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Knowing the Enemy: Tobacco Industry Tactics
Tuesday, December 4, 12:00 p.m. – 1:30 p.m. CST

Safe Routes to School Initiatives: Who is Responsible for What?
Tuesday, December 11, 12 p.m. – 1:30 p.m. CST

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All participants are muted. Type a question into the Q & A panel for our panelists to answer. Send your questions in at any time.

This webinar is being recorded. If you arrive late, miss details or would like to share it, we will send you a link to this recording after the session has ended.
Today’s Agenda

• Introduction (Joelle Lester)

• Why menthol is a critical public health issue (Dr. Valerie Yerger)

• The science of menthol in tobacco products (Dr. Phil Gardiner)

• Options for federal regulation of menthol (Ellen Vargyas)

• Action opportunities to press the FDA on menthol (Desmond Jenson)

• Q&A/Feedback from you (moderated by Joelle Lester)

*The legal information and assistance provided in this webinar does not constitute legal advice or legal representation.*
Youth Smoking Epidemic: Role of Menthol and U.S. Efforts to Prevent

Menthol → Marketing → Af Am Uptake

Properties

Youth Epidemic

Trendsetters

Tobacco Control Act (2009)

Menthol Cigarettes: A Starter Product That The FDA Should Ban

Phillip S. Gardiner, Dr. P. H.
Policy and Regulatory Sciences /Nicotine Dependence and Neurosciences Program Officer, Tobacco Related Disease Research Program (TRDRP) University of California Office of the President &
Co-Chairperson, African American Tobacco Control Leadership Council (AATCLC)

Pressing the FDA on Menthol: A Public Health Law Center Webinar
November 13, 2012
Menthol Cigarettes: A Short History

- Spud: 1925; 1927 Axton-Fisher Company; 1944 – 1963 Phillip Morris
- Kool: Brown & Williamson; R.J. Reynolds 1933 – Present
- Salem: R.J. Reynolds 1956 – Present
- Newport: 1957 – Present
The Ultimate Candy Flavoring; Menthol Helps The Poison Go Down Easier

- Chief Constituent of Peppermint Oil; Minty-Candy Taste; Masks the Harshness of Smoking

- Cooling Sensation; activates taste buds; cold receptors; increases throat grab

- Anesthetic effects; Mimics Bronchial Dilatation

- Independent Sensory Activation Neurotransmitters

- Increases Salivary Flow; Transbuccal Drug absorption

- Greater Cell Permeability (Ferris, 2004; Benowitz, 2004)
Inhibits Detoxification of NNAL

• Menthol inhibits NNAL glucuronidation; that is menthol inhibits the body’s detoxification mechanism for the powerful lung carcinogen NNAL.

• Cigarettes that are characterized as menthol contain on average 3.0mg, of which 20% is absorbed, and a pack-a-day smoker absorbs approximately 12.5mg per day.
Trigeminal Nerve Endings

- Menthol in cigarette smoke stimulates the trigeminal nerve endings in the mouth and throat in a manner similar, yet distinct, to that of nicotine, contributing to the perception of strength of the cigarette smoke.
- Varying nicotine and menthol content to achieve the same result.
All tobacco Products Contain Some Menthol

- **Menthol content of U.S. tobacco products**

- **Product**
  - Regular (non-menthol) cigarettes 0.003
  - Menthol cigarettes (weak effect) 0.1–0.2
  - Menthol cigarettes (strong effect) 0.25–0.45
  - Pipe tobacco 0.3
  - Chewing tobacco 0.05–0.1

(Hopp, 1993)
Who uses Menthol Cigarettes?

- 1.1 million underage adolescents smoked menthol cigarettes
- 18.1 million adults
- 52.2% of all menthol smokers are women

(NSDUH, 2004-2008)
Kids Smoke Menthols Most

Source: 2004 to 2008 SAMHSA National Survey on Drug Use and Health (NSDUH)
Are Mentholated Cigarettes a Starter Product for Youth? —2002 NYTS Hersey, 2006

[Percentages for youth smoking a usual brand of cigarettes.]

