

# Welcome Pioneers for Smoking Cessation



## Menthol: Science, Policy, and Advocacy

Thursday, May 5, 2011 – 1:00 pm ET

## During the Webinar

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## Welcome



- ▶ **Catherine Saucedo**
- ▶ **Moderator**
- ▶ Deputy Director  
Smoking Cessation Leadership Center  
University of California, San Francisco  
[csaucedo@medicine.ucsf.edu](mailto:csaucedo@medicine.ucsf.edu)

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## Agenda

- ▶ Welcome
  - ▶ Catherine Saucedo, Deputy Director, SCLC, **moderator**
  - ▶ Steve Schroeder, MD, Director, SCLC
- ▶ Presentation from Legacy Panel
  - ▶ **Ellen Vargyas**, JD, General Counsel & Corporate Secretary
  - ▶ **David Abrams**, PhD, Executive Director, Schroeder Institute and Professor, The Johns Hopkins Bloomberg School of Public Health
  - ▶ **Amber Thornton-Bullock**, MPH, CHES, Executive Vice President of Program Development
- ▶ Questions & Answers
- ▶ Technical Assistance and Closing Remarks

Disclosures: Faculty speakers, moderator, and planning committee members have disclosed no financial interest/arrangement or affiliation with any commercial companies who have provided products or services relating to their presentation or commercial support for this continuing medical education activity.

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## FDA Regulation of Menthol: From Scientific Evidence to Policy

**Ellen Vargyas, JD**, General Counsel & Corporate Secretary

**David Abrams, PhD**, Executive Director, Schroeder Institute and Professor, The Johns Hopkins Bloomberg School of Public Health

**Amber Thornton-Bullock, MPH, CHES**, Executive Vice President of Program Development

SMOKING CESSATION LEADERSHIP CENTER  
WEBINAR  
MAY 5, 2011

## Today's Panelist

- ▶ **Ellen Vargyas, JD**
  - ▶ General Counsel & Corporate Secretary



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## Menthol: The Legal and Regulatory Framework

Ellen Vargyas, JD  
General Counsel and Corporate Secretary



## Family Smoking Prevention and Tobacco Control Act

- Signed into law on June 22, 2009.
- Gives FDA broad jurisdiction to regulate tobacco products -- although not to ban them.
- Requires, for example, improved warning labels, prohibits the use of “light” and “low tar” descriptors, bans candy-flavored cigarettes, bars health claims outside of an approved “modified risk” process and mandates the submission of detailed product information to FDA.



## Public Health Standard

- FDA may issue tobacco product standards that are **appropriate for the protection of the public health**.
  - May require the reduction or elimination of an additive, constituent or other tobacco product (may reduce but not eliminate nicotine)
- The “public health” standard is new; it differs from the traditional “safe and effective” standard for drugs and medical devices **since tobacco is neither safe nor effective**.



## Public Health Standard

The FDA must evaluate the scientific evidence regarding:

1. Risks and benefits to the population as a whole including both users and non-users of tobacco products;
2. Increased or decreased likelihood that existing users of tobacco products will stop using tobacco products; and
3. Increased or decreased likelihood that those who do not currently use tobacco products, most notably youth, will start to use tobacco products.



## Public Health Standard

Additional Considerations

- Population-based
- Framed in terms of risks, benefits, and likelihoods; **not causation**
  - Equipose
- Countervailing concerns including the possibility of a black market

## Regulation of Menthol: The Act

- While not itself banning menthol, the Act specifically does not limit FDA's authority to regulate menthol under the public health standard.
- It required the Tobacco Product Scientific Advisory Committee (TPSAC) to issue a report reviewing the scientific evidence regarding menthol within a year of its creation.
- TPSAC issued its report on March 18, 2011.

