PUBLIC HEALTH POLICY CHANGE

TELLING THE PUBLIC HEALTH STORY TO THE FDA

Tobacco Control Legal Consortium

CAMPAIGN for TOBACCO-FREE Kids®

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Today’s Agenda

• Introduction (Mike Freiberg)
• Overview of the law, the FDA’s activities, and pending litigation (Matt Myers)
• The role of the local public health community in the federal regulatory process (Joelle Lester)
• Q&A/Feedback from you (moderated by Mike Freiberg)
FDA Regulation of Tobacco:

What It Means for State & Local Tobacco Control

Matthew L. Myers
President
Campaign for Tobacco-Free Kids
May 1, 2012
Goals of Presentation

• What the Bill Does
• Current Status
• What You Can Do
• Role of States & Locals
FDA Law - Key Substantive Elements

1. Require the Industry to provide information to the Gov’t that allows Gov’t to better inform consumers

2. Restrict marketing that appeals to kids, misleads adults, deceptively encourages tobacco use

3. Strengthen restrictions on sales to youth
4. More Accurately Inform consumers
   A. Improved warning Labels
   B. More accurate testing of tar, nicotine and other harmful substances
   C. Standards to prohibit unsubstantiated health claims

5. Regulation of the Contents of the Product to protect consumers

6. Articulate Balance with State authority
Informing Consumers
Disclosures to FDA and the Public

Unprecedented knowledge about tobacco products. FDA knows that more than 4,500 tobacco products exist, where they are made and, for the first time, the ingredients have been revealed to the FDA.
Reporting on Harmful Ingredients – FDA Guidance

• FDA identified 93 harmful and potentially harmful ingredients in tobacco products and tobacco smoke

• Will initially require reporting on 20 of those – in quantities and by brand

• A MAJOR PENDING ISSUE: the need to conduct research to determine how best to communicate information to consumers so that consumers don’t believe that differences in quantities have been shown to make a difference in health

• Comments on guidance due June 4
Meaningful Warning Labels

- Cigarettes - Replaces current small, hard to read warning labels with larger, more specific warning labels covering 50% of the top half of the front and back of each pack with graphics depicting the health consequences of tobacco use.

- Smokeless - Replaces current small, hard to read warning labels with larger, more specific warning labels covering 30% of the front and back of each package and 20% of ads.

- Gives FDA the authority to revise the warning labels without action by Congress.
Smokeless Warnings
Before and After

Before, During and After
Boldly Go Everywhere

Experience Cleaner Tobacco Enjoyment
Small-pouched, Modern tobacco that’s spit-free, mess-free and sold cold for Freshness.

WARNING: This product can cause gum disease and tooth loss.
Proposed Cigarette Health Warnings on Cigarette Packs
The Food and Drug Administration has issued two requests for proposals for an integrated anti-smoking campaign that targeting teens. The combined budget is up to $600 million over the course of five years.

The initiative is one of the first under the FDA's Center for Tobacco Products and Tobacco Control Act, which "grants the FDA the authority to regulate the manufacture, distribution and marketing of tobacco product." President Obama signed the bill into law in 2009, but the FDA, working with the National Institutes of Health, only just launched its first large-scale, national tobacco-related study under the Act last month.

The review also comes as the major tobacco companies and marketing organizations in D.C. continue to appeal the FDA's graphic labeling initiative for 2012, which many are calling the most extreme marketing regulation in U.S. history. And the timing is no coincidence, as the document stated that "the effort supports FDA's execution of its authority for graphic health warnings on cigarette packages and ads."

The major task order for the first RFP, as part of a national public education initiative with a budget of up to $300 million, is to spearhead a campaign to "prevent tobacco use among teens aged 13-17." The scope
Status

- Enhanced smokeless warnings in place
- FDA issued rule for new cigarette labels
- Cigarette warning labels on hold due to litigation. There are 2 cases:
  - KY - District and 6th Circuit Court challenge to most provisions of law; Have upheld the Act’s warning label provision
  - DC: District court ruled against FDA’s specific rule, now on appeal
Limiting Marketing & Sales
Limiting Marketing and Sales of Tobacco Products

• Specific limits on industry marketing, sales, and promotions, including but not limited to marketing that appeals to young people

• Also provides FDA the authority to issue new regulations further restricting tobacco marketing *if appropriate to the protection of the public health* up to the limit of the Constitution

