

The Family Smoking Prevention and Tobacco Control Act

Overview of FDA's New Authority Over
Tobacco Retailers

J. Ben Haas

October 1, 2009

LATHAM & WATKINS

Agenda

- Overview of the Tobacco Control Act and FDA Organization
- Key Retailer Provisions and Effective Dates
- Enforcement and Penalties
- Working With FDA
- What Next?

Purpose of the Tobacco Control Act

- Regulate the manufacture and processing of tobacco from the grower to store shelves
 - cGMPs
 - Registration and Listing
- Subject new products to premarket oversight
 - Testing
 - Modified risk claims (light, mild, etc.)
- Transparency regarding ingredients and risks
 - Disclosure of ingredients and testing
 - Studies on menthol and other constituents
- Additional restrictions on tobacco advertising and promotion
 - Particularly as directed to minors
- Foster the development of less harmful tobacco products and smoking cessation products
- Does not apply to cigars or pipe tobacco

KEY = FDA MAY NOT BAN FACE-TO-FACE SALES OF TOBACCO PRODUCTS OR NICOTINE!

The Tobacco Regulatory Scheme

- Act creates novel regulatory scheme for regulation of tobacco products (affects entire supply chain, from grower/warehouse to retail)
- Scheme loosely based on system for medical devices
 - Premarket review (two avenues)
 - Postmarket controls (advertising/recalls/reporting)
 - GMPs / Registration and listing
- Unprecedented authority over retail facilities (compare to drugs, devices, cosmetics, and foods)
- Scheme funded through industry user fees

FDA Organization

- Office of the Commissioner
 - Commissioner Hamburg
 - Principal Deputy Commissioner Sharfstein
 - Other key staff include David Dorsey, Catherine Lorraine, Stephen Mason
- Office of the Chief Counsel
 - Acting Chief Counsel Michael Landa
 - Other key staff include David Dorsey, Jeff Senger, Rick Blumberg
- Center for Tobacco Products
 - Established August 19, 2009
 - Expected premarket and postmarket divisions
 - Dr. Lawrence Deyton

FDA Organization

- Office of Compliance
 - Enforcement Arm
- Office of Regulatory Affairs
 - FDA Regions and District Offices
 - Kentucky - Central Region
 - Cincinnati District Office
 - Louisville, KY
 - Tennessee - Southeast Region
 - New Orleans District Office
 - Chattanooga, TN
 - Knoxville, TN
 - Memphis, TN
- Reliance on state and local authorities

Retail Provisions - Summary

- Not required:
 - Registration with FDA
 - Recordkeeping (i.e., receipts of individual sales)
- Required:
 - Ensure facility and sales comply with FDA requirements
 - Implement FDA-approved employee training programs
 - Implement procedures for preventing sales to minors (including employee discipline)
- Potential penalties:
 - Civil penalties (fines)
 - “No-tobacco-sale order”

Retail Provisions – Key Actions and Timelines

- **September 22, 2009** – Ban on flavored cigarettes and components (including rolling papers) – illegal to make, illegal to sell (except menthol)
 - FDA electronic form for reporting violations – includes name and address of retail location
- **June 22, 2010:**
 - 1996 Final Rule on advertising and promotion takes effect
 - Ban on “light,” “mild,” and similar descriptors
 - New label requirements for smokeless (including new WARNING statement)
- **By October 1, 2010** – FDA action plan for enforcing advertising and promotion restrictions for menthol and other cigarettes
- **By October 1, 2011** – FDA regulations regarding remote sales and distribution
- **By September 22, 2012** – New label requirements for cigarettes (including new WARNING statement)

Retail Provisions – Other Key Actions

- Guidance on enforcement against retailers (no target date)
 - Must be issued before “no-tobacco-sale orders” can be imposed
- Regulations regarding “equal treatment of retail outlets”
 - Level playing field among all retailers, including adult-only facilities
- Contracting with states to carry out inspections of retailers
- Expert panel to consider raising minimum age for purchasing tobacco products
- Additional regulations on access to, and the advertising and promotion of, tobacco products as “appropriate for the protection of the public health” (906(d) regulations)