## TPSC Report

- TPSAC concluded that the scientific evidence establishes *that the removal of menthol cigarettes from the market would benefit public health in the United States.*
  - Menthol is linked to youth smoking initiation and higher rates of smoking prevalence, particularly among youth and African Americans.
  - Menthol is also linked to lower rates of successful smoking cessation particularly among African-Americans

## Industry Response

- Argument that there is a substantial risk of a black market
- Attack on TPSAC's "equipoise" analysis
- Menthol as a "civil rights" issue

## Next Steps

- FDA is considering the TPSAC report – which is not binding on it.
- If FDA chooses to proceed, it will initiate a formal rulemaking to either prohibit or limit the sale of menthol cigarettes.
- FDA has said that it would make a decision on how to proceed within 90 days of the TPSAC report – about June 16.

## Today's Panelist



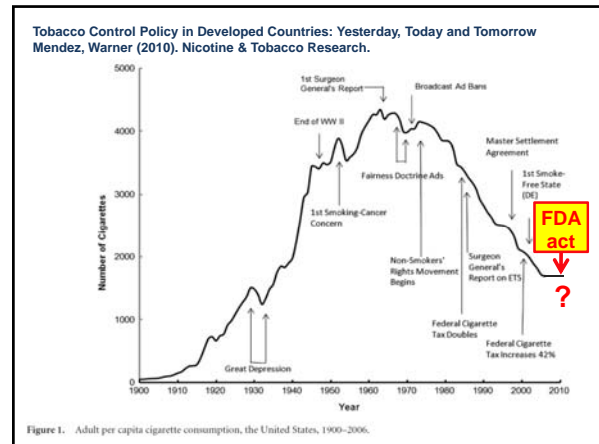
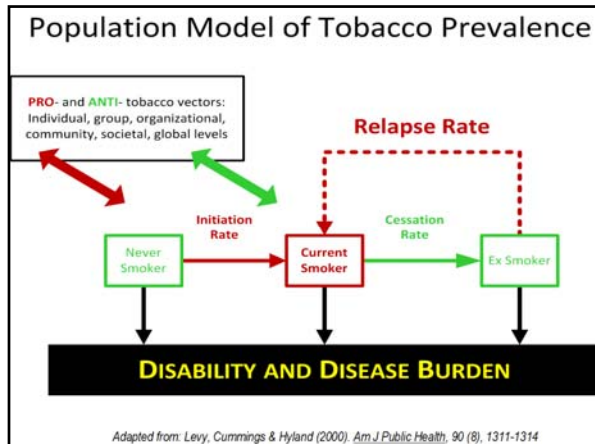
- ▶ **David Abrams, PhD**
  - ▶ Executive Director, Schroeder Institute and Professor, The Johns Hopkins Bloomberg School of Public Health

## THE SCIENTIFIC PERSPECTIVE

**David B. Abrams, Ph.D.**

The Schroeder Institute For Tobacco Research And Policy Studies.  
The Johns Hopkins Bloomberg School of Public Health

[dabrams@legacyforhealth.org](mailto:dabrams@legacyforhealth.org)



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The FDA Act authorizes the Secretary to issue tobacco product standards, **including a ban on menthol**, that are **appropriate for the protection of the public health.**

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- ### National Survey Data: 2008-2009
- 34% of current smokers over age 12 smoked menthols
  - 19.2 million menthol cigarette smokers
  - 1.1 million adolescents ages 12-17
  - 80% of African Americans smoke menthols vs. 24% white & 32% Hispanic smokers
  - Menthol products accounted for 27% of the US cigarette market
  - Major brands: Newport (9.8%), Marlboro Menthol (5.4%), and Kool (2.5%)
- More facts and references: see Legacy fact sheet on Menthol on Legacy website
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**Reviewing and Classifying Evidence  
Background and Recommendations**

Jonathan M. Samet, MD, MS  
Professor and Flora L. Thornton Chair  
Department of Preventive Medicine  
USC Keck School of Medicine  
Director, USC Institute for Global Health


**TPSAC, CTP, FDA  
October 7, 2010**

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**INSTITUTE OF MEDICINE**

**Equipoise and Evidence  
What is it?**

FOR  AGAINST

**The balance point for strength of evidence on causation**

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### TPSAC recommendations for evidence review and classification

– Classification Scheme: **Based around concept of equipoise**

- The evidence is sufficient to conclude that a relationship is more likely than not.
- The evidence is sufficient to conclude that a relationship is at least as likely as not.
- The evidence is insufficient to conclude that a relationship is more likely than not
- There is insufficient evidence to make a determination of strength of evidence.

