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FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009

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Summary

The 111th Congress is considering legislation that would give the Food and Drug Administration (FDA) broad new statutory authority to regulate the manufacture and marketing of cigarettes and smokeless tobacco products under the Federal Food, Drug, and Cosmetic Act (FFDCA). On April 2, 2009, the House passed the Family Smoking Prevention and Tobacco Control Act (H.R. 1256; H.Rept. 111-58, part 1 and 2). On May 20, the Senate Committee on Health, Education, Labor and Pensions approved an almost identical bill (S. 982). Similar legislation was first introduced in the 108th Congress and passed the Senate in 2004 and the House in 2008 with strong bipartisan support. The Administration strongly supports H.R. 1256/S. 982.

H.R. 1256/S. 982 would create a new FFDCA Chapter IX solely for the regulation of tobacco products. While the bill's language draws extensively on the FFDCA's existing provisions for regulating pharmaceutical products and medical devices, tobacco products would be regulated under new legal authority based on a public health standard rather than the safety and effectiveness standard by which the FDA regulates drugs and devices. Under the new language, FDA would have to demonstrate that any proposed tobacco product regulation was appropriate for the protection of public health, taking into consideration the risks and benefits to the population as a whole.

Among its many provisions, H.R. 1256/S. 982 would require all tobacco product manufacturers to register with FDA. All registered facilities would be inspected every two years. H.R. 1256/S. 982 would require the FDA to reissue its 1996 tobacco rule, which was struck down by the U.S. Supreme Court in 2000. The rule would place new restrictions on youth access to tobacco products, end all remaining brand-name sponsorship of sporting and other entertainment events, and limit tobacco advertising in publications with a significant youth readership to black-on-white text only. In addition, the existing health warnings on tobacco product packaging and advertising would be replaced with more explicit and conspicuous health warnings. H.R. 1256/S. 982 would give FDA the authority to develop regulations restricting the sale, distribution, advertising, and promotion of tobacco products, to the extent permitted by the First Amendment. The agency also would have the authority to require changes in the design and characteristics of current and future tobacco products, such as the reduction or elimination of harmful ingredients and additives. FDA would not have the authority to reduce nicotine yields to zero or ban tobacco products.

Under H.R. 1256/S. 982, manufacturers would have to obtain FDA approval in order to market a new tobacco product, unless FDA determined that it was substantially equivalent to a product already on the market, or a minor modification of an existing product. The bill would prohibit the use of descriptors such as "light" and "mild" and require manufacturers seeking FDA approval to market a product for which they intend to make a reduced-risk claim to provide evidence substantiating that claim. H.R. 1256/S. 982 would require FDA to develop new requirements for testing and reporting tobacco product ingredients and smoke constituents, and to issue new recordkeeping requirements to help counter the illicit trade of tobacco products. FDA's new regulatory activities would be paid for by user fees assessed on the manufacturers. This report provides a detailed summary of the provisions in H.R. 1256/S. 982 and discusses some of the public health and legal issues it raises. A companion report, CRS Report R40196, *FDA Tobacco Regulation: History of the 1996 Rule and Related Legislative Activity, 1998-2008*, by C. Stephen Redhead and Vanessa K. Burrows, provides more background on the FDA rule and past efforts to give the agency the authority to regulate tobacco products.

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Introduction

On April 2, 2009, the House passed the Family Smoking Prevention and Tobacco Control Act (H.R. 1256; H.Rept. 111-58, part 1 and 2) by a vote of 298-112. H.R. 1256, introduced by Representative Waxman (D-CA), would give the Food and Drug Administration (FDA) broad new statutory authority under the Federal Food, Drug, and Cosmetic Act (FFDCA)[1] to regulate the manufacture, distribution, advertising, promotion, sale, and use of cigarettes and smokeless tobacco (e.g., snuff and chewing tobacco). Similar legislation passed the House in July 2008, but was never taken up by the Senate. On May 5, 2009, Senator Reid (D-NV) introduced the Family Smoking Prevention and Tobacco Control Act in the Senate, on behalf of its primary sponsor, Senator Kennedy (D-MA). S. 982, which is almost identical to the House-passed measure, was approved with amendments by the Committee on Health, Education, Labor and Pensions on May 20 and now awaits Senate floor action. The Administration has signaled its strong support for the legislation.

