

Overview

Federal Regulation of Tobacco: A Summary
July 2009



Background

On June 22, 2009, President Barack Obama signed into law the Family Smoking Prevention and Tobacco Control Act, giving the U.S. Food and Drug Administration (FDA) comprehensive authority to regulate the manufacturing, marketing, and sale of tobacco products. The new law represents the most sweeping action taken to date to reduce what remains the leading preventable cause of death in the United States.

Before enactment of the new law, tobacco products were largely exempt from regulation under the nation's federal health and safety laws, including the Food, Drug, and Cosmetic Act. The FDA has regulated food, drugs and cosmetics for many decades, but not tobacco products, except in those rare circumstances when manufacturers made explicit health claims.

What the New Law Does

The Family Smoking Prevention and Tobacco Control Act adds a new Chapter IX to the Food, Drug, and Cosmetic Act, establishing and governing the regulation of tobacco products. A new Center for Tobacco Products is created within the FDA to establish tobacco product standards, among other things. Chapter IX vests the FDA with jurisdiction to regulate both current and new tobacco products and restrict tobacco product marketing, while also directly implementing provisions that will, among other things, restrict tobacco product marketing and advertising, strengthen cigarette and smokeless tobacco warning labels, reduce federal preemption of certain state cigarette advertising restrictions, and increase nationwide efforts to block tobacco product sales to youth.

In addition to the FDA's new powers to regulate the structure of tobacco products, the agency has wide-ranging authority to regulate tobacco products and tobacco product marketing. The new law:

- Restricts tobacco advertising and promotion in order to promote overall public health (the judicial system will likely be asked to determine whether any of the legislated advertising restrictions unconstitutionally interferes with free speech under the First Amendment)
- Stops illegal sales of tobacco products to minors
- Bans all cigarettes that have a characterizing flavor, including all fruit and candy flavors, other than tobacco or menthol
- Prohibits health claims about purported reduced risk products, where such claims are not scientifically proven or would cause net public health harms (for example, by discouraging current tobacco users from quitting or encouraging new users to start)



- Requires tobacco companies to disclose the contents of tobacco products, changes to their products, and research about the health effects of their products
- Requires much larger, more visible, and more informative health warning labels, including color and graphics, on cigarette and smokeless tobacco product packages
- Similarly requires much larger, more visible, and more informative health warning labels on advertisements for cigarettes and smokeless tobacco
- Prohibits terms such as “light,” “mild” and “low-tar” on tobacco product packages and advertisements, while authorizing the FDA to restrict additional terms in the future

The law also imposes certain limits on FDA authority. The agency cannot ban conventional tobacco products, such as cigarettes and smokeless tobacco, or require the total elimination of nicotine in tobacco products. However, the FDA may order the reduction of nicotine to non-addictive levels in some or all tobacco products. The agency also has the authority to order an increase in nicotine levels in tobacco products if it determines that doing so will promote overall public health. For their part, states retain the authority to ban all or some tobacco products or the sale of tobacco products containing nicotine.

The law also prohibits the FDA from using its new authority to increase the new federal minimum age of 18 to a higher level, require prescriptions for the purchase of tobacco products, ban tobacco product sales in any particular type of sales outlet, or regulate tobacco farming directly. In all of these areas, the FDA could ask Congress to either take these actions or provide the agency with new authority to do them. Moreover, states have the authority to take such actions without congressional approval.

The Family Smoking Prevention and Tobacco Control Act also mandates restrictions on the marketing and advertising of cigarettes and smokeless tobacco that the FDA itself adopted in 1996 but which the Supreme Court nullified in 2000 on the basis that Congress had not at that time given the FDA the authority to take such action. The new law:

- Bans outdoor advertising within 1,000 feet of schools and playgrounds
- Bans brand sponsorships of sports and entertainment events
- Bans free giveaways of any non-tobacco items with the purchase of tobacco products or in exchange for coupons or proof of purchase
- Bans free samples and the sale of cigarettes in packages that contain fewer than 20 cigarettes
- Limits any outdoor and all point-of-sale tobacco advertising, except in adult-only facilities, to black text on white background only
- Limits advertising in publications with significant teen readership to black text on white background only
- Limits audio-visual advertising, except in adult-only facilities, to black text on white background visuals and spoken words (no music, images or moving images)

- Restricts vending machines and self-service displays to adult-only facilities
- Establishes 18 as a federal nationwide minimum age for legal cigarette and smokeless tobacco sales with strong federal penalties, including the loss of the right to sell tobacco products for chronic, repeat offenders
- Requires retailers to verify age for all over-the-counter sales by checking a photographic ID, and provides for federal enforcement and penalties against retailers who sell to minors

The law also includes a number of other changes as well. For example, it:

- Limits the current federal preemption against state regulation of cigarette advertising under the Federal Cigarette Labeling and Advertising Act, by allowing states to restrict the location, color, size, number and placement of cigarette advertisements
- Grants the FDA exclusive authority in such areas as tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, manufacturing standards and modified risk products, thereby preempting existing state authority in these areas—however, states continue to have authority to adopt fire-safe cigarette laws that regulate the ignition propensity of tobacco products
- Requires the tobacco companies to submit a listing of all tobacco ingredients and additives to tobacco, paper and filters by brand and by quantity in each brand, a description of the content, delivery and form of nicotine in each product, and all documents developed after enactment that relate to the health, toxicological, behavioral or physiological effects of current or future tobacco products
- Revises and strengthens the content of health warnings on both cigarette and smokeless tobacco products, requiring the warnings to cover 50 percent of the front and back of all packages, including graphic images depicting the harmful effects of tobacco use
- Blocks tobacco companies from claiming that the FDA has approved or certified any tobacco product

The law also provides substantial funding for the FDA's new responsibilities by imposing a user fee on tobacco companies. The prescribed funding mechanism is designed to ensure that the agency's tobacco prevention activities are fully funded without taking resources away from the FDA's other work. In 2010, the total fee will be \$235 million, rising to \$450 million in 2011 and increasing 6% a year until 2019, after which it will remain at \$712 million.

To learn more about FDA regulation of tobacco, visit www.tclconline.org.

The Tobacco Control Legal Consortium provides information and technical assistance on issues related to tobacco and public health, but does not provide legal representation or advice. This fact sheet should not be considered legal advice or a substitute for obtaining legal advice from an attorney who can represent you. If you have specific legal questions, we recommend that you consult with an attorney familiar with the laws of your jurisdiction.