

Overview

Federal Regulation of Tobacco: Impact on State and Local Authority
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.

The authority of the FDA to regulate the structure of tobacco products is particularly important because it empowers the agency to order changes in existing or new products designed to render them less harmful or less (or non-)addictive. Such product regulation is enormously complex, requiring extensive oversight and testing expertise and capacity. Most, if not all, states lack such expertise or resources, and none have sought to regulate tobacco products themselves, with the exception of "fire-safe" cigarette laws and bans on flavored cigarettes such as the small, hand-rolled cigarettes called bidis.

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 almost certainly 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 could also order an increase in nicotine levels in some or all tobacco products if it determined that doing so would 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 either to take these actions or to 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 a product 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 (e.g., at point of purchase), 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 (with no preemption of existing state laws or penalties, and preserving state authority to impose higher minimum-age laws)
- 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, including the following:

- 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.

What States Can Do Now that the FDA Will Regulate Tobacco

The looming question for state policymakers and health advocates is what state and local governments can do now that the FDA will regulate tobacco products and tobacco product marketing.

The basic bottom line is that state and local governments will retain the authority to engage in a sweeping array of tobacco control policy actions long championed by the public health advocacy community. A key guide to the state-based actions regarded as being most effective in reducing tobacco use and initiation and exposure to secondhand smoke is the Centers for Disease Control and Prevention's *Best Practices for Comprehensive Tobacco Control Programs*, updated in 2008. Based on thousands of peer-reviewed studies, CDC's guidelines identify the most effective population-based approaches within the following categories:

- **State and community interventions**, which cover a range of activities, including state and local policies and programs, chronic disease and tobacco-related disparity elimination initiatives, and interventions aimed at influencing youth.
- **Health communication interventions and counter-marketing strategies** that employ paid broadcast, billboard, print, and web-based advertising at the state and local levels; media advocacy endeavors; and efforts to reduce or replace tobacco industry sponsorship and promotions.
- **State-supported cessation interventions** encompassing a broad array of policy, system, and population-based measures.

- **State surveillance**, which involves monitoring tobacco-related attitudes, behaviors, and health outcomes at regular intervals.
- **Administration and management** infrastructure and staffing, since internal capacity within a state health department is essential for program sustainability, efficacy and efficiency.

FDA regulation will not interfere with, and in some ways will strengthen, state authority to engage in these well-established best practices. Specifically, state and local governments retain the power to:

- Raise tobacco tax rates
- Enact and enforce smoke-free laws in workplaces and public places
- Fund comprehensive state tobacco prevention programs
- Implement counter-marketing campaigns
- Enhance access to effective cessation treatments
- Restrict the sale, distribution, and possession of tobacco products
- Implement anti-smuggling and tax evasion measures

The new law also notably expands what state and local governments can do to prohibit or restrict certain tobacco product marketing.

The Family Smoking Prevention and Tobacco Control Act blocks state and local governments from taking action specifically to regulate the structure of any tobacco product that is subject to FDA regulation – except that state and local governments retain authority, which a few have already exercised, to enact fire-safe cigarette laws.

Once it is fully implemented, the new law will establish a range of new marketing restrictions and other measures that will apply nationwide to complement, not interfere with, state and local tobacco prevention efforts. The law will also provide assistance to states to enforce restrictions on promotion, advertising and sales to youth, including an emphasis on mentholated cigarettes.

A More In-Depth Look

The Law Expands State and Local Authority to Restrict Cigarette Advertising and Promotion

The Family Smoking Prevention and Tobacco Control Act expands state and local governments' ability to restrict tobacco advertising and marketing. Some health advocates have endeavored, for example, to ban promotions of tobacco products at retail establishments (e.g., buy one, get one free, and discount coupons), but have been hampered by actual or feared federal statutory impediments. Since the adoption of certain amendments to the Federal Cigarette Labeling and Advertising Act (FCLAA) in 1969, federal law had blocked states from restricting cigarette advertising and promotion specifically for health purposes. Some courts had, for example, rejected state and local measures banning free samples. By eliminating the preemption of state laws regulating the time, place or manner of cigarette advertising and promotion, the new law eliminates that problem and allows this kind of state and local regulation. The new law reduces the preemptive effect of the FCLAA, giving states the power to restrict the time, place and manner, though not the content, of cigarette advertising and promotion.