• “Less Experienced” smokers in middle school are more likely to smoke menthol (p = 0.002)
• The same pattern exists for smokers in high school (but n.s.)
### Prevalence of menthol smoking among ever smokers; Hispanic Origin (Delnevo, 2011)

<table>
<thead>
<tr>
<th>Hispanic Origin</th>
<th>Prevalence (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mexican</td>
<td>19.9 (18.3, 21.7)</td>
</tr>
<tr>
<td>Puerto Rican</td>
<td>62.0 (58.0, 65.8)</td>
</tr>
<tr>
<td>Other</td>
<td>26.5 (23.7, 29.5)</td>
</tr>
<tr>
<td>Total</td>
<td>27.1 (26.7, 27.6)</td>
</tr>
</tbody>
</table>
## Hawaii Youth Tobacco Survey, 2000, 2003 and 2009

(Hawaii State Department of Health, 2009)

<table>
<thead>
<tr>
<th></th>
<th>Middle School</th>
<th></th>
<th></th>
<th>High School</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarette</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prevalence</td>
<td>38.4</td>
<td>21.1</td>
<td>17.2</td>
<td>63.3</td>
<td>47.8</td>
<td>36.9</td>
</tr>
<tr>
<td>Menthol</td>
<td>61.5</td>
<td>61.4</td>
<td>70.0</td>
<td>76.1</td>
<td>75.8</td>
<td>78.4</td>
</tr>
<tr>
<td>Brand: Kools</td>
<td>56.1</td>
<td>27.1</td>
<td></td>
<td>61.1</td>
<td></td>
<td>57.6</td>
</tr>
</tbody>
</table>
Filipinos and Menthol

• Menthol cigarettes constituted 55% of the cigarette market in 2007
• Marlboro Menthol Lights; Philip Morris Menthols
• Cigarettes in the Philippines were found to contain 8% more nicotine and 76% more tar than imported brands
  • (Euromonitor Cigarette Report, 2008)
African American Menthol Use Skyrockets

1953  5%

1968  14%

1976  44%

1990  >80%

A new idea in smoking

Salem refreshes your taste

- menthol fresh
- rich tobacco taste
- modern filter, too

Springtime is wonderful. So is the freshness of Salem. The fragrance of all that new growth. And nothing is as Salem. The subtle, smooth taste of Salem's mellow cigarettes. The refreshing taste in every Salem. With a new menthol filter. That's what makes Salem a winner when you're out in everything. Salem refreshed. Salem selected.
Cool ain’t Cold. Newport is. BOLD COLD

A whole new bag of menthol smoking filter kings & 100’s

1970 *Ebony* magazine advertisement
Mentholated Cigarettes Use is Highest among Minority Groups—2002 NYTS

[Percentages for youth smoking a usual brand of cigarettes.] Hersey, 2006
Focus vs. Non Focus Communities  
(Wright, 2009)

- Focus Communities: Inner-city, Colored and Poor  
  - Less expensive, more desirable promotions  
    - Buy 1, Get X Free  
    - Summer/ Holidays

- Non-focus Communities: Upscale, suburban, rural and white  
  - More expensive, less desirable promotions  
    - Buy 2, Get X Free  
    - Buy 3, Get X Free

- Menthol Cigarettes Cheaper  
  - Non-focus- 50 cents off/ pack ($5.00 off/ ctn)  
  - Focus- $1.00-$1.50 off/ pack ($10.00-15.00 off/ ctn)
Predatory Marketing Patterns (Henriksen, 2011)

As the % African American students increased, proportion menthol ads increased:

- Enrollment = 7% AA: 25.4%
- Enrollment = 17% AA: 31.3%
- Enrollment = 27% AA: 37.2%
Menthol Cigarettes: Cheaper for African Americans

• For each 10% increase in the proportion of African American students:
  – Newport discount 1.5 times greater
  – The proportion of menthol advertising increased by 5.9%,
  – Newport promotion were 42% higher and
  – The cost of Newport was 12 cents lower.