• Expands power of States: Permits States to Restrict Time, Place and Manner of tobacco marketing
Specific Advertising Restrictions in the Act (In place except for red)

- Ban remaining tobacco brand sponsorships of sports and entertainment events
- Ban free giveaways of any non-tobacco items with the purchase of a tobacco product or in exchange for coupons
- Ban free samples of cigarettes and the sale of cigarettes in packages that contain fewer than 20 cigarettes; bans sampling of smokeless with narrow exception
- Ban outdoor tobacco advertising near schools and playgrounds after further FDA review
Specific Advertising Restrictions Previously Adopted by FDA

• Limit in-store point-of-sale tobacco advertising to black-and-white text only and limit advertising in publications with significant teen readership (more than 15 percent or 2 million) to black-and-white text only - This provision has been challenged in court and held unconstitutional by the 6th Circuit.

• Restrict vending machines and self-service displays to adult-only facilities
Improving Efforts to Prevent Illegal Sales to Minors

• Contracting with states to enforce provisions of the Act including sales to minors

• Contracted with 39 states; intent to contract with all

• Searchable compliance check database with warning letters, civil money penalty complaints, etc.
Protecting millions of kids from buying tobacco.

- 39 states awarded enforcement contracts in just two years
- 23,297 retailers in 15 states actively keeping tobacco away from kids
- More than 1,000 warning letters issued to retailers for violating the law
Regulating the Product
Review of Product Changes and New Products

• All products introduced or changed after February 15, 2007 must submit for review.

• FDA can deny an application to market a “new” product based on “a lack of showing that permitting such a product to be marketed would be “appropriate for the protection of public health”.

• A different level of review is required for products the FDA has determined are “substantially equivalent”. 
Modified Risk
Tobacco Products

Health Claims

• When a Manufacturer represents that a tobacco product is less harmful than other tobacco products;

What Must Be Shown

• The product, 1) as it is used by consumers, 2) will significantly reduce the risk of tobacco-related disease 3) to individual tobacco users; and 4) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.
Status

- FDA has issued guidance on requirements for substantial equivalence and for new products

- FDA is reviewing substantial equivalence submissions. There are over 3000, but no new product applications

- Guidance issued on requirements for modified risk applications – comments due June 4
Product Regulation - Authority to set Product Standards

• Gives FDA authority to require manufacturers to reduce or eliminate harmful substances, including substances found in tobacco smoke - whether they are added or occur naturally

• Gives FDA authority to reduce nicotine levels to below the point they cause addiction

• Applies to BOTH existing and new products – NO tobacco products exempted or grandfathered

• The Standard: Protection of the Public Health

• Focuses on both Individual Harm and Population Effect
So Where Are We With Menthol?

• Over 1 year ago TPSAC Report concluded that menthol increases initiation and that removing menthol would improve public health

• FDA reviewing TPSAC report and conducting its own scientific review

• FDA still must decide what action is warranted and bring rulemaking process if warranted
Legal Challenges to the Law
TWO CURRENT LEGAL CHALLENGES

There are 2 major pending cases:

• Case in Kentucky challenging many provisions in the law
  • District and Circuit Court Have Ruled
  • Appeals to Supreme Court Probable

• Case in DC challenging the rule issued by the FDA on cigarette warning labels
  • District Court Has Ruled
  • Oral Arguments Have Held in Appeal
6th Circuit Court Upheld Almost All Provisions, Including Warning Labels

- Requirement of large graphic health warnings on cigarette packs
- Prohibition of tobacco companies making health claims about tobacco products without FDA review
- Ban on brand name sponsorships of events like sports and entertainment
- Ban on tobacco-branded merchandise like caps and t-shirts
- Ban on free samples and free gifts with purchase
- Authority of the FDA to impose additional marketing restrictions on tobacco companies
- Prohibition on saying products are FDA approved

One Section held unconstitutional by 6th Circuit
- Restriction of tobacco advertising at point of sale and in magazines with high youth readership to black and white/text only format
DC Challenge to Warning Label Rule

• District Court held the graphic warning labels violate the First Amendment Rights of the tobacco companies because of their size and because the court held they advocate a position instead of simply informing and educating about objective facts

• Recent oral argument on appeal

• We believe District Court was wrong on the law and the science
Tobacco Products Not Yet Regulated
FDA Authority

• Act gave FDA immediate jurisdiction over cigarettes, smokeless, and roll your own (RYO)
• Act gave FDA authority to assert jurisdiction over other tobacco products (cigars, e-cigarettes, etc.)
• CTP has stated its intent to do so
• Will then have to decide what provisions of law to apply to those products
• Evidence of how those products are being marketed and sold in your communities will be critical
FDA Implementation: Role of Tobacco Control Advocates
What is Our Role?

