

- Overview
- Tobacco Product Standards
- Tobacco Product Marketing Restrictions
- Tobacco Product Labeling and Advertising Warnings
- Tar, Nicotine and Other Smoke Constituent Disclosures
- Litigation
- Preemption
- Preventing Illicit Trade in Tobacco Products

Federal Regulation of Tobacco: A Summary

July 2009



Tobacco Control
Legal Consortium



Law. Health. Justice.

Federal Regulation of Tobacco:

A Summary

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 ([H.R. 1256](#)) represents the most sweeping action taken to date to reduce what remains the leading preventable cause of death in the United States.

To help you understand this complex legislation, the Tobacco Control Legal Consortium, a collaborative national network of legal centers, has prepared this summary of key elements in the new law. The publication is divided into the following sections:

1. [Overview](#)
2. [Tobacco Product Standards](#)
3. [Tobacco Product Marketing Restrictions](#)
4. [Tobacco Product Labeling and Advertising Warnings](#)
5. [Tar, Nicotine and Other Smoke Constituent Disclosures](#)
6. [Litigation](#)
7. [Preemption](#)
8. [Preventing Illicit Trade in Tobacco Products](#)

This publication is based in part on the Tobacco Control Legal Consortium's *Factsheets on the Proposed Regulation of Tobacco Products by the U.S. Food and Drug Administration: S. 625 / H.R. 1108* (August 2007), prepared with the support of the Tobacco Control Network.



1

Overview

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.

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 likely 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 also has the authority to order an increase in nicotine levels in tobacco products if it determines that doing so will 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 to either take these actions or 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, 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
- 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.

2

Tobacco Product Standards

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, which are regulations affecting the design or safety of a product. Chapter IX vests the FDA with jurisdiction to regulate both current and new tobacco products.

A fundamental feature of the new law is that it requires FDA review and approval of all new tobacco products before they can be introduced to the market. The agency will thus have the responsibility to regulate—or, if it deems appropriate, prohibit—novel or new products, including their marketing, sale and distribution. The agency may order changes in cigarettes and other existing tobacco products to meet new product standards. Such tobacco product standards are to be based on available medical, scientific and other technological evidence as appropriate for the protection of the public health. “Appropriate for the protection of the public health” is to be determined with respect to the risks and benefits to the population as a whole, including users and non-users of tobacco products, taking into account the increased or decreased likelihood that existing users of tobacco products will stop and that nonusers will start because of the new product standards.

The FDA is specifically authorized to prohibit adulterated or misbranded tobacco products, establish labeling requirements, and regulate manufacturing standards and modified risk tobacco products, thereby generally preempting previously existing state authority in those areas. Similarly, the law preempts states from separately licensing tobacco manufacturers and suppliers specifically and exclusively for tobacco product regulation purposes. The law also preserves, however, state and local governments’ authority to implement fire-safe cigarette laws that regulate the ignition propensity of tobacco products.

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. The FDA has the power to prohibit the use of flavors, including menthol, in all tobacco products.

The law does not allow the FDA to use its new product standard authority to reduce nicotine yields of a tobacco product to zero, but grants the FDA authority to determine whether nicotine can be reduced to levels that do not cause or sustain addiction, and, if so, to reduce nicotine yields to those levels.

The law does not allow the FDA to use its new product standard authority unilaterally to order a complete ban of tobacco products or of any specific type of existing tobacco product (i.e., the FDA could not ban all cigarettes, all small cigars, all big cigars, all smokeless tobacco products, all pipe tobacco or all roll-your-own tobacco), but authorizes the agency to ban any brand new type of tobacco product from being sold in the United States. The law also leaves untouched the power of Congress and the states to ban any tobacco products.

If the FDA determines that an additive or a constituent—in either the tobacco product or the

smoke emitted by the product—is harmful and should be removed, the burden will be on a party challenging the proposed standard to prove that the proposed change will not reduce or eliminate the risk of illness or injury.

New Tobacco Products

The law places requirements and restrictions on new tobacco products that might be offered for sale in the United States. Before introducing any new tobacco product into the market, the law requires that the manufacturer disclose to the FDA information regarding the ingredients, constituents and nicotine level, as well as any documents relating to the health effects of the product or its ingredients and constituents (i.e., the same information manufacturers of all existing tobacco products must provide pursuant to the law). In addition, for any new tobacco product that is similar to existing tobacco products, the law requires that the manufacturer show the FDA that the product is substantially equivalent to a tobacco product already on the market and meets all related product standards for that type of product.

