Public Health Policy Change Series

BEYOND CIGARETTES:

FEDERAL REGULATION OF OTHER TOBACCO PRODUCTS
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You Don’t Say?: Tobacco and the First Amendment
Tuesday, June 18, 12 p.m. – 1:30 p.m. CST

The Tobacco Control Act Four Years Later: Living Up to its Promise?
Monday, June 24, 12 p.m. – 1:30 p.m. CST

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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)

• Design and marketing of OTPs and how they are regulated at the state and local level (Ann Boonn)

• Federal authority over OTPs and related action opportunities (Desmond Jenson)

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

The legal information provided in this webinar does not constitute legal advice or legal representation.
New Products

Old Tricks

Ann Boonn, Associate Director, Research
Campaign for Tobacco-Free Kids
aboonn@tobaccofreekids.org

May 21, 2013
Tobacco Companies under Altria

Philip Morris USA
an Altria Company

U.S. Smokeless Tobacco Co.
an Altria Company

John Middleton
an Altria Company

Numark
an Altria Company
Tobacco Companies under RAI

(formerly Conwood Company)

R.J. Reynolds Vapor Co.
Tobacco Brands

- Camel
- Pall Mall
- Grizzly Snuff
- dissolubles
- Zonnic
- Kool
- Salem
- Viceroy
- Velo
- Natural American Spirit
- Kodiak
- Lucky Strike
- Misty
- VUSE
- Winston
- Carlton
- Barclay
- Capri
- Doral
- Midnight Special
- Monarch
- Tube Rose Scotch Snuff
Companies under **Lorillard**
Roll-Your-Own Tobacco
Cheyenne

Cigarettes -- Little Cigars -- Cigars
Can you find the cigars?
## Taxation and Regulation of Cigarettes vs. Cigars

<table>
<thead>
<tr>
<th></th>
<th>Cigarettes</th>
<th>Little Cigars</th>
<th>“Large” or “Filtered” Cigars</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Taxation</strong></td>
<td>Usually high</td>
<td>Usually equal to cigarettes</td>
<td>Usually Low</td>
</tr>
<tr>
<td>Federal Flavor Ban</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Federal Descriptor Ban</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Retail Placement</td>
<td>No self-service</td>
<td>Anywhere</td>
<td>Anywhere</td>
</tr>
<tr>
<td>Minimum Pack Size</td>
<td>✓</td>
<td>✗ (unless specified)</td>
<td>✗</td>
</tr>
<tr>
<td>Minimum Price (where applicable)</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>
“The grape cigarettes. A lot of my friends are smoking those,” said South Side High School sophomore Jose Bordallo, who is a member of United Hispanic-Americans’ Students Working Against Tobacco.
“Cherry Skoal is for somebody who likes the taste of candy, if you know what I’m saying.”

High School Student describing using Camel Snus:

“It’s easy, it’s super-discreet...and none of the teachers will ever know what I’m doing.”

*Kansas City Star, October 31, 2007*
R.J. Reynolds’ Camel Dissolvables

Original packs test-marketed in Columbus, OH, Portland, OR, and Indianapolis, IN starting in January 2009.

Redesigned the pack to be LESS child-resistant and re-released products in two new test markets, Denver and Charlotte, beginning March 2011.
New Forms of Smokeless, Spitless Tobacco Put Users and Children at Risk

Tobacco companies are test marketing and debuting new "dissolvable tobacco." These products are being promoted as an answer for smokers who are unable to smoke due to smoking restrictions in the workplace, at home and in social situations. Dissolvable tobacco may also be regarded as a way to smoke around children without lighting up or spitting as with other.

Dissolvable tobacco is made from finely milled tobacco, held together with food-grade binders. It is designed to be placed in the mouth, on the tongue or between the cheek and gum where it dissolves to release tobacco. The appeal of dissolvable tobacco is further enhanced by the addition of flavors such as wintergreen, mint and "Java".

While these products are sold in child-resistant packaging, their resemblance to candy and breath mint strips and the likelihood that adults will carry the small packages in their pockets or leave them in other unsecured places, means that children may have easy access to them.

Dissolvable tobacco products contain between 60 to 300% of the nicotine found in one cigarette. Smokers who use these products may get a higher dose of nicotine than they are used to, possibly resulting in adverse reactions such as tremors, nausea, vomiting, and agitation. Children who ingest this dose of nicotine typically become pale, shaky, sweaty and vomit. Access to pleasant tasting, easy to eat dissolvable tobacco, however, might encourage children to

- more -
Philip Morris USA’s Marlboro & Skoal Sticks

Four flavors being test-marketed in select Kansas stores since March 2011. Marlboro Sticks are being placed with cigarettes and Skoal Sticks are being placed with smokeless tobacco products.

