The Tobacco Control Act Four Years Later: Living Up to its Promise?

June 24, 2013
Tobacco Control Legal Consortium Webinar Series

• Providing substantive public health policy knowledge, competencies & research in an interactive format

• Covering public health policy topics related to tobacco

• Tuesdays from 12:00 p.m. to 1:30 p.m. Central Time

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Upcoming Webinars

Local Regulation of Emerging / Other Tobacco Products: Hot Issues
Tuesday, July 23, 12 p.m. – 1:30 p.m. Central Time

Preemption & Tobacco Control: Latest Tales from the Field
Tuesday, August 13, 2013, 12 p.m. – 1:30 p.m. Central Time

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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.
The Tobacco Control Legal Consortium

A national legal network supporting tobacco control policy change.
Tobacco Control before 2009

- Local
- State
Tobacco Control Now

- Federal
- Local
- State

Diagram illustrating the interrelationship of Federal, Local, and State levels in tobacco control.
Where Tobacco Control Can Go

State

Federal

Local
The Tobacco Control Act
The Act: Sets Standards

- No sales of tobacco products (as currently defined) to minors
- No flavored cigarettes (except menthol)
- No use of terms “light,” “mild,” and “low tar” and generally no health claims by the industry
- Disclosures about the contents of tobacco products & FDA approval of products
- Larger, more informative warning labels for cigarettes and smokeless tobacco
- The FDA must require graphic warnings on cigarette packages
- Creation of the Tobacco Products Scientific Advisory Committee
- Tobacco manufacturer user fees
- Restrictions concerning cigarettes and smokeless tobacco through adoption of most of the 1996 regulations (no brand sponsorship of sporting/entertainment events, most free samples prohibited, cigarette packs must $\leq 20$, most self-service sales prohibited)
The Act: FDA Authority

- Regulate sale and distribution of tobacco products (with some limitations)

- Regulate advertising and promotion to the extent permitted under the Federal Cigarette Labeling and Advertising Act and the First Amendment

- Change warning label requirements
The Act: FDA Authority

- Set product standards (rules regarding the design or safety of products)
- Require the disclosure of information about product contents and health effects of the products
- Extend existing requirements to other tobacco products
The Tobacco Control Act Four Years Later: Living Up to its Promise?

Erika Sward
Assistant Vice President, National Advocacy
American Lung Association

Joelle Lester, JD
Staff Attorney
Tobacco Control Legal Consortium

Susan Kansagra, MD, MBA
Acting Deputy Commissioner
NYC Department of Health and Mental Hygiene
THE POLITICS OF TOBACCO REGULATION: 4 YEARS LATER

Erika Sward, American Lung Association
Tobacco and Politics

• Goal: Take politics out of tobacco product regulation & let science dictate the process
INDUSTRY $$
Average Contributions to Members

**Tobacco to House**

- **Dems**
- **Repubs**

**Tobacco to Senate**

- **Dems**
- **Repubs**

Source: Opensecrets.org
Tobacco Lobbying Expenditures

**Top Lobbying Clients, 2012**

<table>
<thead>
<tr>
<th>Client/Parent</th>
<th>Total</th>
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<tbody>
<tr>
<td>Altria Group</td>
<td>$10,560,000</td>
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<tr>
<td>Philip Morris International</td>
<td>$9,830,000</td>
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<tr>
<td>Lorillard Inc</td>
<td>$2,350,000</td>
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<tr>
<td>Reynolds American</td>
<td>$1,045,163</td>
</tr>
<tr>
<td>Vector Group</td>
<td>$550,000</td>
</tr>
</tbody>
</table>

**Lobbying Totals, 1998-2012**

Source: Opensecrets.org
Before the Tobacco Control Act

- No oversight
- Candy flavors in cigarettes allowed
- Joe Camel
- Manipulation of ingredients
- “Light” and “Low” cigarettes
Passage of Tobacco Control Act

- 2009
- Gave FDA immediate authority over cigarettes, smokeless and roll-your-own
- Gave FDA option to “deem” authority over other products
Product Regulation: Where Do Things Stand Now?