FDA's Initial Action - Flavors

- Guidance Document on Ban of Flavorings in Cigarettes
 - Issued September 22, 2009 to clarify tobacco product standard prohibiting cigarettes with certain characterizing flavors
 - Preliminary FDA press release created confusion in the industry due to broad reading of term “cigarette,” to potentially include cigars and other tobacco products
 - Guidance explains that ban applies to traditional cigarettes, as well as loose tobacco and roll-your-own tobacco *and papers or filters*, but not pipe tobacco
 - Leaves unresolved the question of “little cigars”: “The ban applies to all tobacco products with certain characterizing flavors that meet the definition of a “cigarette” even if they are not labeled [as such]”

1996 Final Rule

- Applies to cigarettes/RYO and smokeless tobacco
- First FDA attempt to regulate tobacco products; later struck down by the Supreme Court
- Key Definitions:
 - Packaging, Labeling, and Advertising
 - Package: “pack, box, carton or container of any kind in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers”
 - Retailer: “any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted”
 - Adult only facility – facilities where the retailer ensures that no person younger than 18 is permitted to enter at any time

1996 Final Rule - Advertising

- All labeling and advertising – black text, white background
 - Color permitted in adult-only facilities, so long as advertising is not visible from outside the facility and that it is affixed to a wall or fixture
- Audio – words only with no music or sound effects
- Video – static black text on a white background
- No outdoor advertising, including billboards, posters, or placards, may be placed within 1,000 feet of a playground, ball field, or school

1996 Final Rule - Retail

- Vending machines or self-service displays are generally prohibited except in adult-only facilities
 - Sales only in “direct, face-to-face exchanges”
- No sales to minors (under 18) – must verify by means of photographic ID
 - No verification required for over 26
- May not sell packages of cigarettes containing fewer than 20 cigarettes or smokeless “smaller than the smallest package” distributed by manufacturer”
- No gift or item other than cigarettes or smokeless tobacco in consideration of the purchase of cigarettes or smokeless tobacco (i.e., coupons, credits, proofs-of-purchase)

1996 Final Rule - Responsibilities

- Unlawful to hold tobacco products for sale in violation of regulation
- Retailers must remove all self-service displays, advertising, labeling and other items that do not comply with the regulations
 - Manufacturers have the same responsibility
- Retailers should review agreements to ensure that they are permitted to remove manufacturer items
 - Competitor enforcement
 - Public health groups
- Remember – Equal Treatment of Retail Outlets
- Rules will apply to Indian Tribes

Enforcement

- FDA has a variety of enforcement tools
 - Untitled Letters
 - Warning Letters
 - Civil penalties (fines)
 - Temporary or permanent “no-tobacco-sales” orders
 - Seizure
 - Criminal actions
- Key new concept: If, after opportunity for hearing, FDA finds that a retailer has committed “repeated violations” at a particular outlet, FDA may issue a no-tobacco-sale order and civil penalty
- Initial enforcement likely to be through untitled letters and Warning Letters, pending issuance of enforcement guidance documents

Enforcement - Process

- FDA must issue guidance detailing enforcement process against retailers:
 - Defining “repeated violation” as including at least 5 violations of particular requirements over a 36-month period
 - Notice of prior violations prior to compliance checks and enforcement
 - Hearing process (including telephonic hearings)
 - Modification and termination of no-tobacco-sales orders

Enforcement – Safe Harbor / Mitigation

- Guidance will describe safe harbors
 - No violation of minimum age requirement if “good faith reliance” based on following actions –
 - Adopting and enforcing written policy against sales to minors
 - Informing employees of regulations
 - Imposing disciplinary sanctions against employees
 - Requiring ID checks
 - Reduced penalties upon enforcement if retailer has “approved training program”
 - Training program that complies with standards developed by FDA
- FDA must coordinate with states and must mitigate penalties based on amounts paid to states for same violations

Enforcement - Penalties

- Retailers with FDA-approved training program:
 - 1st violation – Warning Letter
 - 2nd violation within 12-month period - \$250
 - 3rd violation within 24-month period - \$500
 - 4th violation within 24-month period - \$2,000
 - 5th violation within 36-month period - \$5,000
 - 6th violation within 48-month period - \$10,000
- Retailers without FDA-approved training program:
 - 1st violation – \$250
 - 2nd violation within 12-month period - \$500
 - 3rd violation within 24-month period - \$1,000
 - 4th violation within 24-month period - \$2,000
 - 5th violation within 36-month period - \$5,000
 - 6th violation within 48-month period - \$10,000