(Henriksen, et al., 2011)
## Storefront Cigarette Advertising Differs by Racial/Ethnic Community

<table>
<thead>
<tr>
<th></th>
<th>Brookline</th>
<th>Dorchester</th>
<th><em>p</em>-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n=</strong></td>
<td>42</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Retailer w/ Ads</td>
<td>42.9</td>
<td>85.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Small Ads</td>
<td>56.8</td>
<td>20.1</td>
<td>&quot;</td>
</tr>
<tr>
<td>Large Ads</td>
<td>2.0</td>
<td>23.7</td>
<td>&quot;</td>
</tr>
<tr>
<td>Menthol Ads</td>
<td>17.9</td>
<td>53.9</td>
<td>&quot;</td>
</tr>
<tr>
<td>Average Price</td>
<td>$4.94</td>
<td>$4.55</td>
<td>&quot;</td>
</tr>
</tbody>
</table>

(Seidenberg, et al., 2010)
Brazen to say the least

http://mentholchoice.com/index.html

“I CAN DECIDE FOR MYSELF.”

GROWN-UPS SHOULD HAVE THE FREEDOM TO CHOOSE WHETHER TO SMOKE REGULAR OR MENTHOL CIGARETTES.
Blacks Support Banning Menthol

- Survey of 1514 never, former and current smokers

  % support banning menthol

  White      53.4
  Black      68.0
  Other      72.4

(Winickoff, et al., 2011)
# Blacks Support Banning Menthol

- Survey of 303 never, former and current Black smokers

<table>
<thead>
<tr>
<th>Smoking Status</th>
<th>Support Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never Smoker</td>
<td>83.4%</td>
</tr>
<tr>
<td>Former Smoker</td>
<td>71.4%</td>
</tr>
<tr>
<td>Current Smoker</td>
<td>52.8%</td>
</tr>
</tbody>
</table>

(Winickoff, et al., 2011)
If Menthol Were Banned 100,000s of Lives would be saved

<table>
<thead>
<tr>
<th></th>
<th>2010 – 2050</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Menthol Smokers</td>
<td>Black Menthol Smokers</td>
</tr>
<tr>
<td>10%</td>
<td>323,107</td>
<td>91,744</td>
</tr>
<tr>
<td>20%</td>
<td>478,154</td>
<td>164,465</td>
</tr>
<tr>
<td>30%</td>
<td>633,252</td>
<td>237,317</td>
</tr>
</tbody>
</table>

(Levy, et al., 2011)
Reasons to Ban Menthol

- Menthol cigarettes are starter products for Youth
- Menthol cigarettes have greater addiction potential given their Unique Sensory Stimulation Properties
- The Ultimate Candy Flavoring: It helps the poison go down easier
Reasons to Ban Menthol

- Bogus Health Messages; Mass Disinformation Campaign(s)
  - Healthier alternative; soothes sore throats
  - Refreshing; Alive with Pleasure
  - African American smokers think menthols are healthier and safer than regular cigarettes (Tibor Koeves Associates, 1968; Hymowitz, 1995; Richter, 2008; Unger, 2010)
Reasons to Ban Menthol

• Cessation Inhibitor; Relapse Promoter

  – Menthol Cigarettes are Harder to Quit and easier to take back up (Harris et al, 2004; Pletcher et al, 2006; Okuyemi 2003, 2004, 2007; Gandhi et al, 2009)

  – Not all studies (Fu et al., 2008; Hyland et al., 2002; Murray, 2007)
Menthol Harder to Quit!