Under FDA Authority
- Cigarettes
- Smokeless tobacco
- Roll-you-own tobacco

Not Yet
- Cigars
- Little cigars
- E-cigarettes
- Hookah
What Does FDA Regulation Mean?

• Registration
• Product listing
• Ingredient listing
• Good manufacturing practices
• No making unproven health claims
• Restrict sales to kids
• Warning labels
“Appropriate for the Protection of Public Health”

“The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account –

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products;

and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.”
ATTEMPTS TO UNDERMINE THE ACT
Key Threats

• Exempting products
• Reinterpreting key provisions of the statute
• Industry pressure on FDA via Congress
Industries Seeking a Sweetheart Deal

• Cigars
• E-Cigarettes
Exempting products

Senate bill seeks to block FDA from regulating cigars

CIGAR LEGISLATION | AUGUST 7, 2011 | BY: PATRICK LAGREID

House panel warns FDA off regulating ‘premium cigars’

Action Alert

Help Exempt Premium Cigars From FDA Regulation!
H.R. 792 / S. 772 - A bill to clarify the FDA’s jurisdiction over certain tobacco products

Between April 26, 2010 and December 21, 2012 the U.S. Food & Drug Administration publicly posted their intent to deem cigars as subject to federal regulation. Therefore, it’s incumbent upon the cigar enthusiasts of the United States to voice their opposition to any proposed new regulation of premium/traditional cigars by the United States Government.
Exempting products

Regulations.--The Committee understands that on December 20, 2010, FDA announced its intention to make cigars subject to Chapter IX of the Federal Food, Drug, and Cosmetic Act. The Committee reminds FDA that premium cigars have unique characteristics and cost prohibitive price points and are not marketed to kids. Any effort to regulate cigars should take these items into consideration.

Cigar makers are trying to snuff out an effort by the Food and Drug Administration (FDA) to regulate their products for the first time.
Lorillard Tobacco, the largest manufacturer and marketer of menthol tobacco products has already attempted to narrow what is meant by the phrase “appropriate for the protection of the public health” to whether individual smokers show a differing health risk compared to users of non-menthol tobacco products and whether individual smokers of menthol smokers have comparable cessation rates.
Reinterpreting the Tobacco Control Act

FY2012 Ag-FDA Approps
Rehberg Amendment Language from 2011

"None of the funds made available by this Act may be used by the Food and Drug Administration to write, prepare, develop or publish a proposed, interim, or final rule, regulation or guidance that is intended to restrict the use of a substance or a compound unless the Secretary bases such rule, regulation or guidance on hard science (and not on such factors as cost and consumer behavior), and determines that the weight of toxicological evidence, epidemiological evidence, and risk assessments clearly justifies such action, including a demonstration that a product containing such substance or compound is more harmful to users than a product that does not contain such substance or compound, or in the case of pharmaceuticals, has been demonstrated by scientific study to have none of the purported benefits."
“When Congress passed the original Tobacco Control Act, it was really to address two primary points: youth access to tobacco and chemical addition. Premium cigars don’t meet that criteria,” Loope said.

Another trade group for cigar retailers and manufacturers agreed that the FDA is distorting the law.

“It’s our belief that the act was to prevent youth from smoking and curtail the health effects for youth,” said Bill Spann, CEO of the International Premium Cigar & Pipe Retailers Association.
Industry pressure on FDA via Congress

GAO Study will examine:

(1) the status of Center for Tobacco Product’s (CTP) reviews of new tobacco product submissions;

(2) how CTP has responded to requests for meetings from manufacturers and other entities and the length of time CTP has taken to respond to meeting requests; and

(3) how CTP has applied its tobacco user fee funding and staffing resources.
Call to Action

• Remain vigilant on implementation
• Don’t let industry fill the void on Capitol Hill – work with national & state partners to educate your Members
• Serve as eyes & ears for FDA
Four Years of the Family Smoking Prevention and Tobacco Control Act

Joelle M. Lester
June 24, 2013
Highlights

• Established and staffed the FDA Center for Tobacco Products from scratch

• Formed enforcement contracts with 45 jurisdictions

• Adopted a graphic warning label regulation

• Defended its authority and actions against litigation challenges
Disappointments

• FDA has failed to exercise much of its authority under the Act to protect public health.