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### What Data Is Needed To Inform Regulation?

**Typical regulatory standard**

- Animal studies
- Controlled human exposure studies
- Case reports
- Chemical hazard reports
- Toxicologic studies
- Randomized controlled trials
- HARM TO INDIVIDUAL COMPARED TO USE OF (LETHAL) CIGARETTES

**Public health standard**

- Epidemiologic studies
- Economic studies
- Psychological studies
- Sociological studies
- Qualitative research
- Consumer studies
- Review of tobacco industry documents
- Systems science
  - mathematical modeling
  - social networks studies

Tobacco Industry (red diagonal stamp)

Public health community (blue diagonal stamp)

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### Central Questions Re: Menthol

- What is the association between menthol cigarette use and **youth** initiation?
- What is the association between menthol cigarette use and **adult cessation**?
- What is the *likelihood* that prohibiting menthol would reduce the number of smokers and **thereby provide benefit to our nation's public health**?

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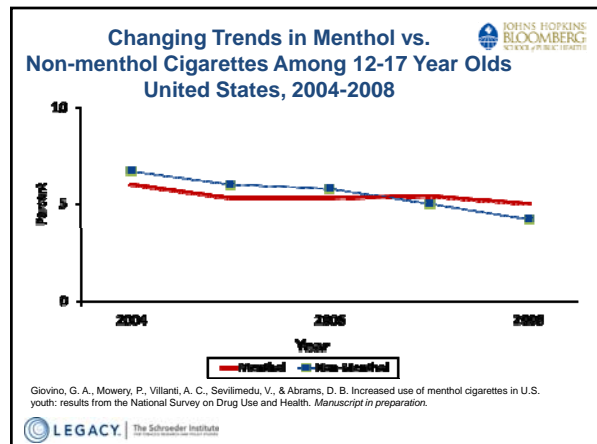
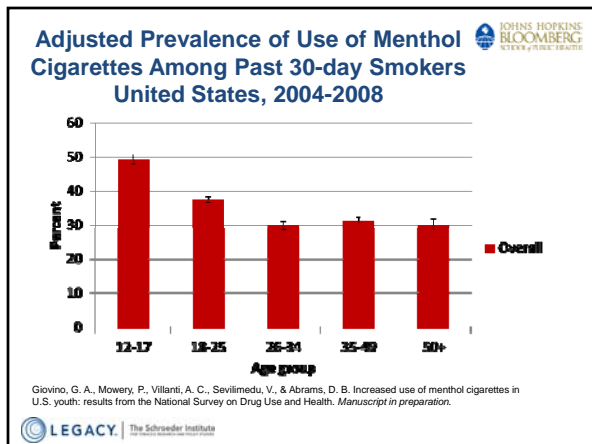
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### Schroeder Institute at Legacy Commissioned Research to Support FDA

**Peer-reviewed publications**

- Tauras, J. A., Levy, D., Chaloupka, F. J., Villanti, A., Niaura, R. S., Vallone, D., et al. & Abrams, D. B. (2010). Menthol and non-menthol smoking: the impact of prices and smoke-free air laws. *Addiction*, 105(s1), 115-123.
- Villanti, A. C., Vargyas, E.J., Niaura, R. S., Beck, S. E., Pearson, J. L., & Abrams, D. B. (2011). FDA Regulation of Tobacco: Integrating science, law, policy and advocacy. *American Journal of Public Health*, in press.
- Levy, D., Blackman, K., Tauras, J. A., Chaloupka, F. J., Villanti, A. C., Niaura, R. S., & Abrams, D. B. (2011). Quit Attempts and Quit Rates among Menthol and non-Menthol Smokers: Findings from a national survey. *American Journal of Public Health*, in press.
- Levy, D. T., Pearson, J. L., Villanti, A. C., Niaura, R. S., & Abrams, D. B. (2011). Modeling the effects of a menthol ban on smoking prevalence in the United States. *American Journal of Public Health*, in press.
- Winickoff, J. P., McMillen, R., Vallone, D., Pearson, J., Tanski, S., Dempsey, J., et al. & Klein, J. & Abrams, D. B. (2011). Attitudes about Banning Menthol in Cigarettes: Results from a Nationally Representative Survey. *American Journal of Public Health*, in press.