• Be the Eyes of the FDA: Proactively submit information to FDA on industry marketing, violations of the Act, introduction of new products; youth use of new products; etc. Why?
  • To support enforcement
  • To point to need for further action

• Respond to requests for public comment: FDA needs 1) to hear whether the position they have taken is correct and who supports or opposes their proposed action; 2) to have a sound factual record in support of what needs to be done

• To Set Priorities: FDA needs to hear what is most important to do
WHAT CAN YOU DO?
Monitor for compliance with the FDA law:

• Ban on flavored cigarettes
• Ban on use of light and low tar descriptors
• Ban on cigarette sampling & compliance with provisions of limited exception for smokeless
• Ban on sponsorships
• Ban on vending machines and self service displays
• New warning labels on smokeless products
• Retailer compliance with youth access provisions
SURGEON GENERAL’S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Terms such as “Lights” and “Ultra Lights” do NOT mean safer. These cigarettes will NOT help you quit smoking. For more information about PM USA, its products or quitting smoking, visit www.philipmorrissusa.com.

© Philip Morris USA 2009 4J417-04 PLEASE PUT LITTER IN ITS PLACE.

YOUR MARLBORO LIGHTS PACK IS CHANGING.

BUT YOUR CIGARETTE STAYS THE SAME.

Federal law requires that all brands of cigarettes remove descriptors such as “Light” from cigarette packaging and advertising. As a result, the pack will be changing, but your cigarette will stay the same.

IN THE FUTURE, ASK FOR “MARLBORO IN THE GOLD PACK.”

For more information, please visit Marlboro.com or call 1-800-845-2765. Site limited to smokers 21 years of age or older.
North Coast Music Festival in Union Park, Chicago, IL, Summer 2010
Cheyenne

Cigarettes  --  Little Cigars  --  Cigars
How to report violations

- 1-877-CTP-1373
- CTPCompliance@fda.hhs.gov
- For General Inquiries: AskCTP@fda.hhs.gov
- For flavored smokeless and cigars: Tobacco2@fda.hhs.gov
- Mail reports (photos accepted) to: FDA Center for Tobacco Products 9200 Corporate Boulevard Rockville, MD 20850-3229
WHAT CAN YOU DO?
Comment on Important Issues

• Harmful ingredient disclosure to consumers
• Modified risk guidance
• Others as they arise
• You can also submit information proactively
What Should States & Localities Do?
Don’t Stop the Tried & True

• Top Priority: Continue with What We Know Works
  • Tobacco Taxes
  • Smoke-free Laws
  • Funding for Tobacco Prevention & Cessation
  • Coverage for Smoking Cessation Services

• FDA is a Complement – not a Substitute
Beyond the Trifecta: What should states and localities do?
Protects & Expands State & Local Authority

- States can still regulate the sale and distribution of all tobacco products (where sold, age of sale, etc.)

- Act permits states to restrict time, place and manner (but not content) of tobacco advertising or promotions, *to the extent permitted under the First Amendment.*
  - Likely want to see how Courts rule to do this
Innovative Policies

• A complement to the tried and true
• Many focused on point of sale
  – Licensing
  – Warning signs
  – Pricing (min price; discount bans)
  – Display bans
• Need evidence; states and locals can be labs
• Must be prepared for litigation and have resources
• Be strategic
The Tobacco Control Legal Consortium

The legal network for tobacco control policy.
What is Rulemaking?

- Method by which agencies create federal laws
- Many requirements to process, including public comment
- Mandated by Congress vs. Initiated by Agency
- Steps to Process: Notice -> Comments -> Final Rule
Guidance Documents

- Do not carry the weight of law.
- Represent FDA’s current thinking on a topic.
- Used by FDA as intermediary step before enacting certain regulations.
Commenting ≠ Lobbying

Commenting on proposed regulations is not lobbying under federal law.