• FDA’s regulatory process is unnecessarily opaque and opportunities for members of the public to engage are challenging and infrequent.
Example: Act prohibited candy and fruit characterizing flavors in cigarettes

FDA has the authority to:
• Add menthol to the flavor prohibition
• Define characterizing flavor
• Extend the flavor prohibition to other tobacco products

Instead, the FDA has taken no steps to strengthen or expand the flavor prohibition.
The FDA should:
Adopt Bold Regulations to Protect Public Health

- Prohibit menthol as a characterizing flavor in cigarettes
  - Kids smoke menthol cigarettes.
  - Menthol cigarettes are used disproportionately in communities of color.
  - One model estimates that if menthol were prohibited as a characterizing flavor in cigarettes, between 2010 and 2020 over 2.2 million would not start smoking. By 2050, the number of people who would not smoke would be 9 million.
  - “Removal of menthol cigarettes from the marketplace would benefit public health in the United States.”
The FDA should:
Adopt Bold Regulations to Protect Public Health

- Prohibit menthol as a characterizing flavor in cigarettes
The FDA should:
Adopt Bold Regulations to Protect Public Health

• Prohibit menthol as a characterizing flavor in cigarettes
• Define “characterizing flavor” for all flavors
• Assert jurisdiction over all tobacco products
• Extend existing regulations to other tobacco products
The FDA should:
Adopt Bold Regulations to Protect Public Health

• Prohibit menthol as a characterizing flavor in cigarettes
• Define “characterizing flavor” for all flavors
• Assert jurisdiction over all tobacco products
• Extend existing regulations to other tobacco products
• Regulate nicotine levels
• Regulate additives
The FDA should:
Adopt Bold Regulations to Protect Public Health

- Prohibit menthol as a characterizing flavor in cigarettes
- Define “characterizing flavor” for all flavors
- Assert jurisdiction over all tobacco products
- Extend existing regulations to other tobacco products
- Regulate nicotine levels
- Regulate additives
- Address color coding
- Address illicit trade and contraband
The FDA should:
Make process more transparent and accessible

- Hold more frequent public hearings
- Provide greater notice for public hearings
- Allow people to testify remotely at hearings
- Allow all public comments on dockets to be viewed by the public
- Affirmatively post information on FOIA reading room
The Tobacco Control Act: New opportunities at the Local Level

Susan Kansagra, MD, MBA
Acting Deputy Commissioner

Division of Health Promotion and Disease Prevention
New York City Department of Health and Mental Hygiene

Tobacco Control Legal Consortium Webinar
June 24, 2013
NYC initiatives that complement TCA or take advantage of opportunities created through TCA:

- Ban on flavored tobacco products
- Media Campaign on Light/Low Tar
- Citizen Petition on Track and Trace
- Proposed bill: Sensible Tobacco Enforcement
- Proposed bill: Product Display Restriction
- Proposed bill: Increasing age to 21
Beyond Cigarettes: Ban on Flavored Other Tobacco Products

• TCA bans flavored cigarettes (except menthol)

• In 2009, NYC enacted local law 69 restricting the sale of flavored tobacco products
  ➢ Exceptions for menthol and ~8 tobacco bars

• Court upheld law March 2013
  ➢ Tobacco industry argued: Law is same as a manufacturing or fabrication requirement
  ➢ Court held: Local governments can restrict sales of subclasses of tobacco products
  ➢ Allowed for simpler, consistent messaging to retailers
Educating New Yorkers about Deceptive Tobacco Marketing

• June 2010 media campaign to educate about tobacco companies deceptive use of colors to get around TCA ban on marketing labels

• In three weeks, campaign generated almost 7000 calls for help to quit smoking

• Campaign generated local, national, and international news coverage
Educating New Yorkers about Deceptive Tobacco Marketing

• June 2010 media campaign to educate about tobacco companies deceptive use of colors to get around TCA ban on marketing labels

• Generated thousands of calls for help to quit smoking and contributed to 40,000 successful quits, resulting in about 13,300 lives saved

WARNING: TOBACCO COMPANIES ARE NOW USING COLORED PACKAGING BECAUSE DECEPTIVE LABELS LIKE “LIGHT” AND “LOW TAR” HAVE BEEN BANNED.

