Tobacco Control Legal Consortium

Fact Sheet 6

Litigation

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

Tobacco litigation has contributed to the cause of tobacco control by uncovering key information about tobacco industry misconduct, in part through the discovery and publication of millions of previously confidential internal tobacco company documents; denormalizing the tobacco industry in the eyes of the public, policymakers and the media; compelling the industry to start to engage in a certain degree of responsible behavior (e.g., publicly admitting that smoking causes cancer); and prompting substantial price increases, thus reducing consumption.

Legal cases against tobacco manufacturers and allied tobacco industry groups have been litigated in the United States since the 1950s. The most recent phase of tobacco litigation, which got under way in 1994, has featured many more cases than in earlier years. The single most important distinguishing characteristic of these cases has been the availability to plaintiffs of substantial new evidence of the industry's internal knowledge of the health effects of tobacco use, its manipulation of nicotine to cause addiction, and its cover-up of such information.

Under the new FDA law, most pending and future litigation against the tobacco industry 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.

- Section 4(a) states that nothing in the Act (or an amendment made by the Act) "shall be construed to . . . affect any action pending in Federal, State or tribal court, or any agreement, consent decree, or contract of any kind."
- Section 917(b) states that "No provision of this chapter [i.e., the 'Family Smoking Prevention and Tobacco Control Act'] relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." It is unclear how the legislation would affect future legal claims based on areas of state law other than product liability (e.g. fraud, consumer protection or contract law.)

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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.

Other potential ramifications of the legislation's effect on tobacco-related litigation do not appear in the explicit text of the legislation but must be inferred. For example, nothing in the language of the legislation creates a shield against liability under state law based on a theory that the tobacco industry's actions have been reviewed or approved by the federal government; however, 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.

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

Tobacco Control Legal Consortium
875 Summit Avenue
Saint Paul, Minnesota 55105-3076
Tel: 651.290.7506 · Fax: 651.290.7515
www.tclconline.org