<table>
<thead>
<tr>
<th></th>
<th>Quit Attempts</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Menthol</td>
<td>38.1%</td>
<td></td>
</tr>
<tr>
<td>Menthol</td>
<td>41.4%</td>
<td>+8.8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Cessation (&gt;3 mo.)</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Menthol</td>
<td>21.2%</td>
<td></td>
</tr>
<tr>
<td>Menthol</td>
<td>18.3%</td>
<td>-13.8%</td>
</tr>
</tbody>
</table>

(Levy, et al., 2011)
Reasons to Ban Menthol: It’s a Social Justice Issue!

• Predatory and Relentless Marketing Toward the Most Vulnerable Populations
  – African Americans
  – Native Hawaiians
  – Filipinos
  – Women
  – Youth

(Appleyard et al, 2001; Gardiner, 2004; Sutton and Robinson, 2004; Yerger, 2007; Healton, 2009)
Social Justice Issue

• The disproportionate marketing and targeting of candy-flavored poison to African Americans and other specially oppressed sectors of our society, is out-right discriminatory and genocidal.
  – Poorest; least informed; fewest resources; indeed the definition of preying on the most vulnerable sections of our society.
Apply the Same Logic to Menthol

- No special commissions and advisory committees
- No comparing lung cancer rates between vanilla cigarette users and regular cigarette users.
- No calls for 5, 10, or 20 more years more of research on these products
- Outlawed because they were starter products
TRDRP

• Research for a Healthier California

• [www.trdrp.org](http://www.trdrp.org)
• [phillip.gardiner@ucop.edu](mailto:phillip.gardiner@ucop.edu)
• Grant funding
• Scientific Conferences
• Dissemination of Research Findings
MENTHOL AND THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

NOVEMBER 14, 2012
ELLEN VARYAS

GENERAL COUNSEL AND CORPORATE SECRETARY

AMERICAN LEGACY FOUNDATION
FSPTCA MENTHOL-SPECIFIC PROVISIONS

• Menthol is **NOT** included in candy/fruit “characterizing” flavors ban

• **BUT** Secretary can exercise authority over menthol under the **PUBLIC HEALTH STANDARD**

• TPSAC to issue a report within a year on “the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities” addressing the considerations listed in [the public health standard].
PUBLIC HEALTH STANDARD: OVERVIEW

• “Appropriate for the protection of the public health”

• A flexible standard focused on the overall goal of reducing the number of individuals who die or are harmed by tobacco products.

• New standard: traditional safe and effective standard doesn’t apply to tobacco
PUBLIC HEALTH STANDARD: ELEMENTS

• Overall
  ◦ Science-based
  ◦ Population-based
  ◦ Likelihoods and not causation

• Three principal prongs
  ◦ *Risks* and *benefits* to the population as a whole, including users and non-users of tobacco products
  ◦ Increased or decreased *likelihood* that current users will stop using tobacco products (Cessation)
  ◦ Increased or decreased *likelihood* that non-users will start using tobacco products (Prevention)
• Additional considerations:
  ◦ Countervailing health effects such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this subchapter and the significance of such demand
  ◦ Scientific evidence that the proposed standard will not reduce or eliminate the risk of illness or injury
• Approved in March 2011; finalized in July 2011

• Exhaustive review of scientific literature regarding menthol cigarettes

• Is the scientific evidence sufficient to conclude that various outcomes are above, at or below “equipoise”.