Don’t be fooled. The color of the pack doesn’t matter. ALL CIGARETTES CAUSE LUNG CANCER.

Quit Smoking Today. For help call 311 or visit nysmokefree.com
Illegal Cigarettes Undermine Health

- Average pack price in NYC is over $11
- Can buy contraband cigarettes from Virginia for about $5
- Littered pack studies estimate 40-70% of packs are non-local
- Law-abiding retailers cannot compete
Use TCA Authority to Decrease Tax Evasion

- Section 920(b) of the statute, the Secretary shall:
  - promulgate regulations regarding the establishment and maintenance of records
  - consider which records are needed to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products
  - may require codes on the labels of tobacco products for the purpose of tracking and tracing
Calling on the FDA to Implement the National Track-and-Trace Tobacco System

- Citizen’s Petition filed with the FDA March 2013
- Docket open for comment: FDA-2013-P-0285
Bill Proposed: Sensible Tobacco Enforcement

1. Expanded enforcement authority and increased **penalties** for retailers who evade tobacco taxes or sell tobacco without a license

2. Retailers cannot redeem **discounts** for tobacco products

3. Requires a **minimum price** per pack of $10.50

4. Cheap cigars and cigarillos must be sold in **packs of at least 4**, and little cigars must be sold in **packs of 20** for no less than the **$10.50** price floor

   o Cigars that cost more than $3 each are exempt from the packaging rule
Cheap Cigar Use Increasing Among Youth

- Between 1995 and 2008, national sales increased by:
  - 316% for little cigars
  - 255% for cigarillos
  - 17% for large cigars
- The proportion of underage smokers who smoke cigars increased from 25% in 2001 to 44% in 2009
- Why?
  - Sold individually for $1-2
  - Pack of 20 “little cigars,” can cost half the price of cigarettes
Bill Purpose: Restricting the Display of Tobacco Products

- TCA amends FCLAA to allow localities to impose bans or restrictions on the time, place, and manner, but not content, of advertising or promotion

- NYC bill would require tobacco products to be stored out of customers’ sight (e.g., in drawers or cabinets or behind curtains)
Bill Proposed: Raising the Minimum Sale Age to 21

- TCA requires that by April 2015, FDA shall issue report on public health implications of raising minimum age to purchase tobacco products
- NYC proposes to raise the minimum sale age to reduce access to tobacco products in stores
- Public health rationale: 90% of people purchasing cigarettes for minors were between ages 18 and 20
- In Needham, MA, after a Tobacco-21 law, high school smoking rates declined from **12.9% to 5.5%** between 2006 and 2012
- Estimated that over time raising the minimum age would decrease smoking prevalence by 67% for 14-17 year olds and 55% for 18-20 year olds
Adult Smoking in NYC Down Over 30% Since 2002

Source: New York City Department of Health and Mental Hygiene, Community Health Survey.
Youth Smoking Has Also Declined

Source: Youth Risk Behavior Surveillance System.
Life Expectancy Increasing Faster in NYC than Nationally

Life Expectancy at Birth, New York City and US, 2001-2010

Citations

Questions?

Questions Now?
• Q&A panel on your screen

Questions Later?
• publichealthlawcenter.org
• publichealthlaw@wmitchell.edu
• 651-290-7506
Resources

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.

SUBTOPICS
- Federal Regulation of Tobacco
- Resources

FEATURED PUBLICATIONS
- **Comments to FDA on Tobacco Industry's Product Manufacturing Practices Proposal (2013)**
  Comment to FDA urging the FDA to consider the past actions of the tobacco industry when weighing the industry's proposed tobacco product manufacturing regulations.

- **Beyond Cigarettes: Federal Regulation of Other Tobacco Products**
  Date: Tue, 05/21/2013
  Time: 12:00PM
  The Family Smoking Prevention and Tobacco Control Act of 2009 granted the U.S. Food and Drug Administration