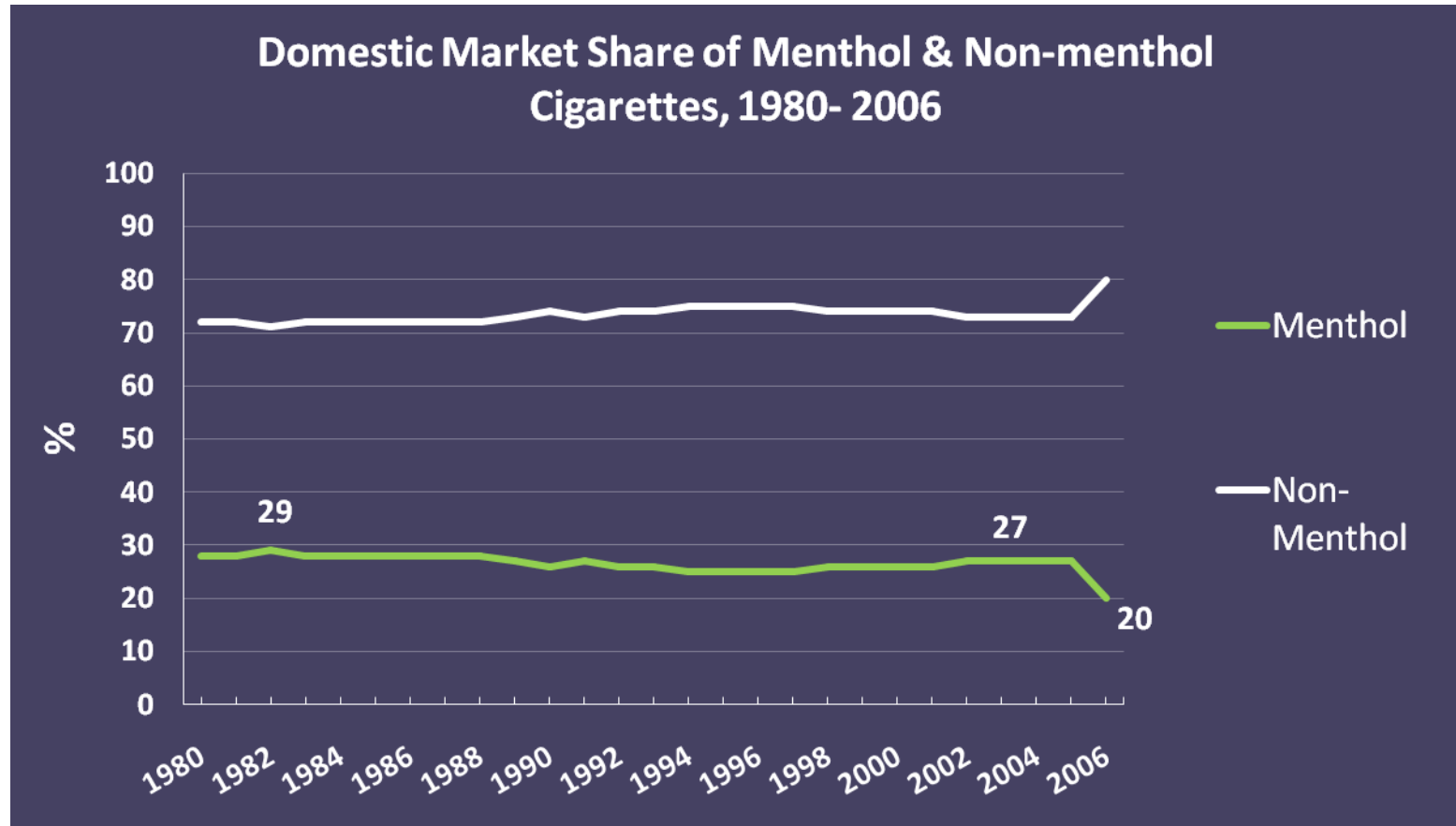
June 22, 2009: President Obama signs into law the Family Smoking Prevention and Tobacco Control Act

FDA banned flavored cigarettes, except for menthol

Tobacco Control Act Sec 907...a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol)...