Resemblance to:
As the state’s health agency, KDHE is particularly concerned about the potential appeal of these new tobacco sticks to youth,” KDHE Secretary Dr. Robert Moser said. “The packages are so small that they could easily be concealed in a shirt or pants pocket and youth could use tobacco sticks in front of parents or teachers while appearing to have a simple toothpick in their mouth. We are also concerned about the risk of young children accidentally ingesting these products.”
Altria’s newest smokeless product

Announced in May 2012 and will be test-marketed in select Sheetz stores in Virginia.

VERVE discs are a new kind of tobacco product designed to appeal to adult smokers interested in innovative types of spit-free tobacco product alternatives to cigarettes.
RAI’s newest smokeless products

Only in North Carolina as of late 2012
Big Tobacco getting into the E-Cigarette Game

Lorillard Inc. Announces Acquisition of Blu Ecigs
Wednesday, 25 Apr 2012 07:03am EDT

Reynolds developing new smokeless products

Altria to sell an electronic cigarette
Posted: Friday, April 26, 2013 12:00 am | Updated: 12:18 am, Sat Apr 27, 2013.
Big E-Cigarette vs. Little E-Cigarette

R.J. Reynolds Vapor Co.

NuMark
an Altria Company
State & Local Regulation

- Flavor restrictions
  - NYC & Providence

- Coupon redemption
  - Providence ordinance
  - NYC proposal

- Minimum pack sizes (cigars)
  - Boston, Baltimore, Prince George’s County (MD), DC
  - NYC proposal

- Display ban
  - NYC proposal

- Youth access (e-cigarettes)
  - Madison County (KY), MN, NH, NJ, NY, WI, several localities in MA, several localities in WA
  - 2013 youth access proposals

- Taxation
  - Definitions, rates
  - E-cigarette tax proposals
Ann Boonn
aboonn@tobaccofreekids.org
(202) 296-5469
Federal Regulation of Other Tobacco Products

Desmond Jenson, J.D.
May 21, 2013
FDA Authority over Tobacco Products

21 U.S.C. § 321(rr)(1): “The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product . . .”
21 U.S.C. § 387a(b):
“This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.”
FDA Authority over Tobacco Products

The Tobacco Products Chapter of the Food, Drug and Cosmetic Act (as amended by the Tobacco Control Act) applies to all tobacco products.

Any products “deemed” to be subject to the Act are automatically subject to existing regulation of “tobacco products.”
FDA Authority over Tobacco Products

FDA regulation of “tobacco products” includes:

– Regulation of adulterated and misbranded tobacco products
– Compelled registration of tobacco product manufacturers and compelled disclosure of product lists and health information
– Premarket review of new products
– Regulation of “Modified Risk Tobacco Products”
– Other additional provisions
FDA Authority over Tobacco Products

Some tobacco product regulations created by the FDA with its new authority only apply to specific products.

For example, advertising and marketing restrictions only apply to cigarettes and smokeless tobacco. The graphic warning regulation only applied to cigarette packages and advertisements.
The FDA does have the authority to extend its current regulation of cigarettes and smokeless tobacco to any “tobacco product” that it “deems” subject to the Act.
FDA Authority over Tobacco Products

- Sales and Distribution:
  - Establish a minimum age of 18 and require verification of all persons not over the age of 26
  - Prohibit non-face-to-face sales including vending machines
  - Establish minimum package sizes and prohibit breaking of packages
  - Prohibit sampling
FDA Authority over Tobacco Products

- Product Regulation:
  - Prohibit characterizing flavors including menthol
  - Establish warning labels
FDA Authority over Tobacco Products

- Advertising and Marketing:
  - Prohibit tobacco product brand and trade names of non-tobacco products
  - Prohibit brand and trade name sponsorship of sporting and cultural events
  - Require notice of all advertising in any non-traditional medium
FDA Authority over Tobacco Products

- FDA Cannot:
  - Prohibit the use of tobacco products
  - Prohibit the sale of an entire class of tobacco product
  - Prohibit the sale of tobacco products in a specific category of retail outlets
  - Require a prescription for tobacco products
  - Levy taxes on tobacco products
  - Raise the minimum purchase age of tobacco products
FDA Authority over Tobacco Products

What is the FDA doing with its authority over other tobacco products?