• Overall Conclusions (above equipoise):
  ◦ Menthol cigarettes have an adverse impact on public health in the United States
  ◦ There are no public health benefits of menthol compared to non-menthol cigarettes
• Key specific conclusions (above equipoise):
  ◦ Menthol increases experimentation and regular smoking
  ◦ Menthol marketing increases prevalence of smoking beyond anticipated prevalence if such cigarettes were not available for the whole population, and for youth and African Americans
  ◦ Menthols increase likelihood of addiction and degree of addiction in youth smokers
  ◦ Menthols result in lower likelihood of smoking cessation success in African Americans as opposed to smoking non-menthols
• Key specific conclusions (below equipoise). The evidence is insufficient to conclude that:
  ◦ menthol smokers have increased risk for disease as compared to non-menthol smokers
  ◦ menthol smokers inhale more smoke per cigarette or are exposed to higher levels of nicotine and other tobacco toxins

FDA ACTION POST TPSAC REPORT: SECOND LEVEL REVIEW

• June 2011, FDA announced that its internal experts were conducting another “independent” review of the science on menthol.
  ◦ Internal report was to be submitted to external “peer review” in July 2011.
  ◦ Report and comments would be published for public comment in the Federal Register.
  ◦ Early on there was suggestion of a November 2011 publication date
• Unusual step

• NOTHING HAS BEEN PUBLISHED; NO INFORMATION AVAILABLE AS TO STATUS
POSSIBLE FDA ACTIONS

- Publish “independent review” for public comment
- Commence rule-making process for a menthol ban either through an Advance Notice of Proposed Rulemaking (ANPRM) or Notice of Proposed Rulemaking (NPRM)
- Conclude that additional scientific evidence is needed before initiating rulemaking:
  - Solicit and/or fund additional research
  - Wait for additional research to be generated
- No action; maintain status quo
INFORMAL RULEMAKING PROCESS

1. Congress Passes a Law
2. Agency writes implementation regulation
3. 90 day OMB Review
4. Notice of Proposed Rulemaking (NPRM)
5. 90 day public comment period
6. Agency analyses comments and reissues regulation
7. 90 day OMB Review
8. Final Rule (Major Rules must sit for 60 days)
9. Possible: Congressional Action or Lawsuits

Source: James C. Capretta for the “Understanding the Regulatory Process” course by Capitol.net
OPPORTUNITIES FOR ADVOCACY IN THE RULEMAKING PROCESS

**Prelude**
may include:

- Solicit Public Input
- Scientific Advisory Committee, in this case, Tobacco Products Scientific Advisory Committee (TPSAC)
- ANPRM
- Petitions
- Meetings & workshops

**Drafting**

- Considerations & Consultation
- Required analysis
- OMB Review

**Proposal**
may include:

- Publish in Federal Register
- Public Comment – written &/or possibly a hearing
- FDA considers all comments
- Considerations & Consultation
- Required analysis
- Revise
- OMB review

**Final Rule**

- Publish in Federal Register
- Effective Date
- Implementation
- Potential litigation

Graphic source: American Lung Association Presentation 2009
Pressing the FDA to Restrict the Sale of Menthol Tobacco Products

Desmond Jenson, J.D.
Restrictions on Engagement with the FDA

• Be aware of restrictions on lobbying:
  – Lobbying Disclosure Act
  – Internal Revenue Code
  – 2012 Consolidated Appropriations Act
  – State & Local laws
  – Contracts with Funders

• Contact your attorney before taking action
Agencies Operate Differently than Congress

- Agencies are unelected
- Agencies depend on public engagement
Opportunities for Engaging the FDA

Range from formal to informal:

- Comment on proposed rules
- Comment on guidance documents
- Submit a citizen petition
- Submit scientific research
- Mail, call, email
Citizen Petition vs. Grassroots Petition

- Grassroots petitions are informal and do not compel an agency to act.
- Contact Bob Doyle with questions.
Citizen Petitions

- Formal process to compel agency action
- Authorized by statute, governed by regulations
- Agency has a legal obligation to respond:
  - Approve Petition
  - Deny Petition
  - Tentative Response
Menthol Citizen Petition

• Opportunities for action:
  – Submit Comments
    • Submit research data on menthol
    • Explain why this issue is important to you
    • Describe the impact of menthol in your community
How do I submit comments?

Submit your comments on proposed regulations and related documents published by the U.S. Federal government. You can also use this site to search and review original regulatory documents as well as comments submitted by others.

