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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- Webinar is being recorded
- Questions are encouraged throughout via the chat box

Welcome

- Catherine Saucedo, Deputy Director, SCLC, moderator
- Steve Schroeder, MD, Director, SCLC
- 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

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

Agenda
- Welcome
- Catherine Saucedo, Deputy Director, SCLC, moderator
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- 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.
**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

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**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.

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**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**.

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**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.

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**Public Health Standard**

Additional Considerations
- Population-based
- Framed in terms of risks, benefits, and likelihoods; **not causation**
  - Equipoise
- 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
dabrams@legacyforhealth.org

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
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.

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

Reviewing and Classifying Evidence
Background and Recommendations
Jonathan M. Samat, 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
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.

What Data Is Needed To Inform Regulation?

Typical regulatory standard
- Animal studies
- Controlled human exposure studies
- Case studies
- Clinical trial reports
- Epidemiologic studies
- Randomized controlled trials
- HARMs to individual compared to use of (lethal) cigarettes

Public health standard
- Epidemiologic studies
- Economic studies
- Psychological studies
- Sociological studies
- Consumer behavior studies
- Review of tobacco industry documents
- Systems science
  - Mathematical modeling
  - Social networks studies

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?

Schroeder Institute at Legacy Commissioned Research to Support FDA

Peer-reviewed publications

Adjusted Prevalence of Use of Menthol Cigarettes Among Past 30-day Smokers United States, 2004-2008

Changing Trends in Menthol vs. Non-menthol Cigarettes Among 12-17 Year Olds United States, 2004-2008
Menthol Brand Switching Among Youth and Young Adult Smokers, Overall and Selected Groups* – United States, 2003-2005

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

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


**Effect on cessation in TUS-CPS**

<table>
<thead>
<tr>
<th></th>
<th>Quit attempt in the past year &amp; 3 months and ≥ 3 months</th>
<th>Quit ≥ 3 months and ≤ 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of total smokers</td>
<td>Percent difference from non-menthol</td>
<td>Percent difference from non-menthol</td>
</tr>
<tr>
<td>Total</td>
<td>100.0%</td>
<td>36.8%</td>
</tr>
<tr>
<td>Non-menthol</td>
<td>70.0%</td>
<td>39.3%</td>
</tr>
<tr>
<td>Menthol</td>
<td>25.9%</td>
<td>40.9%</td>
</tr>
<tr>
<td>No Preference</td>
<td>4.2%</td>
<td>28.8%</td>
</tr>
</tbody>
</table>

2007 Total

<table>
<thead>
<tr>
<th></th>
<th>Quit attempt in the past year &amp; 3 months and ≥ 3 months</th>
<th>Quit ≥ 3 months and ≤ 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of total smokers</td>
<td>Percent difference from non-menthol</td>
<td>Percent difference from non-menthol</td>
</tr>
<tr>
<td>Total</td>
<td>100.0%</td>
<td>38.8%</td>
</tr>
<tr>
<td>Non-menthol</td>
<td>70.2%</td>
<td>38.1%</td>
</tr>
<tr>
<td>Menthol</td>
<td>25.7%</td>
<td>41.4%</td>
</tr>
<tr>
<td>No Preference</td>
<td>4.1%</td>
<td>35.4%</td>
</tr>
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</table>


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

<table>
<thead>
<tr>
<th></th>
<th>Lives saved</th>
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</thead>
<tbody>
<tr>
<td>TOTAL POPULATION</td>
<td></td>
</tr>
<tr>
<td>10% change</td>
<td>323,107</td>
</tr>
<tr>
<td>20% change</td>
<td>478,154</td>
</tr>
<tr>
<td>30% change</td>
<td>633,252</td>
</tr>
</tbody>
</table>

AFRICAN AMERICANS ONLY

<table>
<thead>
<tr>
<th></th>
<th>Lives saved</th>
</tr>
</thead>
<tbody>
<tr>
<td>10% change</td>
<td>91,744</td>
</tr>
<tr>
<td>20% change</td>
<td>164,465</td>
</tr>
<tr>
<td>30% change</td>
<td>237,317</td>
</tr>
</tbody>
</table>

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)

[Image]
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 General’s 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.”

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

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
Building Upon Evidence – Getting the Word Out

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

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

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, CSNewsTobaccoRetailing.com, 10/14/2010

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
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 Announcement (unreleased text for Federal Action)
- Legacy Resources Call for Prohibition of Menthol Products
- World Health Organization Calls for Ban

Policy Statement
- Menthol Policy Statement

Policy Briefs
- Menthol Fact Sheet
- Consumer Viewpoint
- Legacy’s counter-view to the messages from the tobacco industry

Legacy in the Public Record
- Updated Menthol Data 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 Healton 03/31/2010
- Family Smoking Prevention and Tobacco Control Act 09/24/2009

For more information, please contact:
Karen Martin
Senior Director, Collaboration and Outreach
kmartin@legacyforhealth.org

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:
- David T. Levy, PhD – Modeling the Future Effects of a Menthol Ban on Reduced Smoking Prevalence and Deaths Averted in the US:
- Jonathan Winickoff, MD – Public Attitudes on Prohibiting Menthol Cigarettes:

Questions & Answers

› Feel free to ask questions via the chat box.

Contact the SCLC

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

Call us toll-free:
1-877-509-3786
Closing Remarks

Please help us by completing the post-webinar survey.

Thank you for your continued efforts to combat tobacco.

SAVE THE DATES:

Thursday, June 2nd from 1-2:30 pm ET
Dr. Jill Williams, “Update in Smoking in Schizophrenia”

Tuesday, June 28th from 2-3:30 pm ET
Dr. Jodi Prochaska, “Tobacco Use & Bipolar Disorder: Results from a Large Online Survey”