Before introducing any brand new tobacco product that is not similar to existing tobacco products, the law requires additional premarket review by the FDA based on the manufacturer’s submission of, among other things, samples of the product and its proposed labeling; information on the tobacco product’s ingredients, properties and principles of operation; available information on the health risks of the product; and information on how the product complies with existing tobacco product standards. Based on the goal of protecting overall public health, the FDA may permit the product to be sold, forbid its sale, or allow its sale subject to restrictions on its sale, distribution, and marketing.

Modified Risk Tobacco Products

Any tobacco products for which manufacturers make explicit health claims are subject to FDA authority under existing law, but the FDA has not applied this authority to reduced risk claims. The law does not change the FDA’s authority in relation to tobacco products that are intended to be used for the treatment of tobacco dependence or for smoking cessation, or in relation to tobacco products claiming other health benefits separate from tobacco use risk reduction. But all tobacco products that manufacturers advertise or market, explicitly or implicitly, as offering a reduced risk of harm or disease compared to other tobacco products fall under the new provisions of the law relating to “modified risk tobacco products.”

The law defines modified risk tobacco products as tobacco products sold or distributed to reduce harm or the risk of disease compared to other tobacco products, including, among other things, any product whose labeling or advertising explicitly or implicitly presents it as being less harmful than other commercially available tobacco products or having lower levels (or being free) of a specific substance.

Manufacturers will be required to obtain premarket approval before marketing or selling a modified risk tobacco product by providing the FDA with the information required of proposed brand new tobacco products, plus more extensive information on the product’s effect on tobacco-related diseases and health and its ability to reduce risk. The law authorizes the FDA to approve a proposed modified risk tobacco product based on the submission of thoroughly substantiated

information regarding the benefit of the product to overall public health.

For an approved product, the law requires the FDA to ensure that the advertising and labeling of such a product will enable the public to understand the modified risk characteristics of the product and its relative significance in relation to total health and all of the health harms associated with tobacco use. The FDA can also impose restrictions and requirements on the product's labeling and advertising and marketing to educate consumers or to protect public health.

Approval as a modified risk tobacco product will last for five years. The law requires manufacturers to conduct and annually report to the FDA post-market surveillance of such modified risk product's actual usage. If that surveillance, or any other evidence, shows that the availability of the product is not promoting overall public health gains, the FDA can rescind or not renew the approval.

Related Provisions

The law requires tobacco product manufacturers to disclose to the agency detailed information regarding ingredients, additives, nicotine, and harmful product and smoke constituents. This provides the FDA with information that it is authorized to use to order changes to tobacco products for purposes of reducing the harm they cause and to educate the public about the chemicals in tobacco products and health effects of tobacco use.

The law establishes a Tobacco Products Scientific Advisory Committee to help guide the FDA on the effects of alterations in the nicotine yields of tobacco products and on whether there exists a threshold level below which nicotine does not cause addiction in the case of a given tobacco product. The committee will also provide its review of "other safety, dependence, or health issues relating to tobacco products" when requested by the FDA. The committee will consist of 12 members and be heavily weighted toward public health. Voting members will include seven scientists or health professionals, one government official and one representative of the general public. Non-voting members, described by the law as serving in a "consulting" role, will include two representatives of the tobacco industry and one representative of tobacco growers. The law establishes additional protections against conflicts of interest—disallowing certain tobacco industry ties among voting members—and prohibits non-voting members from chairing the Advisory Committee.

Adulterated and Misbranded Tobacco Products

Adulterated and misbranded products are prohibited by the Food, Drug, and Cosmetic Act (FDCA). Most of the provisions in the FDA law are part of a new tobacco product section that has been added to the FDCA, including definitions of what constitutes prohibited adulterated and misbranded tobacco products. Under the amended statute, a tobacco product will be regarded as adulterated if, among other things, it is contaminated by any added poisonous or deleterious substance, its manufacturing facilities are not sanitary or fail to satisfy applicable product standards, or it does not have required premarket approval. The law further defines prohibited misbranded tobacco products to include, among other things, any tobacco product with packaging that fails to meet the specified packaging and labeling requirements or that was not manufactured in a facility duly registered under the Act. Ordinary cigarettes and other tobacco products are not considered adulterated or misbranded.

