

Preemption of State and Local Authority

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 measures to 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 law also preempts certain state and local regulatory authority, as described below.

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.

The Law Blocks State Authority to Regulate the Content of Cigarette Advertisements or to Prescribe Health Warning Labels on Tobacco Product Packages

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. The new law also expands states' ability to restrict tobacco advertising and marketing by amending the Federal Cigarette Labeling and Advertising Act (FCLAA), which no longer prohibits states from restricting cigarette advertising and promotion specifically based on concerns related to smoking and health.

At the same time, the new law prohibits states from placing requirements on cigarette or smokeless tobacco product labeling or on the content of cigarette advertisements. State and local governments can, however, impose warning mandates 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 Blocks Most State and Local Regulation of the Content of Tobacco Products

The new law 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 and local authority to do so. Similarly, the law generally preempts state and local governments from separately licensing tobacco manufacturers and suppliers specifically and exclusively for tobacco product regulation purposes.

There are exceptions. First, the new law's product standard section directly prohibits any cigarettes with a characterizing flavor other than tobacco or menthol, but it 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 law 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. Finally, the law specifically allows state and local governments 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 Includes Limited Preemption of Some Tobacco-Related Litigation

Most litigation continues to be 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." Still, the tobacco industry may attempt to argue that the inclusion of a "grandfather clause" in the law suggests that actions filed in the future that are not considered to arise under a state product liability law (such as consumer fraud) are preempted. In addition, in some states consumer protection laws cannot be used to challenge corporate practices that are regulated or approved by federal agencies.

Questions of interpretation aside, the preemptive effect of Section 5(b) of the FCLAA, as amended, still clearly applies: 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.

[To learn more about FDA regulation of tobacco, visit www.tclconline.org.](http://www.tclconline.org)

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