



FOOD AND DRUG ADMINISTRATION REGULATION OF TOBACCO PRODUCTS

Kathleen Hoke Dachille
Center for Tobacco Regulation
kdachille@law.umaryland.edu; (410)706-1294
MD QUIT Annual Meeting 2010
January 21, 2010


A Little History

- Pre-1996: FDA does not regulate tobacco products; agency indicates lack of authority
 - 1996: FDA Commissioner asserts jurisdiction (authority) and promulgates regulations
 - 2000: Supreme Court rules FDA lacks authority to regulate tobacco (Congress has not granted that authority)
- 

A Little More History

- ▶ 2001: Kennedy–DeWine Bill introduced in Congress (pre–cursor to current legislation); failed to get out of committee
 - ▶ 2004: Kennedy–DeWine Bill PASSES SENATE
 - ▶ 2007: Kennedy–DeWine Bill PASSES key House Committee
 - ▶ 2008: Companion House Bill passes but too late for Senate to pass
- 

Family Smoking Prevention and Tobacco Control Act of 2009

- ▶ Bill passes House 298 - 112 on April 2nd; slightly different version passes Senate 97 to 17 on June 11; House passes Senate version June 12;
 - ▶ And . . .
- 



President Obama signs the bill into law >>

June 22, 2009

Provisions of the Act


Sales / Marketing Restrictions

Applies to cigarettes and smokeless only, effective June 2010, unless otherwise noted

- ▶ Prohibits tobacco brand sponsorship of sports and entertainment events (more rigorous than the Master Settlement Agreement);
- ▶ Bans the giving away of non-tobacco items with the purchase of a tobacco product or redemption of coupon (i.e., no free t-shirt with purchase of 2 packs);
- ▶ Prohibits the giving away of CIGARETTES in all venues;

Provisions of the Act

Sales / Marketing Restrictions

- ▶ Prohibits the giving away of SMOKELESS tobacco except in very limited venues (adults-only; i.d. check at door; no alcohol sold; etc.);
 - ▶ Requires that cigarettes be sold in a minimum package of 20;
 - ▶ Requires retailers to check identification of customers who are under 27;
- 

Provisions of the Act

Sales /Marketing Restrictions

- ▶ Prohibits tobacco product vending machines (except in limited adult-only facilities);
- ▶ Prohibits self-service tobacco products displays (except in limited adult-only facilities);
- ▶ Requires FDA to promulgate rules to restrict youth access to tobacco products via Internet and regulation of marketing on Internet (regulations due December 2010);
- ▶ Sets federal minimum purchase age of 18; FDA cannot raise.

Provisions of the Act

Sales /Marketing Restrictions

Potential First Amendment Issues

- ▶ Bans certain outdoor ads near schools and playgrounds;
- ▶ Prohibits all but black and white text ads outdoors and inside retail stores (unless adult-only);
- ▶ Prohibits all but black and white text ads in magazines with significant youth readership (15% of readers or 2 million);
- ▶ Audio-visual ads only in black and white with spoken words—no images or music.

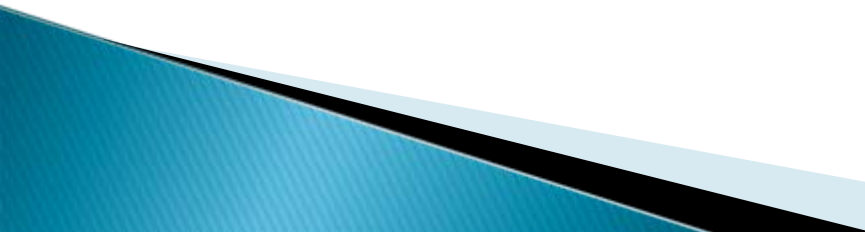
Provisions of the Act

Sales / Marketing Restrictions

- ▶ **NEW WARNINGS!!!!**
 - 50% of front and back of cigarette package;
 - 30% of front and back of smokeless packages;
 - 20% of advertisements;
 - Graphic and textual warnings;
 - FDA has authority to change warnings.