Tobacco Product Marketing Restrictions

The Family Smoking Prevention and Tobacco Control Act requires a number of restrictions on cigarette and smokeless tobacco product advertising and other marketing, and also grants the FDA authority to impose additional restrictions on the advertising, promotion and other marketing of tobacco products in order to promote overall public health. All such restrictions will be subject to review under the First Amendment, which protects certain commercial speech. The FDA finding as to whether such regulation would be appropriate for the protection of the public health will be determined with respect to the population as a whole, including users and non-users of tobacco.

The new law gives the FDA wide-ranging authority to regulate tobacco product marketing. Apart from the agency's power to implement new regulations in the future, the law mandates certain specific changes, as follows:

- Restricts tobacco advertising and promotion in order to promote overall public health (the judicial system will almost certainly be asked to adjudicate whether any of the legislated advertising restrictions unconstitutionally interferes with free speech under the First Amendment)
- Stops illegal sales of tobacco products to minors
- 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)
- 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
- 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 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, except in adult-only facilities, to black text on white background visuals and spoken words (no images, music or sound effects)
- 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
- 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 includes other significant changes, as well. For example, it:

- Limits the previously existing 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. (It leaves unchanged local and state government power to regulate smokeless tobacco or other tobacco products.)
- Blocks tobacco companies from claiming that the FDA has approved or certified any tobacco product

4

Tobacco Product Labeling and Advertising Warnings

The new law prescribes stronger health warning labels on certain tobacco product packages and advertisements. Currently, the warning labels for cigarettes read as follows, as they have for the past quarter century:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health

SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide

Under the new law, the warnings for cigarettes will be changed to read as follows (no later than 39 months after enactment):

WARNING: Cigarettes are addictive

WARNING: Tobacco smoke can harm your children

WARNING: Cigarettes cause fatal lung disease

WARNING: Cigarettes cause cancer

WARNING: Cigarettes cause strokes and heart disease

WARNING: Smoking during pregnancy can harm your baby

WARNING: Smoking can kill you

WARNING: Tobacco smoke causes fatal lung disease in non-smokers

WARNING: Quitting smoking now greatly reduces serious risks to your health

The law mandates that the new warnings cover 50 percent of the top half of the front and back of each pack with graphics depicting the health consequences of tobacco use, and that the word "WARNING" appear in 17-point type in black and white text only. Warnings will be randomly displayed in each 12-month period and rotated quarterly.

Currently, the warning labels for smokeless tobacco products read as follows:

WARNING: This product may cause mouth cancer

WARNING: This product may cause gum disease and tooth loss

WARNING: This product is not a safe alternative to cigarettes

Under the legislation, the warnings for smokeless tobacco products will be changed to read as follows (12 months after enactment):

WARNING: This product can cause mouth cancer

WARNING: This product can cause gum disease and tooth loss

WARNING: This product is not a safe alternative to cigarettes

WARNING: Smokeless tobacco is addictive

The smokeless tobacco warnings will cover 30 percent of the two principal display panels of each package, and the word "WARNING" will appear in 17-point type in black and white text only. Warnings will be randomly displayed in each 12-month period and rotated quarterly.

The law requires the placement of the same cigarette and smokeless tobacco product warning labels in advertisements, rotated at random and in equal proportion in each 12-month period. The warnings will comprise at least 20 percent of the entire area of each advertisement and appear in black and white text only.

The FDA is also authorized to further revise the labeling requirements for cigarettes and smokeless tobacco products, including changing the text, format and type size, without new action by Congress. The FDA may also establish warning labels on other tobacco products.

Through an amendment to the Federal Cigarette Labeling and Advertising Act, the new law grants the FDA authority to require the posting of information concerning tar and nicotine yields on cigarette packages or advertisements. The FDA can also require disclosure of information relating to other tobacco product constituents—in package or advertising inserts, or in other ways—if the agency determines that such disclosure would benefit public health or otherwise increase consumer awareness of the health consequences of tobacco use.

Unrelated to warning labels per se, but likewise affecting the messages to which consumers are exposed, the law prohibits the use of such terms as "light," "mild" and "low-tar" on tobacco product packages and in advertisements because of such terms mislead consumers into believing that certain cigarettes are safer than others.