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**Menthol Brand Switching Among Youth and Young Adult Smokers, Overall and Selected Groups\* – United States, 2003-2005**

	Percent switched menthol to non-menthol (95% CI)	Percent switched non-menthol to menthol (95% CI)
<b>Overall</b>	<b>15.0</b> (10.8 – 19.2)	<b>6.9</b> (4.9 – 8.9)
<b>Non-Hispanic Whites</b>	<b>20.4</b> (14.6 – 26.1)	<b>5.6</b> (3.7 – 7.5)
<b>Some college/ college grad</b>	<b>16.8</b> (11.1 – 22.5)	<b>5.1</b> (3.1 – 7.0)

\*All percentages and 95% CI weighted to be nationally representative

Giovino, G. A., Mowery, P., Villanti, A. C., Sevilimedu, V., & Abrams, D. B. Increased use of menthol cigarettes in U.S. youth: results from the National Survey on Drug Use and Health. *Manuscript in preparation.*



**Effect on cessation in TUS-CPS**

	Percent of total smokers	Quit attempt in the past year		Quit ≥ 3 months and ≤ 1 year		Quit ≥ 3 months and ≤ 5 years	
		Percent	Percent difference from non-menthol	Percent	Percent difference from non-menthol	Percent	Percent difference from non-menthol
<b>2003 Total</b>	<b>100.0%</b>	<b>39.4%</b>		<b>4.3%</b>		<b>20.8%</b>	
Non-menthol	70.0%	39.3%	4.4%	4.4%	21.2%		
Menthol	25.9%	40.9%	4.3%	4.2%	-3.9%	18.8%	-11.3%
No Preference	4.2%	28.8%	-26.7%	4.8%	8.6%	32.4%	53.1%
<b>2007 Total</b>	<b>100.0%</b>	<b>38.8%</b>		<b>4.6%</b>		<b>20.7%</b>	
Non-menthol	70.2%	38.1%	4.6%	4.6%	21.2%		
Menthol	25.7%	41.4%	8.8%	4.1%	-12.2%	18.3%	-13.8%
No Preference	4.1%	35.4%	-7.1%	7.5%	61.0%	31.6%	48.7%

Levy, D., Blackman, K., Tauras, J. A., Chaloupka, F. J., Villanti, A. C., Niaura, R. S., Abrams DB. (2011). Quit Attempts and Quit Rates among Menthol and non-Menthol Smokers: Findings from a national population survey. *American Journal of Public Health, in press.*



**Written Document to Support FDA-TPSAC Presentation on Monday, Jan. 10, 2011**

**“What Menthol Smokers Report They Would Do If Menthol Cigarettes Were No Longer Sold”**

Anne Hartman, M.S., M.A., Biostatistician

Risk Factor Monitoring Branch/Applied Research Program

Division of Cancer Control and Population Sciences  
National Cancer Institute



**Table 2 “If menthol cigarettes were no longer sold, which of the following would you most likely do?” TUS-CPS, May 2010**