Menthol Use & Tobacco Industry



- 20% of market share (previously 27%)

Tobacco Products Scientific Advisory Committee (TPSAC)

- HHS Required report w/in 1 yr of establishment
- “Impact of the Use of Menthol in Cigarettes on the Public’s Health”
 - Demographic Patterns
 - Sensory Qualities and Topography
 - Advertising and Consumer Perceptions
 - Smoking Initiation
 - Nicotine Dependence
 - Smoking Cessation
 - Potential Health Effects of Menthol
- Menthol Subcommittee report due March 23rd
(meeting in February)



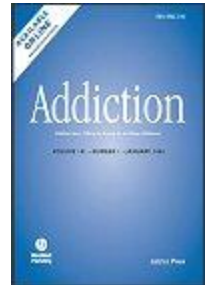
National Conferences on Menthol Cigarettes

- 2002: 1st Conference on Menthol Cigarettes: Setting the Research Agenda (March 2002), GA
- 2009: Conference on Menthol Cigarettes, DC
- Key summary points
 - Focusing on youth is a better strategy
 - Enough evidence to call for banning menthol
 - Increased uptake
 - Advertising
 - Cessation difficulty
 - FDA should demand tobacco industry to release its data on menthol
- CDC sponsored supplement to summarize conference findings (*Nicotine and Tobacco Research*, Winter 2010/2011)



Addiction Menthol Journal Supplement

- NCI-sponsored
- Nationally Representative Surveys
 - Tobacco Use Supplement to the Current Population Survey (TUS-CPS): 2003, 2006-2007
 - National Health Interview Survey-Cancer Control Supplement (NHIS-CCS): 2005
- Editorial Team: Kola Okuyemi, MD (lead), Linda Alexander, George Hammons, and Deirdre Lawrence
- Invited researchers with experience in menthol research and/or analyzing national datasets.



Correlates and Patterns

- What sociodemographic factors are associated with smoking menthol cigarettes?
- What smoking factors are associated with menthol smoking?
- Is there a relationship between smoking initiation and smoking menthol cigarettes?



Menthol and Cessation

- Does smoking mentholated cigarettes delay cessation?
- If so, is this effect the same across racial/ethnic categories?
- Do menthol smokers have the same access to smoking cessation programs as non-menthol smokers?
- Are menthol smokers more dependent than non-menthol smokers?



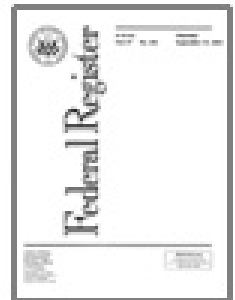
Policy Factors and Concurrent Risk Factors

- Do tobacco control policies have a differential effect on menthol vs. non-menthol cigarette smokers?
- Are menthol smokers more likely to have exposure to home and workplace bans?
- Are health characteristics and health seeking behaviors different for menthol smokers vs. non-menthol smokers?



Proactively Informing US Policy

- Next TPSAC meetings
 - Presentations during open comment
 - Comments submitted to the open docket
 - Anticipate FDA's scientific needs
 - Quickly respond to inquiries from FDA employees
- Federal Register
 - TPSAC and other FDA advisory committee meetings
 - FDA draft Guidance, Compliance Regulatory Information
 - National surveys on tobacco use
 - Adhere to deadlines
- Special Government Employee (SGE)



Industry Testimony to FDA

- Menthol has a long history of use in a wide range of consumer products, including cigarettes.
- Menthol is a well-established flavor preference that a significant percentage of adult smokers have used for decades.
- Menthol added to cigarettes does not increase the inherent health risks of cigarette smoking.
- Menthol cigarettes do not play a unique role in smoking initiation, dependence or cessation.
- There is no science- or evidence-based reason that would support a TPSAC recommendation to ban menthol cigarettes or otherwise impose additional restrictions

Additional Resources

- *Addiction* Supplement: The Role of Mentholated Cigarettes on Smoking Behaviors in U.S. Populations
- Executive Summary of the 1st Conference on Menthol Cigarettes¹
- Menthol Cigarettes—Setting the Research Agenda (2004). *Nicotine and Tobacco Research* (vol. 6, suppl 1)²
- CDC Special Supplement (*NTR*) about 2nd Conference on Menthol Cigarettes
- NCI Menthol Bibliography
http://dccps.nci.nih.gov/tcrb/documents/menthol_bibliography_508.pdf
- FDA Tobacco Products Scientific Advisory Committee (TPSAC)
 - Review of Scientific Evidence, March 30-31, 2010³
 - Industry Response, July 15-16, 2010⁴

¹http://cancercontrol.cancer.gov/tcrb/MentholExecSumRprt4_10-16.pdf

²<http://www.informaworld.com/smpp/title~content=g713942500~db=all>

³<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm207149.htm>

⁴<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm220024.htm>