How and Why SRNT Members Should Participate in the FDA’s Rulemaking on Menthol

August 22, 2013
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Welcome SRNT members to a special webinar training for scientists interested in engaging with the FDA’s regulation of tobacco products
Agenda

• Tobacco Regulation and the Importance of Science
  
  Carolyn Dresler, FDA Center for Tobacco Products

• Why Participation by Scientists is Important
  
  Mark Greenwold, Campaign for Tobacco-Free Kids

• How Scientists Can Participate
  
  Joelle Lester, Tobacco Control Legal Consortium

• Q & A
“… 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) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary’s authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

21 U.S.C. § 387g(a)(1)(A)
Menthol in Cigarettes

Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee . . ., the Secretary shall refer to the Committee for report and recommendation, . . . The issue of 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. . . . Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required . . . Nothing in this subsection shall be construed to limit the Secretary’s authority to take action under this section or other sections of this Act applicable to menthol

21 U.S.C. § 387g(e)(1)-(3)
Menthol in Cigarettes

- June 22, 2009 – Tobacco Control Act signed into law
- March 17, 2011 – TPSAC Menthol Report Issued
- March 18, 2011 – FDA announces that it will independently study menthol
- April 12, 2013 – Tobacco Control Legal Consortium and 18 other organizations submit a Citizen Petition asking the FDA to prohibit menthol as a characterizing flavor in cigarettes
- July 24, 2013 – FDA issues preliminary evaluation and accepts comments on Advanced Notice of Proposed Rulemaking
Tobacco Regulatory Science

Carolyn Dresler, MD, MPA
Associate Director for Medical and Health Sciences
Office of Science
Center for Tobacco Products

Disclaimer: The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy.
Family Smoking Prevention and Tobacco Control Act
June 22, 2009
FDA/CTP Public Health Goals

- Prevent Americans—especially youth—from starting to use tobacco
- Encourage current users to quit
- Decrease the harms of tobacco product use
CTP Uses a Public Health/Population Health Regulatory Standard

- Tobacco products cannot be regulated using FDA’s traditional “safe and effective” standard
- The Tobacco Control Act mandates its regulation using a population health standard taking into account both users and non-users of tobacco products
FDA Authority Under
the Tobacco Control Act

• Gives FDA direct authority over cigarettes, roll-your-own and smokeless tobacco products

• “Tobacco product” is defined any product made or derived from tobacco that is intended for human consumption, including any component part, or accessory of a tobacco product

• FDA announced that it will propose a rule deeming products that meets the definition of a “tobacco product” to be subject to FDA’s jurisdiction

• CTP is funded solely via “user fees” from tobacco company assessments - $505 million for FY13 – caps at $712 million in FY19
Specific Authorities Include:

- Premarket applications for new and modified risk tobacco products
- Testing and reporting levels of harmful and potentially harmful constituents by brand and sub-brand
- Tobacco product standards
- Health warnings on cigarettes and smokeless tobacco products & ads
- Advertising and promotion restrictions
- Industry registration and listing of ingredients
- FDA has authority to conduct research to support tobacco product regulation
Tobacco Control Act -- Limitations

In general, CTP’s regulatory authorities do not extend to:

- Setting tax rates for tobacco products
- Regulating therapeutic products, such as those marketed to treat tobacco dependence (regulated by CDER, FDA)
- Setting clean indoor air policies
- Regulating tobacco growing
- Requiring the reduction of nicotine levels to zero
FDA’s Framework for Tobacco Product Regulation

1. Understand the regulated products
2. Control product changes that could impact public health
3. Prohibit false/misleading product claims that state/imply reduced risk
4. Restrict marketing and distribution, particularly to youth
5. Decrease the harms of the product
6. Ensure industry compliance
7. Educate the public related to FDA's regulatory actions
8. Expand the science base for regulatory action & evaluation
Tobacco Science Regulatory Decision Making

The science of tobacco products, individual risk, and population health informs FDA’s regulatory decisions

- Product
  - Chemistry
  - Engineering
  - Microbiology

- Tobacco User
  - Toxicology, pharmacology
  - Clinical medicine
  - Behavior, use, addiction

- Population
  - Epidemiology
  - Social science
  - Statistical analysis
FDA-CTP Research Priorities Differ from NIH Priorities

• FDA-CTP funds cannot be used to support research on:
  – Diagnosis of disease
  – Treatment of disease or tobacco use
  – Mechanisms of disease
  – Clinical practice