Previously, advocates of restrictions on cigarette advertising and marketing were required to carefully tailor regulations to pass legal muster (e.g., by making a case for enacting such laws

for reasons other than public health), with no assurance that doing so would survive legal challenges. Removal of the preemption, as described above, appears to eliminate this problem.

Notably, there existed no similar federal preemption of state or local efforts to regulate or prohibit the advertising or promotion of tobacco products other than cigarettes, although, as in the case of cigarettes, such restrictions may be subject to constraints imposed by the First Amendment's protections of commercial speech.

The new law permits state and local governments to:

- Expand the law's requirement that retail ads for cigarettes and smokeless tobacco products be limited to black-and-white text to cigar and other tobacco product advertisements
- Restrict or eliminate the display of so-called power walls of cigarette packages at retail outlets, which will be the only presentation of cigarette brand logos, labels and colors permitted in retail outlets under the new law ("power walls" are the large displays of cigarettes found near cash registers at such places as convenience stores and gas stations)
- Limit the number and size of tobacco ads at retail outlets
- Require that tobacco products and advertisements be kept a minimum distance from cash registers in order to reduce impulse purchases by smokers trying to quit

The caveat is that the enactment of some of the measures noted above are likely to face legal challenges by tobacco or allied interests. States and localities will be able to engage in all such actions to the extent they are determined by the judicial system to be permissible under the free speech protections of the First Amendment. This should not unduly dissuade advocates and policymakers from pursuing such policies, but when doing so, advocates are advised to take steps to strengthen the case that such regulations are valid under the First Amendment. Policymakers must conscientiously develop both a strong legislative history and a substantial evidentiary record demonstrating that such restrictions (e.g., prohibiting power walls) directly advance the legitimate and substantial government interest of preventing youth tobacco use, reducing adult tobacco use or otherwise protecting and promoting public health. The legislative record should also make explicit that the restrictions will not entirely prevent tobacco companies from communicating truthful information to their legal adult customers, and that the restrictions are reasonably related to the government interests they seek to address.

With an eye toward effective use of the powers newly granted by the Family Smoking Prevention and Tobacco Control Act, advocates and policymakers may also consider using age-based criteria to avoid potential First Amendment concerns. For example, while the new law already limits outdoor and point-of-sale tobacco advertising to black-and-white text only, except in adult-only facilities, a state or locality could potentially prohibit outright point-of-sale advertising and require keeping tobacco products and paraphernalia out of sight in venues that admit persons under age 18.

The Law Leaves States and Localities Free to Engage in a Wide Range of Traditional State Tobacco Control Policy Actions

State and local governments remain free to adopt all of the major "best practices" policies, including tobacco tax hikes, smoke-free laws, restrictions on sales to youth and other sales restrictions, increased tobacco prevention program funding, and enhanced access to tobacco

cessation services. The Family Smoking Prevention and Tobacco Control Act has no effect on state authority to restrict the sale, distribution, and possession of tobacco products. States may prohibit the sale of cigarettes or any other tobacco products entirely or to persons of any age, may change the age of sale, and may restrict sales to specified locations. They can, to take one example, prohibit tobacco product sales at pharmacies, as the cities of San Francisco and Boston have already done. Another example is prohibiting the sale of tobacco products in venues admitting persons under the age of 18 or, possibly, prohibiting sales within 1,000 feet of a school. States also retain the authority to implement anti-smuggling and tax evasion measures.

The Law Blocks Most, Though Not All, State Regulation of Tobacco Products Themselves

The Family Smoking Prevention and Tobacco Control Act gives the FDA exclusive authority to establish tobacco product standards, prohibit adulterated or misbranded tobacco products, establish labeling requirements, and regulate manufacturing standards and modified-risk tobacco products, thereby preempting previously existing state authority to do so. Similarly, the bill generally preempts states from separately licensing tobacco manufacturers and suppliers specifically and exclusively for tobacco product regulation purposes.