	% Switch to non-menthol cigarettes (95% CI)	% Switch to some other tobacco product (95% CI)	% Quit smoking and not use any other product (95% CI)	% None of the above (95% CI)	% Don't Know/ Refused (95% CI)
<b>Overall</b> (n = 2,887)	36.2 (33.9-38.6)	7.7 (6.7-8.9)	39.0 (36.8-41.1)	9.4 (8.2-10.6)	7.7 (6.6-9.1)
<b>NH-White</b> (n = 1,704)	42.2 (39.3-45.3)	7.9 (6.5-9.6)	34.2 (31.5-37.0)	7.4 (6.1-9.0)	8.3 (6.6-10.3)
<b>NH-Black</b> (n = 763)	25.7 (22.6-29.1)	7.6 (5.6-10.1)	46.7 (42.5-51.1)	12.2 (9.9-14.9)	7.8 (6.0-10.3)
<b>Males</b> (n = 1,170)	38.7 (35.3-42.3)	9.9 (8.1-12.0)	35.6 (32.1-39.3)	8.2 (6.6-10.0)	7.0 (6.0-9.6)
<b>Females</b> (n = 1,717)	34.1 (31.2-37.0)	5.9 (4.7-7.4)	41.8 (39.2-44.5)	10.4 (8.9-12.2)	7.8 (6.4-9.5)
<b>18-44 yrs</b> (n = 1,484)	36.5 (33.4-39.8)	8.1 (6.7-9.7)	40.6 (37.4-43.9)	8.3 (6.8-10.2)	6.5 (5.0-8.3)
<b>45+ yrs</b> (n = 1,403)	35.8 (32.9-38.8)	7.3 (5.9-9.0)	36.7 (33.6-39.9)	10.8 (9.0-12.8)	9.5 (7.7-11.6)

**Estimated Number of Lives Saved After Menthol Ban, 2010-2050**

	Lives saved
<b>TOTAL POPULATION</b>	
10% change	323,107
20% change	478,154
30% change	633,252
<b>AFRICAN AMERICANS ONLY</b>	
10% change	91,744
20% change	164,465
30% change	237,317



**The Schroeder Institute at Legacy Presented Data that Supports the Conclusions Reached by TPSAC’s Report to FDA in March 2011**

**Removal of menthol cigarettes from the marketplace would benefit public health in the United States**

**Evidence is sufficient that:**

- The availability of menthols results in lower likelihood of smoking cessation success in African Americans (Above Equipoise)
- The availability of menthol cigarettes results in lower likelihood of smoking cessation success in other racial/ethnic groups (At Equipoise)



## TPSAC Report to FDA – CTP (Continued):

### Evidence is sufficient that:

- There is a causal relationship between the availability of menthol cigarettes and regular smoking among youth (Above Equipoise)
- Menthol cigarette marketing increases prevalence of smoking beyond anticipated prevalence if such cigarettes were not available -- for the whole population, and for youth and African Americans (Above Equipoise)

## Industry Counter Actions

- Industry report: **“Menthol Cigarettes: No Disproportionate Impact on Public Health”** (March 2011)
  - Uses Surgeon Generals Report causality framework to assess evidence
  - “This approach contrasts sharply with TPSAC’s adoption of an **unorthodox standard using the amorphous concept of equipoise**, which historically has been used to address issues not relevant here – such as how to ethically conduct randomized clinical trials or award veterans’ benefits.”

## Industry Counter Actions

- Advertisements freedom of choice
- Lorillard Website Visits to Congress
- Support from African American Leadership Groups
- Black market and economic concerns
- **INDUSTRY MADE** presentations to TPSAC
  - Menthol smoking “misclassified” in national surveys
  - “insufficient evidence to suggest age-related trends for menthol cigarette preference”
  - “smoking has declined much more rapidly among African Americans among whom menthol smoking is more prevalent, and that decline is most pronounced among young African Americans”

## What’s Ahead

- FDA–CTP review of TPSAC menthol report and will consider:
  - TPSAC’s report
  - The Tobacco industry perspective reports
  - FDA-CTP will continue its ongoing review of the available science and regulatory options available under the Tobacco Control Act
  - CTP intends to provide its first progress report on its review of the science in June 2011.

## Challenges

- **Decision-making with incomplete data**
  - Effects of menthol ban cannot be determined without a ban
- **Difficult to receive funding for this type of research**
  - Resources dwarfed by industry funding
- **Balance of science and advocacy**
- **Consensus building among scientific community**
- **The Industry “Playbook”:** remember the 1960’s?