• “The term ‘lobbying contact’ does not include a communication that is … made in response to a notice in the Federal Register … soliciting communications from the public and directed to the agency official specifically designated in the notice to receive such communications …”


• Each organization must consider its own limitations based on its legal structure, funding sources and relevant law.
What topics does the FDA care about?
What topics does the FDA care about?

Regulatory Information

- Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List
- Cigarette Packaging and Advertising Compliance Update – Impact of Ongoing Litigation
- Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products; Extension of Comment Period
- Proposed Rule: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (Amends Brand Name Provision (1140.16(a)) (PDF - 77KB)
- Advance Notice of Proposed Rulemaking on Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products
- July 2011 HHS Unified Agenda (PDF - 407KB)
- December 2010 HHS Unified Agenda (PDF - 1.5MB)
- Enforcement Action Plan for Promotion and Advertising Restrictions
- Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco
- Competitive Request for Proposal: Tobacco Retail Inspections
What kind of information will help the FDA?
How do I submit comments?

Regulations.gov is your source for U.S. government regulations and related documents. On this site you can find, read and comment on documents. Share your knowledge and make your voice count.
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
How detailed should my comments be?

Mary Sinclair Applegate - Comment

Document ID: FDA-2012-D-0049-0004

This is comment on Notice: Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act; Availability

Docket ID: FDA-2012-D-0049

View Document:

+ More

As a public health physician, I am writing to support the proposed requirement that tobacco companies disclose harmful and potentially harmful ingredients added to cigarettes and other tobacco products they sell. Tobacco itself is well documented as a major cause of death and morbidity. The other constituents added to tobacco products can also have serious negative health impacts. Researchers need to know what the other constituents are so that they can study them and make valid conclusions about the health risks involved, and the public needs to know what they are being exposed to. My particular area of expertise is maternal and infant health. Tobacco is the leading cause of preventable death among infants due to its connection with risk of low birth-weight and SIDS. Other substances added to tobacco products may cause birth defects and have other harmful impacts. We need to be able to assess the risks and inform the public. Sincerely yours, Mary Applegate, MD MPH Associate Dean for Public Health Practice
January 10, 2011

RE: FDA-2010-N-0568 (Required Warnings for Cigarette Packages and Advertisements)

To Whom It May Concern:

On behalf of the New York City Department of Health and Mental Hygiene (DOHMH), I write in response to the Food and Drug Administration’s (FDA) request for comments and information concerning the required warnings for cigarette packages and advertisements. We strongly support FDA’s efforts to make tobacco warnings more effective. Since the purpose of graphic warnings are to make consumers and would-be consumers consider the severe health consequences of smoking we advocate for the use of realistic images of these consequences. Also, we strongly suggest that information about accessing cessation resources accompany the graphic warnings and that the
How detailed should my comments be?

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
U.S. Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket Number FDA-2010-N-0568

Dear Colleagues:

I am the director of Public Health for Goodhue County Health and Human Services located in Red Wing, Minnesota. I would like to thank the Food and Drug Administration (FDA) for the opportunity to provide comments on the proposed rule on required warnings for cigarette packages and advertisements.

Our public health agency has been involved in working to reduce the harm caused by tobacco for many years. We have received funding to support this work from the Minnesota Department of Health and for the last five years, from ClearWay MinnesotaSM. We have educated the public in our county about the dangers of tobacco use and secondhand smoke exposure. We have encouraged our residents who want to quit using tobacco to take advantage of the tobacco cessation resources available to them.
How detailed should my comments be?

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-AG-41

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”). Specifically, we would like the agency’s proposed rule of November 12, 2010 to cover...
How detailed should my comments be?

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
How are my comments used?

- Agency addresses comments
- Substantially similar rule goes into effect
- Significantly changed rules require further comments.
Current Open Dockets

1. Draft guidance document on harmful and potentially harmful constituents (HPHC)

2. Draft guidance document on modified risk tobacco products (MRTP)

Deadline for both: June 4, 2012
Legal Challenges to Rules

Successful legal challenges must show that:

– The rule is arbitrary and capricious or unsupported by the record
– The rule exceeds statutory authority, or
– The rule is a “bolt out of the blue”
Consortium Resources on Tobacco Regulation

- Presentations
  - Conferences
  - Webinars
- Publications
- Website action center
- Email alerts
Questions?

Contact us:
Tobacco Control Legal Consortium
(651) 290-7506

Campaign for Tobacco-Free Kids
(202) 296-5469