On the other hand, the legislation does not prevent state action regarding any products or activities over which the FDA has not asserted jurisdiction or taken action. For example, tobacco manufacturers' production, marketing and sale of flavored tobacco products is an area of concern to health authorities and tobacco control advocates. The new law's product standard section directly prohibits any cigarettes with a characterizing flavor other than tobacco or menthol, but does not apply to any other tobacco products. States may themselves ban any or all categories of tobacco products—e.g., all cigarettes or smokeless tobacco—as a function of states' authority over sales and distribution.

The legislation also does not appear to impede a state's ability to require licenses and permits from manufacturers or other tobacco industry entities for any other purpose. Moreover, the new law specifically allows states to implement fire-safe cigarette laws and permits states to impose additional reporting requirements, including ingredient disclosures, on tobacco product manufacturers in the event states identify any information that has not already been obtained or shared by the FDA.

The Law Blocks State and Local Authority to Prescribe Health Warning Labels on Product Packages and Advertisements

The Family Smoking Prevention and Tobacco Control Act prescribes stronger health warning labels and warning label formats on cigarette and smokeless tobacco product packages and advertisements, and authorizes the FDA to establish warning labels on other tobacco products. At the same time, the law prohibits states from placing requirements on cigarette or smokeless tobacco product labeling or on the content of cigarette or smokeless tobacco advertisements.

State and local governments can, on the other hand, impose warning requirements that do not affect tobacco product packages or ads. For example, the New York City Board of Health has proposed requiring all tobacco retailers to prominently display point-of-sale warnings and cessation messages, possibly including graphic images to depict the adverse health effects of tobacco products.

The Law Permits Most Tobacco-Related Litigation

Most litigation is permitted under state and other laws, while some forms of litigation, or of specific legal claims within permitted lawsuits, are preempted. The law does not have a preemptive effect on most state-based civil claims, stating that it cannot be used to “modify or otherwise affect” any lawsuits or court rulings based on state product liability law. The law further states that it does not “affect any action pending in Federal, State or tribal court, or any agreement, consent decree, or contract of any kind,” thus preserving pending smoking and health actions and all “light” cigarette fraud cases.

The preemptive effect of Section 5(b) of the Federal Cigarette Labeling and Advertising Act, as amended, still applies, which means that litigation against cigarette companies based on their “failure to warn” remains preempted by federal law. Thus, plaintiffs in products liability cases cannot claim that cigarette companies failed to warn them of the health effects of smoking after 1969, when the preemptive language went into effect. Nor can plaintiffs bring claims based on legal theories of negligence or misrepresentation by omission.

Many legal actions against tobacco companies have been based on legal theories other than product liability. For example, “light” cigarette cases rest largely on state consumer protection laws, and some cases have been based on state racketeering (or “RICO”) laws. The impact of the legislation on such cases is unclear. In some states, these consumer protection laws cannot be used to challenge corporate practices that are regulated or approved by federal agencies. Some legal claims under some of these state laws might be disallowed.

As a practical matter, tobacco company defendants can be expected to use the fact of FDA regulation in an effort to persuade courts and juries not to assess significant punitive damage awards. Those are the monetary penalties that have been assessed in many cases against tobacco companies to punish the bad behavior of the defendants and to deter such misconduct in the future. The companies may argue that, since they are now more tightly regulated, there is no need to punish them or discourage future wrongdoing. How their arguments fare in courts of law remains to be seen.

Conclusion

The technical question of state authority aside, an intriguing strategic question concerns how enactment of the Family Smoking Prevention and Tobacco Control Act might affect the tobacco control advocacy environment. Once certain major changes (e.g., the strengthening of health warning labels and the implementation of the 1996 FDA tobacco rule restricting or eliminating a variety of tobacco marketing activities) take effect, pending the outcome of likely legal challenges, how such changes might influence public perspectives and those of decision-makers cannot be predicted with certainty. What will emerge as the top tobacco control policy priorities of state and local advocates in the years ahead? Answering these questions will require careful consideration of research and data regarding the relative effectiveness of the available (including newly available) options, their political viability, and the impact of those options (and the advocacy of such options) on building and strengthening the tobacco control movement or otherwise making additional future progress easier.

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

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