The Family Smoking Prevention and Tobacco Control Act would create a new FFDCA Chapter IX solely for the purpose of regulating tobacco products. Among its many provisions, the legislation would:

- require all tobacco product manufacturers to register with the FDA and provide the agency with a detailed product list;
- mandate biennial inspection of all registered establishments;
- replace the existing health warning labels with more explicit health warnings in bold type occupying at least 30% of the front and back of the product package;
- require the manufacturer of a new tobacco product to submit a marketing application for FDA approval before entering the market, unless the new product is determined to be substantially equivalent to a tobacco product already on the market or it represents a minor modification of an existing product;
- require manufacturers seeking FDA approval, in order to market a product with a reduced-risk or reduced-exposure claim (including the use of descriptors such as “light,” “mild,” and “low”), to provide scientific evidence substantiating that claim and agree to conduct postmarket surveillance;
- give FDA the authority to regulate the sale, distribution, advertising and promotion of tobacco products in order to protect public health;
- require FDA to regulate Internet tobacco sales;
- authorize FDA to establish tobacco product standards requiring changes to the design and characteristics of tobacco products in order to protect public health (e.g., reducing nicotine yields and eliminating other harmful constituents);
- require FDA to establish good manufacturing practices for tobacco product manufacturers;
- require FDA to develop new regulations for the testing, reporting, and public disclosure of tobacco product ingredients and smoke constituents;
- preserve the authority of states and localities to take additional measures to restrict the distribution, advertising, promotion, sale, access to, and use of tobacco products;

[1] 21 U.S.C. § 301 et seq.

- instruct FDA to issue new recordkeeping requirements to help counter the illicit trade of tobacco products; and
- assess user fees on manufacturers to pay for the cost of FDA tobacco regulation.

In addition, H.R. 1256/S. 982 would require FDA to reissue its 1996 tobacco rule, which the U.S. Supreme Court struck down. The FDA rule consisted of three sets of provisions aimed at reducing underage tobacco use: restrictions on the sale and distribution of cigarettes and smokeless tobacco to reduce youth access to those products; restrictions on tobacco product marketing and advertising; and a new labeling requirement for packaging and advertising (see text box). Several provisions in the FDA rule were incorporated in the 1998 Master Settlement Agreement (MSA) between the states and the major cigarette companies. A summary of the MSA's public health provisions is provided in the **Appendix**.

Summary of 1996 FDA Tobacco Rule

Youth Access Restrictions

- Prohibited the sale of cigarettes or smokeless tobacco to persons under age 18.
- Required retailers to check photo ID to verify age of purchasers under age 27.
- Required that retail sales be conducted in a direct, face-to-face exchange.
- Prohibited the sale or distribution of individual cigarettes.
- Required the sale and distribution of cigarettes in packs of at least 20.
- Prohibited tobacco-product vending machines except in adult-only facilities.
- Prohibited self-service displays of tobacco products except in adult-only facilities.
- Prohibited free samples of cigarettes and smokeless tobacco.

Labeling Requirement

- Required tobacco product packaging and advertising to include the statement: "Nicotine-Delivery Device for Persons 18 and Older."

Advertising and Promotion Restrictions

- Prohibited outdoor advertising (e.g., billboards, posters, placards) within 1,000 feet of a school or playground.
- Limited advertising in publications with significant youth readership to a black-on-white, text-only format.
- Limited advertising in audio format to words with no music or sound effects; limited advertising in video format to static, black-on-white text.
- Prohibited the use of a non-tobacco trade or brand name as a tobacco product brand name, unless that tobacco product brand name existed on January 1, 1995.
- Prohibited the marketing, licensing, distribution, or sale of all non-tobacco promotional items and services identified with a cigarette or smokeless tobacco brand name (e.g., tee shirts and caps).
- Prohibited gifts, credits, and coupons linked to the purchase of tobacco products.
- Prohibited brand-name sponsorship of sporting and other cultural events.