Tar, Nicotine and Other Smoke Constituent Disclosures

The new law requires tobacco product manufacturers to disclose ingredients, including tar, nicotine and harmful smoke constituents, in their tobacco products. Effective six months after enactment of the law, tobacco companies will be required to disclose to the FDA the following information for each tobacco product brand and sub-brand:

- All ingredients added to the product or its tobacco, paper, filter or other part
- A description of the content, delivery and form of nicotine in each product
- A list of all constituents, including smoke constituents, identified by the FDA as harmful or potentially harmful to health
- All documents relating to the health, toxicological, behavioral or physiological effects of current or future tobacco products or to their constituents, ingredients, components or additives

Manufacturers will also be required to inform the FDA of any changes to the contents of a given product, and to submit all such information at least 90 days prior to the introduction of new brands. The FDA, in turn, will be charged with publicly disseminating a brand-specific list of harmful and potentially harmful constituents.

The law further requires tobacco companies to provide, at the request of the agency, all documents relating to:

- Research on the health, harms or effects of tobacco products or any of their constituents or additives
- Whether the health risks of a tobacco product could be reduced by using a technology available or known to the tobacco company
- Tobacco product marketing research or the effectiveness of tobacco product marketing practices

Pursuant to regulations that the FDA will issue, the companies will be required to test and report on all tobacco product constituents, ingredients and additives, including smoke constituents, by brand and sub-brand, that the FDA determines should be tested to protect the public health.

Though not specifically set forth in the new FDA law, existing federal law will require tobacco companies, upon direction from the FDA, to turn over all documents identified above in electronic form, thus protecting the agency against inundation with potentially millions of pieces of paper.

The new law also amends the Federal Cigarette Labeling and Advertising Act (FCLAA) to require a rulemaking proceeding to determine whether cigarette and other tobacco product manufacturers should be required to disclose tar and nicotine levels on their advertising, packaging or labels. The FDA is authorized to establish new methods for measuring tar and nicotine levels. The same amendment allows the adoption of additional FCLAA-based rule-making that would require further

disclosures to the public—but not on product labels or ads—relating to other tobacco product constituents if such disclosure were determined to increase consumer awareness of the health consequences of tobacco use or otherwise benefit public health.

The law also provides that states retain the power to require tobacco manufacturers to disclose ingredients and other information, including information currently exempt from disclosure under federal law, in the event states identify any information that has not already been obtained or shared by the FDA.

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.)

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.

Preemption

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. 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, and increase nationwide efforts to block tobacco product sales to youth.

“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 new FDA law eliminates much of the federal preemption of state and local efforts to restrict, prohibit, or otherwise regulate cigarette advertising or promotion, which had been in place since 1969, while reserving to the federal government the authority to regulate tobacco products themselves, except through so-called “fire-safe” laws.

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, a local government may require tobacco retailers to prominently display point-of-sale warnings and cessation messages, including graphic images depicting 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.

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.

8

Preventing Illicit Trade in Tobacco Products

The new FDA law finds that tobacco products have been used to facilitate and finance criminal activities both domestically and internationally, and that illicit trade in tobacco products has been linked to organized crime and terrorist groups. The legislation defines “illicit trade” as “any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.”

To combat illicit trade in tobacco products, the law requires that:

- The labels, packaging and shipping containers of tobacco products sold in the United States “bear the statement ‘sale only allowed in the United States’”
- The FDA issue new regulations providing for detailed industry recordkeeping and close monitoring of the movement of tobacco products from the point of manufacture through distribution to retail outlets, and provide the U.S. government with inspection rights relating to such records
- Tobacco product manufacturers and distributors report suspected contraband trafficking of tobacco products
- The Comptroller General of the United States collect data on cross-border advertising and trade in tobacco products and submit a report to Congress within 18 months of the law’s enactment that includes recommendations on monitoring cross-border tobacco product trade and preventing and eliminating cross-border advertising of tobacco products

In addition, the law forbids several “prohibited acts,” including:

- Manufacturing, selling, holding or dispensing counterfeit tobacco products or counterfeit components of any tobacco product, including any counterfeit labels, tax stamps, or other markings
- Making, holding, selling or concealing any punch, die, plate, stone or other item designed to make counterfeit labels, markings or stamps in order to create counterfeit tobacco products
- Doing any other act that causes a tobacco product to become a counterfeit tobacco product
- Selling tobacco products in violation of a no-sale order (which would occur when the FDA has determined that a person has committed repeated violations of mandated marketing restrictions at a particular retail outlet)

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. These fact sheets 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.

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