## Strengths

- **Coordinated response from scientific, legal, and advocacy perspectives**
  - Anticipate legal challenges
  - Address statutory standard
- **“Just in time” policy-relevant research**
- **Direct response to tobacco industry arguments**
  - Re-analysis of data
  - Responses to submitted comments from industry
- **Provide framework for assessing evidence under public health standard**

## Today's Panelist



- ▶ **Amber Thornton-Bullock, MPH, CHES**
- ▶ Executive Vice President of Program Development

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## Community & Advocacy Perspective

Amber Thornton-Bullock, MPH, CHES  
Executive Vice President of Program Development



## Community & Advocacy Overview

- Historical Context
- Bringing the issue front and center: Pre Act - Family Smoking Prevention and Tobacco Advocacy efforts
- Building Upon Evidence – Getting the Word Out



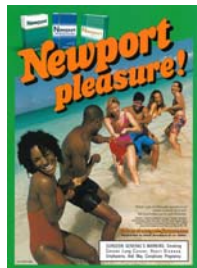
## Community/Advocacy Overview

- TPSAC Report
- No Big Surprise – Industry Response
- Community Challenges & Opportunities



## African American Community: Historical Context

- Built over time
- Ties that bind
  - Financial Support
  - Employment
- Menthol Wars (1960s to 1980s)
- Increased prevalence of use amongst African Americans and many other disparate population groups




## Bringing the Issue Front & Center

- Menthol excluded from “candy flavored cigarette ban” in proposed law
- Rationale for candy flavor ban is to reduce youth initiation uptake – but what about communities of color youth who uptake with menthol?
- Advocacy efforts – most notably NAATPN and others
- Result: New law directed FDA to make menthol a priority



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## Building Upon Evidence – Getting the Word Out




- 2<sup>nd</sup> Menthol Conference – encouraged a broader definition of menthol harm
- Addiction Journal
- SNRT Journal
- Tobacco Industry Documents

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## Building Upon Evidence – Getting the Word Out

- Priority Population & Mainstream Organizations Call for a Ban (NAACP Legal Defense Fund, NAATPN, AATCLC, CASA, AAP, etc.)
- Educational Webinars – NAATPN & AATCLC
- TPSAC Testimony & Submitted Comments



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## TPSAC Report

- **“..removal of menthol cigarettes from the market would benefit public health in the United States”.**
- If menthol is ban – many lives – across all community and multi-population sectors - could be saved
- More than half of Americans support a ban on menthol, with greater support among African Americans

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## No Big Surprise – Industry Response

- Industry pitch points:
  - Underground market & crime
  - Choice: “..unfairly target African American Smokers” (CORE)
  - “Paternalistic”
- Economic conflict of interests: “Our inner city stores are our menthol stores”\*

\*Source: Cindy Gross, Buyer and Marketing Coordinator, Handee Marts Inc., a 7-Eleven licensee as quoted from Menthol Ban Unlikely, Say C-store Execs, CSNewsTobacco Retailing.com, 10/14/2010

**UNDERSTANDING MENTHOL**  
A HISTORY OF MENTHOL IN AMERICAN CIGARETTES

## FREEDOM OF CHOICE FOR GROWN FOLKS



**Who Should Make Our Choices?**  
Recently, some self-appointed activists have proposed a legislative ban on menthol cigarettes in a misguided effort to force people to quit smoking by limiting their choices. So far, wiser heads have prevailed and the ban on menthol has not passed. It could come up again. It shouldn't.

**When government "reforms" intrude into our lives to the point of restricting freedom of individual choices on what we can enjoy, our basic concept of liberty is threatened.**

**Who Should Make Our Choices?**  
In the American tradition, laws restricting freedom of choice must be based on sound reasoning, rational public policy and verifiable data while allowing for a minimum of governmental intrusion. Menthol is a matter of taste and preference. The body of scientific evidence does not support the conclusion

that menthol cigarettes increase the known risks from smoking. The effort to ban menthol is just another in a long series of attempts by the politically correct crowd to force Americans to give up their freedom to choose to smoke a cigarette.

**"Informed grown-ups who decide to smoke should have the freedom to choose menthol cigarettes"**

**Shouldn't People Keep Fighting For The Freedom Of Choice?**  
The history of African Americans in this country has been one of fighting against paternalistic limitations and for freedoms. We all agree that children should not smoke, but grown-ups who can and should assess the risks of smoking should have the freedom to choose whether to smoke or not. If they choose to smoke, they should have the freedom to choose to smoke regular or menthol cigarettes. Please visit [www.mentholchoice.com](http://www.mentholchoice.com) and learn more about how you can help prevent this ban on menthol from being considered.