In asserting jurisdiction over tobacco products, FDA argued that the FFDCA gave it the authority to regulate tobacco products based on its determination that cigarettes and smokeless tobacco are delivery devices for nicotine, an addictive drug. Under the FFDCA, drug and device manufacturers must demonstrate that their products are both safe and effective in order to gain FDA marketing approval. The safety and effectiveness standard poses a difficult challenge for regulating tobacco products, which are manifestly unsafe when used as intended. In 2000, the U.S. Supreme Court invalidated the FDA tobacco rule, finding that the agency's action was inconsistent with the congressional intent expressed in the FFDCA's overall regulatory scheme

and in other tobacco-related legislation.[2] For example, the Court concluded that if the FDA asserted jurisdiction based on the FFDCA's existing drug and device authorities, it would have no choice but to prohibit the marketing of such harmful products. A ban on tobacco products, argued the Court, would plainly contradict congressional policy. The Court's decision made it clear that Congress would have to enact legislation giving FDA new statutory authority over tobacco products in order for the agency to assert jurisdiction.

Lawmakers first drafted such language in the 105th Congress (1997-1998) as part of an unsuccessful attempt to legislate the proposed national tobacco settlement. The language drew extensively on the FFDCA's existing drug and device provisions, but with modifications. By attempting to establish a new legal authority within the FFDCA for regulating tobacco products, the bill's sponsors sought to address the unique challenges tobacco products present and avoid the safety and effectiveness standard that applies to the regulation of drugs and devices. Under the new language, FDA would have to demonstrate that any proposed tobacco regulation was appropriate for the protection of public health. Such a determination would involve a consideration of the risks and benefits to the population as a whole, including both users and nonusers of tobacco products.

Following the Supreme Court's decision, and building on the language developed in the 105th Congress, a bipartisan, bicameral group of lawmakers first introduced the Family Smoking Prevention and Tobacco Control Act in the 108th Congress (H.R. 4433, S. 2461).[3] The legislation was the product of months of negotiations in which lawmakers sought to balance the competing interests of public health groups and the tobacco industry. Both sides supported giving FDA the authority to regulate cigarettes and smokeless tobacco products, but they disagreed on the central question of how much regulatory control the agency should be given.

Public health advocates want FDA to have broad authority to take whatever actions the agency considers necessary to protect public health. They argue that giving FDA limited authority would invite tobacco companies to mount a legal challenge to every proposed regulatory action and would shield tobacco companies from liability. A weak FDA tobacco bill would, in their view, be worse than no bill at all. The tobacco companies, on the other hand, want to see certain restrictions placed on FDA's authority. They believe that having the federal government regulate and approve their products will help reduce future uncertainty and restore predictability for the industry by creating a uniform set of federal standards for the manufacture and marketing of tobacco products. But they oppose giving FDA unfettered authority to modify their products to the point that they are no longer acceptable to adult smokers, for example, by eliminating nicotine.

The current Family Smoking Prevention and Tobacco Control Act (H.R. 1256, S. 982) represents a compromise between those two competing positions. Leading public health groups and Philip Morris, the nation's largest cigarette manufacturer with about half of the U.S. market, strongly support the bill's regulatory framework. The other major cigarette companies, however, have broken ranks with Philip Morris and are opposed to the legislation. While they continue in principle to support FDA regulation of their products, they fear that the sweeping new regulatory

[2] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

[3] During the 108th Congress the Senate added S. 2461 as an amendment to a corporate tax package, but the language was subsequently removed in conference. The Family Smoking Prevention and Tobacco Control Act was reintroduced in the 109th Congress (H.R. 1376, S. 666) and again in the 110th Congress (H.R. 1108, S. 625), during which it was approved by the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pension (HELP). The House passed H.R. 1108 in July 2008 by a wide margin, but no further action was taken in the Senate.

authority outlined in the legislation, including the likelihood of tight restrictions on marketing, will help further consolidate Philip Morris's market dominance.

Comprehensive FDA tobacco legislation received an important endorsement from the Institute of Medicine (IOM). In a May 2007 report on reducing tobacco use in the United States, the IOM concluded that while strengthening existing tobacco control measures (e.g., state anti-smoking programs, excise taxes, indoor smoking restrictions) would result in some additional decline in smoking prevalence, more substantial and enduring reductions in tobacco use would only come from stronger federal regulation.[4] Several of the IOM's recommendations would be implemented by the Family Smoking Prevention and Tobacco Control Act. They include conferring on FDA broad regulatory authority over the sale, distribution, and marketing of tobacco products; empowering FDA to regulate the design and characteristics of tobacco products; strengthening health warning labels on packages and advertising; and establishing science-based standards for evaluating reduced-harm products.