New Cigarette Warnings

Effective September 2012

- ▶ WARNING: Cigarettes are addictive
 - ▶ WARNING: Tobacco smoke can harm your children
 - ▶ WARNING: Cigarettes cause fatal lung disease
 - ▶ WARNING: Cigarettes cause cancer
 - ▶ WARNING: Cigarettes cause strokes and heart disease
 - ▶ WARNING: Smoking during pregnancy can harm your baby
 - ▶ WARNING: Smoking can kill you
 - ▶ WARNING: Tobacco smoke causes fatal lung disease in non-smokers
 - ▶ WARNING: Quitting smoking now greatly reduces serious risks to your health
- 

New Smokeless Warnings

Effective June 2010

- ▶ **WARNING:** This product can cause mouth cancer
 - ▶ **WARNING:** This product can cause gum disease and tooth loss
 - ▶ **WARNING:** This product is not a safe alternative to cigarettes
 - ▶ **WARNING:** Smokeless tobacco is addictive
- 

Provisions of the Act

Sales/Marketing Restrictions

June 2010


- ▶ Prohibits use of LIGHT, MILD, and LOW TAR as product descriptors;
- ▶ Allows FDA to add prohibited terms.

December 2009

- ▶ Allows FDA to require disclosure of certain contents (i.e. tar and nicotine).
- 


Provisions of the Act

Product Standards

- ▶ Prohibits the sale of flavored cigarettes (in effect since September 2009);
 - ▶ EXCEPTS MENTHOL!!!
 - ▶ Allows FDA to impose restrictions on sale and marketing of flavored smokeless and/or cigars.
 - ▶ Requires FDA to study menthol issue and allows FDA to prohibit menthol.
- 

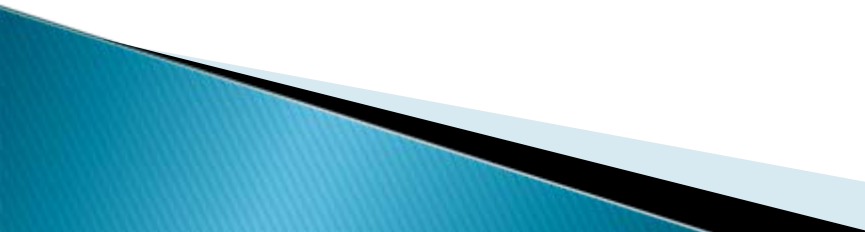
Provisions of the Act

Product Standards

- ▶ Allows FDA to require reductions (or increases) in nicotine yields;
 - ▶ Forbids FDA from requiring elimination of all nicotine from tobacco products.
 - ▶ FDA may order removal of a particular constituent found to be harmful.
- 


Provisions of the Act

Product Standards—New Products

- ▶ Requires disclosure of ingredients, constituents, nicotine content of any new product as well as any health effects research on that product;
 - ▶ If new product is NOT substantially similar to an existing product, requires PRE-MARKET APPROVAL by FDA after more complete disclosures;
 - ▶ FDA may prohibit marketing of new product or limit marketing and sale in any manner.
- 

Provisions of the Act

Reduced Harm Products

- ▶ Manufacturers may not make health claims about any product without approval of FDA;
 - ▶ Creates comprehensive program for approval of products that may be marketed as presenting reduced risk/harm.
- 

Provisions of Act

State and Local Power

- ▶ Reverses a comprehensive preemption clause that had operated to prohibit much state and local tobacco marketing regulation since 1965;
 - Specifically, state and local governments may regulate the time, place, location, number, color, size, and placement of ads; not content.
- ▶ Allows for state and local regulation in most areas, reserving only certain products standards/new product approval/reduced harm product regulation exclusively for FDA.

Impact of Act

**STAY
TUNED . . .**



For more detailed information about the Family Smoking Prevention and Tobacco Control Act:

Congressional Research Service, “FDA Tobacco Regulation : History of the 1996 Rule and Related Legislative Activity, 1996–2008,” (February 2009), available at

- ▶ https://www.policyarchive.org/bitstream/handle/10207/18799/R40196_20090204.pdf?sequence=2

Family Smoking Prevention and Tobacco Control Act of 2009, available at

- ▶ <http://www.govtrack.us/congress/billtext.xpd?bill=h111-1256>

Tobacco Law Center, “Federal Regulation of Tobacco: A Summary,” (July 2009), available at <http://www.tobaccolawcenter.org/documents/federal-regulation-tobacco-summary.pdf>.

Tobacco Law Center, “Federal Regulation of Tobacco: Impact on State and Local Authority,” (July 2009), available at <http://www.tobaccolawcenter.org/documents/federal-regulation-of-tobacco-impact.pdf>

Campaign for Tobacco Free Kids: FDA Authority Page:

- ▶ http://www.tobaccofreekids.org/reports/fda/index.shtml?utm_source=home&utm_medium=home&utm_campaign=fda_passage