Not much…
FDA Authority over Tobacco Products

• Unified Regulatory Agenda Deadlines:
  – Spring 2010 FDA promises to regulate cigars by June 2010
FDA Authority over Tobacco Products

• Unified Regulatory Agenda Deadlines:
  – Spring 2010 FDA promises to regulate cigars by June 2010
  – Fall 2010 FDA promises to regulate cigars by June 2011
FDA Authority over Tobacco Products

• Unified Regulatory Agenda Deadlines:
  – Spring 2010 FDA promises to regulate cigars by June 2010
  – Fall 2010 FDA promises to regulate cigars by June 2011
  – Spring 2011 FDA promises to regulate all tobacco products by October 2011
FDA Authority over Tobacco Products

• Unified Regulatory Agenda Deadlines:
  – Spring 2010 FDA promises to regulate cigars by June 2010
  – Fall 2010 FDA promises to regulate cigars by June 2011
  – Spring 2011 FDA promises to regulate all tobacco products by October 2011
  – Fall 2011 FDA promises to regulate all tobacco products by December 2011
FDA Authority over Tobacco Products

- Unified Regulatory Agenda Deadlines:
  - Spring 2010: FDA promises to regulate cigars by June 2010
  - Fall 2010: FDA promises to regulate cigars by June 2011
  - Spring 2011: FDA promises to regulate all tobacco products by October 2011
  - Fall 2011: FDA promises to regulate all tobacco products by December 2011
  - 2012: FDA promises to regulate all tobacco products by April 2013.
FDA Authority over Tobacco Products

• Unified Regulatory Agenda Deadlines:
  – Spring 2010 FDA promises to regulate cigars by June 2010
  – Fall 2010 FDA promises to regulate cigars by June 2011
  – Spring 2011 FDA promises to regulate all tobacco products by October 2011
  – Fall 2011 FDA promises to regulate all tobacco products by December 2011
  – 2012 FDA promises to regulate all tobacco products by April 2013.
FDA Authority over Tobacco Products

What can the public health community do?
FDA Authority over Tobacco Products

- Citizen Petition:
  - 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
FDA Authority over Tobacco Products

- A Citizen Petition creates opportunities for action:
  - Submit Comments
    - Submit research data on other tobacco products
    - Explain why this issue is important to you
    - Describe the impact of other tobacco products in your community
FDA Authority over Tobacco Products

Submitting comments

Participate Today!
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.

SEARCH for: Rules, Comments, Adjudications or Supporting Documents:

A Commenter's Checklist
View Tips for More Effective Commenting

Regulations With Comments Due Soon
Today (2)
Next 3 Days (91)
Next 7 Days (170)
Next 15 Days (363)
Next 30 Days (720)
Next 90 Days (1,011)

Newly Posted Regulations
Today (116)
Last 3 Days (116)
Last 7 Days (481)
Last 15 Days (912)
Last 30 Days (1,890)
Last 90 Days (6,114)

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FDA Authority over Tobacco Products

Submitting comments

Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke

Docket Folder Summary

Docket ID: FDA-2013-F-0435
Agency: Food and Drug Administration (FDA)
Parent Agency: Department of Health and Human Services (HHS)

Primary Documents

- Acknowledgement Letter to Tobacco Control Legal Consortium, et al. (ID: FDA-2013-F-0435-0002)

Supporting Documents

No documents available.

Comments

No comments posted.
### Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke

**Docket ID:** FDA-2013-P-0435  
**Agency:** Food and Drug Administration (FDA)  
**Parent Agency:** Department of Health and Human Services (HHS)

#### Primary Documents

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<th>Comment Status</th>
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<td>Acknowledgement Letter to Tobacco Control Legal Consortium, et al</td>
<td>Other</td>
<td>05/15/2013</td>
<td>FDA-2013-P-0435-0002</td>
<td>Comment Period Closed</td>
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<tr>
<td>Tobacco Control Legal Consortium, et al - Citizen Petition</td>
<td>Other</td>
<td>05/15/2013</td>
<td>FDA-2013-P-0435-0001</td>
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</tr>
</tbody>
</table>

#### Supporting Documents

No documents available.

#### Comments

No comments posted.
FDA Authority over Tobacco Products

Submitting 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
FDA Authority over Tobacco Products

Submitting comments
FDA Authority over Tobacco Products

Submitting comments
FDA Authority over Tobacco Products

Submitting 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:

3. UPLOAD FILE(S)
   - Choose File: No file chosen
   - Preview Comment
   - Submit
FDA Authority over Tobacco Products

Submitting comments
FDA Authority over Tobacco Products

How detailed should my comment be?