This report focuses on the Family Smoking Prevention and Tobacco Control Act. It includes a brief discussion of the contrasting views of FDA tobacco regulation held by the public health community and the industry, and provides some analysis of a number of key regulatory issues that the bill raises. **Table 1** provides a detailed summary of all the provisions in H.R. 1256 (as passed by the House) and the key differences in S. 982 (as reported out of committee). A companion report, CRS Report R40196, *FDA Tobacco Regulation: History of the 1996 Rule and Related Legislative Activity, 1998-2008*, by C. Stephen Redhead and Vanessa K. Burrows, provides some analysis of the 1996 FDA tobacco rule and the industry's successful legal challenge that overturned it. It also reviews the 1997 proposed national tobacco settlement and the implementing legislation that was introduced and debated in the 105th Congress. That report concludes with a summary of legislative activity on the Family Smoking Prevention and Control Act in the 108th, 109th, and 110th Congresses.

Contrasting Views on FDA Tobacco Regulation

Public Health Viewpoint

The Campaign for Tobacco-Free Kids is a leading anti-tobacco lobby. Working in partnership with the American Lung Association, the American Cancer Society, and the American Heart Association, the Campaign has championed comprehensive federal regulation of tobacco products.[5] It argues that such regulation is necessary to reduce the enormous public health impact of tobacco use. According to the Centers for Disease Control and Prevention (CDC), more than 400,000 deaths each year are attributable to tobacco use, including one-third of all cancer deaths. Tobacco use accounts for almost $100 billion in annual health care costs.[6] Despite the harm they cause, the Campaign notes that tobacco products are exempt not just from the FFDCA, but also from other federal consumer protections laws such as the Consumer Product Safety Act and the Controlled Substances Act. Thus, they are exempt from basic consumer protections like ingredient disclosure and product testing. The Campaign believes that the tobacco companies have taken advantage of this lack of regulation by marketing their products to youth, deceiving the public about the addictiveness of their products, and discouraging current tobacco users from

[4] IOM (Institute of Medicine), *Ending the Tobacco Problem: A Blueprint for the Nation* (Washington, DC: National Academies Press, 2007).

[5] The Campaign maintains an extensive website at http://www.tobaccofreekids.org.

[6] CDC statistics on the health and economic impact of tobacco use are available at http://www.cdc.gov/tobacco.

quitting. The Campaign argues that strong and effective federal regulation is necessary to change industry practice.

The Campaign believes that FDA is the only agency with the necessary scientific and regulatory expertise to effectively regulate the manufacture, marketing, labeling, and sale of tobacco products. Along with numerous pubic health and other organizations, it strongly supports H.R. 1256/S. 982.

Industry Viewpoint

In 2001, Philip Morris issued a white paper in support of legislation giving FDA authority to regulate cigarettes. The company explained that its support for such legislation did not signal a reversal of its earlier opposition to the FDA's attempt to regulate cigarettes as restricted medical devices. Philip Morris opposed the 1996 FDA rule on the grounds that it would have left the agency with no choice but to ban the sale of cigarettes. The company argued that cigarettes simply cannot be found to be safe and effective as required under the FFDCA's existing drug and device provisions, a position with which the Supreme Court agreed in the *FDA v. Brown & Williamson Tobacco Corp* decision.

In the white paper, Philip Morris argued for giving FDA new legal authority to regulate cigarettes, not as drugs or medical devices but in a manner that reflects the "unique challenges that cigarettes present." Such regulation, said the company, "would provide greater consistency in tobacco policy, more predictability for the tobacco industry, and an effective way to address issues that are of concern.... These issues include youth smoking; ingredient and [smoke] constituent testing and disclosure; content of health warning on cigarette packages and in advertisements; use of brand descriptors such as 'light' and 'ultra light'; good manufacturing practices for cigarettes; and standards for defining, and for the responsible marketing of any reduced risk or reduced exposure cigarettes." Philip Morris set out in the white paper several principles for FDA tobacco legislation:

- Tobacco regulation should reflect the unique health, social and economic issues associated with such products. Cigarettes should be regulated as cigarettes, not as a medical device.
- Regulation should not equal prohibition. Adults should be able to make their own decision whether to smoke. The government should continue to inform the public about the dangers of tobacco products and discourage their consumption, but should not restrict an adult's ability to make a decision about smoking.
- FDA should require that ingredients added by the manufacturers do not increase the inherent risks or addictiveness of smoking. The agency should have the authority to impose mandatory design changes to cigarettes to help reduce harm, provided the changes do not significantly diminish adult smokers' enjoyment of the product.
- Regulation should define reduced exposure and reduced risk products and establish guidelines for communications about such products in a way that is consistent and accurate and does not encourage smoking or discourage quitting.
- FDA should continue to address the broad issues of disclosure (e.g., the content of warning labels, information about ingredients and smoke constituents) so that adults smokers remain informed about health risks.