Help improve Federal regulations by submitting your comments.
How do I submit comments?

1. ENTER INFORMATION
   - First Name:
   - Middle Name:
   - Last Name:
   - Country:
     - Select One:
   - State or Province:
   - Organization Name:
   - Submitter’s Representative:
   - Category:
     - Select One:

2. TYPE COMMENT
   - Comment:
     - 2000 characters remaining

3. UPLOAD FILE(S)
   - Choose File: No file chosen

   Preview Comment
   Submit
I work for New York State's Tobacco Control Program youth modality which is Reality Check. Cigars should absolutely fall under FDA control. Cigars is just as dangerous product as cigarettes and other tobacco products. Recently cigar products have become more popular with people in New York State because they do not fall under the high tax as cigarettes. Cigars have become popular with youth because of the fruit flavoring. Cigars are a loophole for the tobacco industry to target youth. It is fact that youth like products with fruit flavoring. When fruit flavors were outlawed in cigarettes, the tobacco industry started to put them more prominently in cigars and cigarillos. This also lead to the creation of little cigars. The tobacco industry needs to be halted and the opportunity to target youth as replacement smokers stopped. The tobacco industry has been one of the most manipulative businesses in world's history and continues this today. I have attached a photo of a local store, to show how the tobacco industry targets cigar products to youth.
January 11, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fisher’s Lane, Room 1061
Rockville, MD 20852

Re: Required Warnings for Cigarettes Packages and Advertisements

Docket No. FDA-2010-N-0568
RIN 0910-AG41

Dear Commissioner Hamburg:

The Tobacco Control Legal Consortium ("the Consortium"), America’s legal network for tobacco control policy, is pleased to submit these comments to assist the FDA ("the agency") in designing more effective cigarette warning labels as part of the agency’s responsibilities under Section 201 of the Family Smoking Prevention and Tobacco Control Act ("FSPTCA" or "the Act")¹. Specifically, we applaud the agency’s proposed rule of November 12, 2010.²  Our firm...
January 11, 2011

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

COMMENTS OF LORILLARD TOBACCO COMPANY

Request for Comment: Proposed Rule on “Warnings” for Cigarette Packages and Advertisements Restrictions
Docket No. FDA-2010-N-0568; RIN 0910-AG41

These comments are respectfully submitted by Lorillard Tobacco Company

(Lorillard) in response to FDA’s Proposed Rule “for the display of health warnings on cigarette
Informally Engaging the FDA

- Opportunities for action:
  - Engage the FDA Center for Tobacco Products
    - Call CTP: 1-877-287-1373
    - Email CTP: AskCTP@fda.hhs.gov
    - Talk to CTP employees when you see them
FDA Tobacco Action Center

In June 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act, giving the Food and Drug Administration unprecedented authority to protect the public health by regulating tobacco products. The ultimate success of the law will depend on an active and engaged public health community that works to support the FDA with the best evidence and input available. This is particularly important given the antics of the tobacco industry in the regulatory process so far. The tobacco industry has opposed nearly every action the agency has taken and has already filed four lawsuits in efforts to block various provisions in the law. The public health community must provide a strong counterbalance to the tobacco industry’s immense resources to ensure that the FDA enacts bold regulations to protect public health.

Take Action Today

Comment on Proposal
Read and comment on guidance to require tobacco companies to disclose harmful chemicals in tobacco products.

Contact Us
On occasion prohibiting tobacco companies from marketing a tobacco product as less harmful without evidence that harm is actually reduced.

Sign-up for FDA Tobacco Action Alert
Sign up to receive our FDA Tobacco Action Alerts notifying you of opportunities to strengthen FDA regulation of tobacco.
Contact Us:

desmond.jenson@wmitchell.edu
(651) 965-7612

joelle.lester@wmitchell.edu
(651) 695-7603
Questions?