• Tobacco regulatory science
  – Research to inform FDA’s regulatory authority with respect to manufacture, marketing, and distribution of tobacco products
How will Research Inform CTP’s Regulatory Authorities

• Preventing youth access
• Advertising restrictions
• Information dissemination, e.g., health warnings, harmful and potentially harmful constituents
• Public education campaigns
• Product standards
• New and modified risk tobacco products
FDA-CTP Research Areas of Interest

• Nicotine dependence threshold among youth and adults and impact of nicotine reduction on tobacco product use behavior
• Initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence and toxicity of:
  • Cigars (small, large, cigarillos), smokeless tobacco, e-cigarettes, hookah, pipes, dissolvables
• Impact of tobacco product features (e.g., ingredients, constituents, components, additives such as flavors, and labeling and marketing) on initiation
FDA-CTP Research Areas of Interest

• Toxicity thresholds for each of the 20 harmful and potentially harmful constituents
• Statistical modeling of the public health impact of FDA/CTP regulation of potential modified risk tobacco products
• Consumer perceptions of tobacco products including the impact of labeling and marketing
• Effective communication strategies regarding harmful and potentially harmful constituents and risks of tobacco products
Notice-and-Comment Rulemaking and FDA’s Regulation of Menthol in Cigarettes

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August 22, 2013
Some potential product standards

• Maximum nicotine yield for a product

• Reduction or elimination of other constituents, including smoke constituents, or harmful components of a product

• Reduction or elimination of components, ingredients, additives

• Restrictions on product design
Notice-and-Comment Rulemaking

FDA rule must be based on what is in the administrative record.

Only documents submitted to FDA in the appropriate docket are in the administrative record. FDA cannot rely on information outside the administrative record.

Anyone can file a comment. FDA is obligated to consider and respond to all comments.

A comment need not address every issue raised by FDA’s proposed rule or every question identified in an FDA notice.

A comment may be valuable even if it is not based on peer-reviewed published literature.
Advance Notice of Proposed Rulemaking Regarding Menthol

- FDA is seeking information to provide the basis for a proposed rule that may be issued in the future.

- There is currently no proposed rule.
Public Health Standard

• In determining whether a proposed product standard is “appropriate for the protection of the public health” FDA must consider scientific evidence concerning

  the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

  the increased or decreased likelihood that nonusers will start using such products;

  the increased or decreased likelihood that existing users of tobacco products will stop using such products.
Primary scientific issues

Does the availability of menthol cigarettes increase the likelihood that adolescents will initiate tobacco use and progress to regular smoking?

Does the availability of menthol cigarettes decrease the likelihood of cessation by any segment of the population?
Important scientific input

Research about the impact of menthol on youth initiation or progression to regular smoking by adolescents or cessation by existing users

Evaluation of industry-sponsored research on these subjects

Evaluation of industry arguments attacking the validity or sufficiency of research cited by FDA or TPSAC in support of their conclusions
Additional Issues

• FDA notice identifies numerous specific questions, including asking whether FDA should consider the issuance of a standard prohibiting mentholated cigarettes.

• Input from scientists on any or all of the questions posed by FDA is important.

• A comment need not address all the questions and need not specifically address any of them.

• A comment that addresses one question effectively is more valuable than a comment that addresses all questions superficially.
How and Why SRNT Members Should Participate in the FDA Docket on Menthol

Joelle M. Lester, J.D.
How to submit a comment

- Nuts and bolts of the commenting process
- What kinds of information to include
- Resources available to help you participate in the FDA’s regulatory process
Where do I find docket information?
Where do I find docket information?

www.publichealthlawcenter.org
Menthol in Cigarettes, Tobacco Products: Request for Comments

Primary Documents

- Altria Client Services Inc. - Request for Extension
- RAI Services Company - Comment
- Menthol in Cigarettes, Tobacco Products; Request for Comments

Supporting Documents
No documents available.

Comments

In 2009, under the Family Smoking Prevention and Tobacco Control Act (FSPTCA), artificial or natural flavors—such as fruit, chocolate, coffee, etc.—were...
How do I submit comments?
How detailed should my comments be?

This is a comment on the Food and Drug Administration (FDA) Proposed Rule: Menthol in Cigarettes, Tobacco Products; Request for Comments. For related information, open Docket Folder.

Comment:
I am a research at the University of Minnesota who conduct population research about tobacco use. The TPSAC report has made it very clear that menthol is not only a flavor but also an ingredient that enhance the addictiveness of cigarettes and other tobacco products. It provides analgesic effect to the throat so that tobacco use becomes more tolerable. Such an effect is very similar, if not the same, to cough drop. Such ingredient should not be present in addictive products that are commercialized and freely available to anyone over the age of 17. I urge the FDA to remove menthol from all tobacco products to product the health of the Americans.
How detailed should my comments be?

