

Fact Sheet 7

Preemption

Proposed Regulation of Tobacco Products by the U.S. Food and Drug Administration

S. 625/H.R. 1108

“Preemption” refers to the restriction or prohibition imposed by one level of government (e.g., the federal government) on the enactment or enforcement of laws by lower levels of government (e.g., states). The FDA legislation would eliminate much of the existing federal preemption of state efforts to restrict, prohibit, or otherwise regulate cigarette advertising or promotion, which has been in place since 1969, while reserving to the federal government the authority to regulate the actual tobacco products, themselves, except through so-called “fire-safe” laws.

- **STATE REGULATION OF TOBACCO PRODUCT MARKETING PERMITTED:** Currently states are preempted by the Federal Cigarette Labeling and Advertising Act (FCLAA) from prohibiting or regulating cigarette advertising and promotion. There is no federal preemption of state efforts to regulate or prohibit the advertising or promotion of tobacco products other than cigarettes, although such restrictions are subject to constraints imposed by the First Amendment’s protections of commercial speech. The legislation would amend the FCLAA to enable states to impose bans or restrictions on the time, place and manner, but not the content, of the advertising or promotion of cigarettes to the extent allowed under the First Amendment.
- **STATE REGULATION OF THE SALE, DISTRIBUTION AND POSSESSION OF TOBACCO PRODUCTS PERMITTED:** States now have the authority to regulate, or even prohibit, the distribution and sale of tobacco products. In the case of cigarettes, however, legal disputes have arisen over whether a state restriction is a preempted regulation of advertising and promotion or a permitted regulation of distribution and sale. Those restrictions found to be the former are prohibited; e.g., court rulings have blocked some states and localities from banning free samples. By eliminating the current preemption of state laws regulating the time, place or manner of cigarette advertising and promotions, the pending FDA legislation seeks to eliminate that problem and allow all such currently blocked state regulations to go into effect. Accordingly, the legislation would leave intact the existing authority of state and local governments to enact a wide range of tobacco control policies, including regulating the sale, distribution and possession of tobacco products; restricting or eliminating smoking in workplaces and public places; raising tobacco excise taxes; restricting youth access to tobacco products; and imposing additional reporting requirements on tobacco manufacturers.
- **STATE REGULATION OF TOBACCO PRODUCTS PREEMPTED:** The legislation would grant the FDA exclusive authority in such areas as tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, manufacturing standards, and modified-risk products. This provision would preempt existing state authority in these areas, which, by providing for a single national standard, is consistent with federal law providing for the FDA’s regulation of drugs, devices and food.





- STATE “FIRE-SAFE” LAWS PERMITTED: Although the FDA tobacco legislation generally reserves to the FDA the authority to regulate tobacco products themselves, it includes an exemption that allows states to enact “fire-safe cigarette” laws, requiring tobacco products to meet reduced ignition propensity standards.
- SOME LITIGATION PERMITTED, OTHER LITIGATION PREEMPTED:
 - PENDING LITIGATION AGAINST TOBACCO COMPANIES PERMITTED: The FDA legislation would not “affect any action pending in Federal, State or Tribal court, or any agreement, consent decree, or contract of any kind.”
 - FUTURE LITIGATION AGAINST CIGARETTE COMPANIES BASED ON “FAILURE TO WARN” AFTER 1969 PREEMPTED: The preemptive effect of Section 5(b) of the Federal Cigarette Labeling and Advertising Act, as amended, still applies. Under that provision, as interpreted by the Supreme Court, plaintiffs in tobacco 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.
 - FUTURE PRODUCT LIABILITY LITIGATION AGAINST TOBACCO COMPANIES PERMITTED: The legislation contains a specific provision stating that the new law could not be used either to “modify or otherwise affect” any lawsuits or court rulings based on state product liability law.
 - OTHER TYPES OF FUTURE LITIGATION AGAINST TOBACCO COMPANIES: Many legal actions against tobacco companies have been based on legal theories other than product liability. For example, “light” cigarette cases rest largely on consumer protection laws, some personal injury claims rely on warranty theories, and some cases have been based on state RICO laws. The impact of the proposed legislation on such cases is unclear.
 - FUTURE LITIGATION AGAINST TOBACCO COMPANIES UNDER STATE CONSUMER PROTECTION LAWS: All states have laws to protect consumers against unfair and deceptive acts and practices; these laws have been very important for many tobacco-related cases, including the actions by state governments in the 1990s and more recent actions involving “light” cigarettes. In some states, these consumer protection laws cannot be used to challenge corporate practices that are regulated or approved by federal agencies. If the FDA legislation becomes law, some potential legal claims under some of these state laws would be barred, but the scope of this effect and its practical impact are uncertain.