April 1, 2013
Division of Dockets Management (HFA-305)
Food and Drug Administration
5680 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-1032-0001, Smokeless Tobacco Product Warning Statements

The undersigned organizations submit these comments in response to the request by the Food and Drug Administration (FDA) for comments on what changes to the current statutory warnings on smokeless tobacco products, if any, would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

In summary form, these comments support the following conclusions about the statutory smokeless tobacco warnings:
FDA Authority over Tobacco Products

How detailed should my comment be?

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1001
Rockville, Maryland 20852

Re: Docket No. FDA-2012-N-1032 – Comments on Smokeless Tobacco Product Warning Statements: Request for Comments and Scientific Evidence

Altria Client Services Inc. ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA") and U.S. Smokeless Tobacco Company LLC ("USSTC"). submits these comments in response to the above-referenced docket and January 29, 2013, Federal Register notice (the “Notice”).2 FDA requests “comments, supported by scientific evidence, regarding what changes to the smokeless tobacco product warnings, if any, would promote greater public understanding of the risks associated with the use of smokeless tobacco products.”

We believe the public should be guided by the messages of public health authorities worldwide in making decisions concerning the use of tobacco products. Adult tobacco consumers are entitled to tobacco warnings that are clear, accurate and grounded in science and evidence. With accurate information, adult tobacco consumers can make their own informed decisions about quitting or the comparative risks of different types of tobacco products.

Our comments address four topics. First, smokeless tobacco warnings should be driven by science and evidence and comport with statutory and constitutional requirements. Second, FDA should replace the “not a safe alternative to cigarettes” warning. Third, FDA should not consider graphic warnings or size or format changes until it has the legal and evidentiary foundation necessary to make a reasoned decision. Fourth, FDA should provide a reasonable effective date and “sell-through” transition as part of any changes in smokeless tobacco warnings.

1 PM USA and USSTC are wholly-owned subsidiaries of Altria Group, Inc. ("Altria"). ALCS provides certain services, including regulatory affairs, to the Altria group of companies. "We" and "our" are used throughout to refer to PM USA and USSTC.
This would be a good way to make sure that illegal products are not being bought to ensure that high taxes on tobacco products are doing what they are suppose to by giving people incentive to quit smoking. There is one major issue in Western New York and that is Native made and sold cigarettes. The cigarettes are made and sold on the reservation. Even though non-Natives are suppose to pay tax on tobacco products, no store makes them. This is allowing millions of dollars on untaxed tobacco products to be bought. This is also a loophole for smokers in our area to get around paying state tax on tobacco products and be able to smoke at a high rate. The track and trace initiative will help with cigarettes made in foreign countries, but the issue of cheaper brands being made in the country will go untouched.
How detailed should my comment be?

I support a track-and-trace system, as it would promote public health objectives in at least two important ways:

- It would cut down both the threat of smuggling and the tobacco industry’s use of the threat of smuggling whenever FDA proposes to restrict or reduce the use of any ingredient or constituent, including menthol, in any tobacco product and;
- It would enable the government to counter the tobacco industry’s claims that high prices lead to more illicit trade. Thus, it would help to maintain high tobacco prices that drive down tobacco use and ensure compliance with regulations issued under the 2009 Tobacco Control Act. By reducing evasion of tobacco taxes, it would also increase revenues for federal, state and local governments. As tobacco companies exaggerate the extent of cigarette smuggling in their efforts to defeat tobacco tax increases and other tobacco control measures being considered by FDA, a track and trace system would also help counter such arguments.
FDA Authority over Tobacco Products

Where do I find docket information?
FDA Authority over Tobacco Products

Where do I find docket information?

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 amount 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 an effort to block various provisions in the act. The public health community must provide a strong counterweight to the tobacco industry’s immense resources to ensure that the FDA enacts bold regulations to protect public health.

Take Action Today

- **Call on the FDA to Prohibit Menthol Cigarettes**
  Public health groups are petitioning the FDA to prohibit menthol as a characterizing flavor in cigarettes. Submit your supporting comment today.

- **Urge FDA to Implement Track and Trace Program**
  Public health groups are urging the FDA to take steps to combat tobacco contraband. Submit your comment supporting this important program.

- **Weigh in on Good Manufacturing Practices**
  Tobacco manufacturers proposed their own “Good Manufacturing Practices.” Add the public health perspective by submitting comments by May 20, 2013.

Sign up to receive our FDA Tobacco Action Alerts notifying you of opportunities to strengthen FDA regulation of tobacco
Where do I find docket information?
Where do I find docket information?
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