**Lordillard**  
TOBACCO COMPANY

[www.mentholchoice.com](http://www.mentholchoice.com)

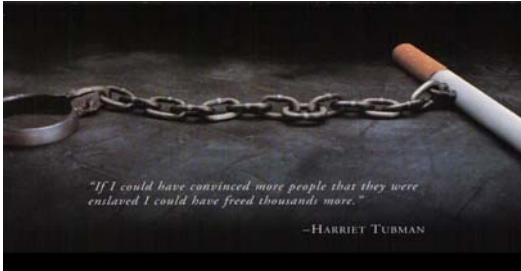
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## Community Challenges & Opportunities

- Impacting the “ties that bind”
- Educate, educate – and don't stop
- We've had success before (Boston – X cigarette test market, etc.)
- Community organizing & youth voice - beyond traditional public health



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*"If I could have convinced more people that they were enslaved I could have freed thousands more."*  
—HARRIET TUBMAN

Source: www.whitelies.tv (2002 – Indiana Tobacco Prevention and Control brochure)

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## Legacy Resources on Menthol

The following resources are available in the Menthol News section on Legacy's homepage, LegacyforHealth.org:

Press Releases

- [FDA Advises the Removal of Menthol Cigarettes Would Benefit Public Health in the United States](#)
- [New Menthol Special Journal Issue Underscores Need for Federal Action](#)
- [Legacy Reiterates Call for Prohibition of Menthol Products](#)
- [Should Menthol Cigarettes Be Banned?](#)

Policy Statement

- [Menthol Policy Statement](#)

Fact Sheet

- [Menthol Fact Sheet](#)

Consider Your Source

- [Legacy's counter-view to the messages from the tobacco industry](#)

Legacy in the Public Record

- [Updated Menthol Data 1/28/2011](#)
- [Legacy Response to Compass Lexecon Report on Menthol Contraband 1/28/2011](#)
- [The Impact of the Use of Menthol in Cigarettes on the Public Health Comments 11/19/2010](#)
- [Menthol Report Subcommittee of Tobacco Products Scientific Advisory Committee Public Comments 9/17/2010](#)
- [Legacy FDA Submission on Menthol 7/26/2010](#)
- [Menthol Marketing to Youth and Minorities Group Comments 7/26/2010](#)
- [FDA Testimony by Dr. Cheryl Heiston 6/30/2010](#)
- [Family Smoking Prevention and Tobacco Control Act 09/24/2009](#)

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## FDA Center for Tobacco Products – Menthol Resources

**Tobacco Products Scientific Advisory Committee's Menthol Report Overview:**  
<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm247605.htm>

**Expert Testimony:**

- Gary Giovino, PhD – *Patterns of and Recent Trends in Use of Mentholated Cigarettes in the United States:*  
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM234658.pdf>
- David T. Levy, PhD – *Modeling the Future Effects of a Menthol Ban on Reduced Smoking Prevalence and Deaths Averted in the US:*  
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM246001.pdf>
- Jonathan Winickoff, MD – *Public Attitudes on Prohibiting Menthol Cigarettes:*  
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM234656.pdf>


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For more information, please contact:

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Senior Director, Collaboration and Outreach  
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## Questions & Answers

► Feel free to ask questions via the chat box.



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## Contact the SCLC

Visit us online:  
<http://smokingcessationleadership.ucsf.edu>

Call us toll-free:  
**1-877-509-3786**




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## Closing Remarks

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Please help us by completing the post-webinar survey.

Thank you for your continued efforts to combat tobacco.

### SAVE THE DATES:

Thursday, June 2<sup>nd</sup> from 1-2:30 pm ET

*Dr. Jill Williams, "Update in Smoking in Schizophrenia"*

Tuesday, June 28<sup>th</sup> from 2-3:30 pm ET

*Dr. Jodi Prochaska, "Tobacco Use & Bipolar Disorder: Results from a Large Online Survey"*