Comment:
I am writing in support of the Citizen Petition (Document ID FDA-2013-P-0435-0001) to prohibit the addition of menthol to cigarettes. As described in the Petition, the weight of the scientific evidence suggests that menthol contributes to smoking initiation and that banning menthol cigarettes would have a positive impact on public health. Attached, please find a commentary from the peer-reviewed literature that also speaks to this point. Thank you.

Attachments:
- Lawrence Carter Comment Addiction 2013
How detailed should my comments be?

June 5, 2013

Mr. Mitchell Zeller, J.D.
Food and Drug Administration
Center for Tobacco Products
Document Control Center, Room 020J
9200 Corporate Boulevard
Rockville, Maryland 20850

Dear Mr. Zeller:

The Minnesota Department of Health enthusiastically joins the call to petition the U.S. Food and Drug Administration (FDA) to assert its authority to require the immediate removal of menthol flavor from all cigarettes. In 2009, the FDA took the bold step of banning certain characterizing flavored cigarettes such as strawberry, grape, orange, clove, vanilla, chocolate and coffee.

Removing menthol from cigarettes is one of the most effective actions FDA can take to improve the public's health.

The damage caused by tobacco use is staggering. Tobacco use continues to be the leading preventable cause of death. In Minnesota over 5100 people die each year from smoking. Over 625,000 adults in Minnesota smoke and 77,000 young people use tobacco.

Menthol flavoring in cigarettes plays a major role in increasing youth initiation of smoking, making smoking enticing to current smokers, and creating an environment which fuels the lack of health equity in our society.

- Menthol Cigarettes Hurts Minnesota's Kids
COMMENT ON
CITIZEN PETITION
ASKING THE U.S. FOOD AND DRUG ADMINISTRATION TO
PROHIBIT MENTHOL AS A CHARACTERIZING FLAVOR
IN CIGARETTES
DOCKET NO. FDA-2013-P-0435

Lorillard Tobacco Company
May 23, 2013

On April 12, 2013, the Tobacco Control Legal Consortium and nineteen other organizations
(collectively, Petitioners) filed a Citizen Petition requesting “that the Commissioner of the U.S.
Food and Drug Administration (FDA) prohibit menthol as a characterizing flavoring of cigarettes
(Citizen Petition).” Lorillard Tobacco Company (Lorillard) respectfully submits that the FDA
should deny the Citizen Petition.

The Citizen Petition urges the FDA to extend the prohibition on characterizing flavors in
cigarettes set forth in the Family Smoking Prevention and Tobacco Control Act (Act) to include
menthol. The Citizen Petition states “the science on this issue justifies immediate action to
reduce the human toll resulting from mentholated tobacco products” and that any countervailing
effects from the prohibition of menthol “are trivial in comparison to the highly significant public
health benefits that such a prohibition would produce.” Lorillard disagrees. The best available
science with respect to the health effects of menthol cigarettes compared to nonmenthol
cigarettes does not provide basis for the FDA to prohibit the use of menthol as a characterizing
flavor in cigarettes. Epidemiology studies, as well as those of biomarkers of exposure and harm,
smoking topography, toxicology and chemistry, show that menthol smokers have no greater risks
diseases than nonmenthol smokers, and in fact may have reduced risks of developing some...
What kinds of information and evidence are helpful to the FDA?
What kinds of information and evidence are helpful to the FDA?

• Survey data and other research

• Published articles
  – Include your credentials with the submission
  – Explain relevance of the article

• Your observations about the impact of menthol tobacco products on public health
Additional Resources

Tell the FDA to Prohibit Menthol in Cigarettes and Other Tobacco Products

April 12, 2013

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

CITIZEN PETITION

The undersigned submit this petition pursuant to Title 21, Chapter 9, Subchapter V, Part A of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 10.30 to request that the Commissioner of the U.S. Food and Drug Administration (FDA) prohibit menthol as a characterizing flavoring of cigarettes. The authority to adopt tobacco product standards that would restrict the addition of menthol as a characterizing flavor is found in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).
Additional Resources

Tobacco Control Legal Consortium
www.publichealthlawcenter.org
(651) 290-7506

Campaign for Tobacco-Free Kids
www.tobaccofreekids.org
(202) 296-5469
Questions?

Carolyn Dresler
Mark Greenwold
Joelle Lester
Andrea Villanti