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. While the law changes state authority to regulate tobacco products and tobacco product marketing in various respects—either enhancing or, in some cases, preempting state authority—there are many ways in which state power remains unchanged, as described below.

States Retain Important Tobacco Control Authority

First and foremost, it is important that advocates and policymakers understand that, following enactment of the new law, states retain the authority to engage in a sweeping array of tobacco control policy actions long championed by the public health 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.

Specifically, FDA regulation leaves fully intact state authority to engage in all of the following well-established best practices:

- Raise tobacco tax rates
- Enact and enforce smoke-free laws in workplaces and public places
- Increase funding for 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 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.

There are exceptions, however, that preserve significant state regulatory authority in the area of tobacco product standards. 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 mandate similar changes in other tobacco products. States retain their authority to ban any or all categories of tobacco products as a function of states’ authority over sales and distribution. States could, for example, outlaw all classes of tobacco products (e.g., all cigarettes or smokeless tobacco).

The law also makes clear that states continue to have the authority to implement fire-safe cigarette laws, and it 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. Nor does the law appear to change states’ ability to require licenses and permits from manufacturers or other tobacco industry entities for purposes other than tobacco regulation.

The new law requires FDA review and approval of all new tobacco products before they are allowed on the market. While the FDA will have the responsibility to regulate (and, when it deems appropriate, prohibit) novel or new products, including their marketing, sale and distribution, states retain the power to ensure that any new products that are allowed on the market by the FDA are marketed and sold in compliance with federal law and do not hamper state tobacco control efforts. States can take regulatory action to prevent any new products from being marketed in such a way as to increase initiation among youth or impede cessation.
Other actions that states retain the authority to take include:

- Mandating minimum pack sizes for all tobacco products, to discourage initiation and usage among youth
- Prohibiting the sale of non-tobacco products containing nicotine that have not been approved by the FDA
- Short of prohibiting the sale of unapproved, non-tobacco products containing nicotine, taxing or restricting such products.

The Law Permits Most State-Based Tobacco-Related Litigation to Continue, Preserving State Authority in the Area

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.”

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.