Enforcement – Warning Labels

- Protection against enforcement of new cigarette and smokeless tobacco warning requirements if *packaging*:
 - Contains a warning label
 - Is supplied to the retailer by a license- or permit-holding manufacturer, importer, or distributor

AND

- Is not altered by the retailer in a way that is material to the warning requirements
- Retailers liable if they display advertisement without Warning Label or modify Warning Label

Enforcement - Role of States and Localities

- States and localities may impose additional requirements related to sale, distribution, possession, use, access to, advertising, and promotion of tobacco products
 - “Time, place and manner restrictions”
- Inspections likely to be done through states
- Competitors, health groups, localities, and states likely to be primary source of complaints and enforcement
 - Notification page on FDA website

First Amendment Challenge

- First Amendment challenge to advertising restrictions filed on August 31 by RJR, Commonwealth, Conwood, Discount Tobacco City & Lottery, National Tobacco Co., and Lorillard
 - Ban on color and graphics in advertising (black-and-white text provision)
 - Ban on outdoor advertising
 - Ban on brand-name merchandise
 - Ban on distributing product samples
 - Ban on coupons, gifts, etc.
- Seeking resolution by the end of this year

Interacting with FDA

- Brand new/historic regulatory scheme with numerous unanswered questions
- FDA has established avenues for industry to engage with the Agency:
 - FDA Tobacco Docket FDA-2009-N-0294
 - Email account to monitor questions regarding implementation (tobacco2@fda.hhs.gov)
 - FAQ on tobacco webpage
 - Email subscription for tobacco updates
 - Listening sessions for industry participation

Input from Stakeholders on Retail Provisions

- Tobacco Docket
 - American Academy of Pediatrics
 - Urges FDA to prohibit sales of tobacco in pharmacies, including those located in grocery stores, and to ban the sale of candy or gum that looks like tobacco
 - Seattle and King Counties, Washington State
 - Urges FDA to prohibit vending machines unless the *entire* facility is adult-only at *all* times
 - National Association of Tobacco Outlets (NATO)
 - Raises concerns about the breadth of the prohibition on flavorings in cigarettes that went into effect September 22, 2009
 - Requests clarification regarding advertising/marketing requirements in light of the pending 1st amendment litigation
 - Raises concerns about effects of stringent regulation on small businesses

Input from Stakeholders on Retail Provisions

- FDA Listening Session for Retailers (September 18, 2009)
 - Concerns about effect on retailers of loopholes for internet and remote sales, and request that FDA tightly control internet advertising
 - Concerns about tracking and tracing requirements on retailers
 - Concerns about requirement for identification checks to ensure enforcement conforms to the purpose of the requirement
 - Concerns about state enforcement of FDA requirements before FDA has officially stated its policies

Input from Stakeholders on Retail Provisions

- FDA Listening Session for Retailers (September 18, 2009) (cont.)
 - Disagreement over what kind of retail establishment could constitute an adult-only facility (night clubs? stand-alone tobacco stores?)
 - Request for procedural notice of violations at locations other than the retail outlet
 - Request for guidance on approved training programs
 - Request for clarification on retail sale of smoking cessation products
 - Request for block of time to sell off noncompliant goods once rules are implemented

Interaction with FDA

- Additional pressure points:
 - Office of the Commissioner
 - Center for Tobacco Products
 - Office of the Chief Counsel
 - Office of the Deputy Commissioner
 - Department of Health and Human Services (“HHS”)
 - Office of Management and Budget (“OMB”)
 - Congressional Oversight Committees (Senate HELP and House Energy and Commerce)

Next Steps

- Watch the Agency
 - Monitor the docket to shed light on FDA's priorities
 - Prepare for upcoming actions and implementation deadlines
 - Actively follow FDA's implementation activities, i.e., development of the Center for Tobacco Control
 - Monitor actions of state Attorneys General
 - Monitor Warning Letters database
- Engage the Agency
 - Meetings with Center Director and Principal Deputy Commissioner