Philip Morris maintains that any new legislation must recognize cigarettes as legal products and respect the decision of adults to smoke. The company opposes any proposals that would give

FDA the authority to ban cigarettes outright or to achieve a de facto prohibition by imposing ever-lower tar and nicotine yields that would render the product unpalatable to adult smokers. Such product changes, argues the company, would drive smokers towards illicit, unregulated products, where there are no standards for ingredients or tar and nicotine levels. FDA used a similar line of reasoning in developing the tobacco rule when it concluded that banning tobacco products under the FFDCA's drug and device provisions was not an option. The agency reasoned that a ban on cigarettes would encourage cigarette smuggling and the development of a black market supplying smokers with unregulated and potentially more dangerous products.

While Philip Morris actively supports the Family Smoking Prevention and Tobacco Control Act, the other major cigarette companies—R. J. Reynolds (which merged with Brown & Williamson in July 2004) and Lorillard—have criticized the legislation. Like Philip Morris, Lorillard supports additional regulation of tobacco manufacturers and tobacco products, but emphasizes that the FDA may "ultimately move to ban the conventional cigarette product" and that some legislation may "allow the FDA to alter what occurs naturally in the [tobacco] leaf."[7] Lorillard believes that federal legislation "must advocate the research and oversee the development of potentially reduced exposure products" and "should codify the marketing and advertising restrictions already agreed to" in the Master Settlement Agreement. R.J. Reynolds would support additional "reasonable" regulation of tobacco products provided that tobacco remains legal and that any new regulation preserves the rights of adults to choose and purchase a wide range of "consumer-acceptable" cigarette brands.[8] But they also stress the importance of maintaining a level playing field upon which manufacturers can compete for the business of adult smokers. This final point appears to lie at the heart of their opposition to the proposed legislation. R.J. Reynolds and Lorillard, which together account for approximately 38% of the U.S. cigarette market, may fear that sweeping new regulation of their products, including tight restrictions on marketing, will be to Philip Morris's advantage, allowing the nation's number one cigarette manufacturer to lock in its leading market share. They may worry that new restrictions on advertising would force consumers to rely on brand recognition and product placement, which would give industry-leader Philip Morris an advantage.[9]

Tobacco Product Regulation under H.R. 1256/S. 982

The Family Smoking Prevention and Tobacco Control Act would result in a number of important changes in the labeling, advertising, and marketing of cigarettes and smokeless tobacco. As previously noted, H.R. 1256/S. 982 would require the FDA to reissue its tobacco rule (minus the labeling provision). That would place new restrictions on youth access to tobacco products and on tobacco advertising, beyond those included in the MSA (see **Appendix**). For example, all remaining brand-name sponsorship of sporting and other entertainment events would come to an end, and advertising in publications with a significant youth readership would be limited to black-on-white text. In addition, more explicit and conspicuous health warnings would appear on all tobacco product packaging and advertising. FDA would have the authority to revise the size and content of the warnings and add color graphics, if it determined that such changes would promote a greater public understanding of the health risks of tobacco use.

[7] Lorillard Tobacco Company, Does Lorillard Favor Government Regulation of its Products? at http://www.lorillard.com/index.php?id=6#70.

[8] R. J. Reynolds Tobacco Company, Our Position on Further Federal Regulation, at http://www.rjrt.com/legal/fedRegPosition.asp.

[9] More information on each company's position on federal regulation of its products is available online at http://www.rjrt.com (R. J. Reynolds Tobacco Company) and http://www.lorillard.com (Lorillard Tobacco Company).

H.R. 1256/S. 982 also would give FDA the authority to develop regulations restricting the sale, distribution, advertising, and promotion of tobacco products, to the full extent permitted by the First Amendment. Any proposed regulation would have to meet a new public health standard. That standard would require FDA to demonstrate that the proposal was appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole, including users and nonusers of tobacco products. In addition, FDA would have the authority to require changes in the design and characteristics of current and future tobacco products, such as the reduction or elimination of harmful ingredients and additives. Again, the agency would have to show that any such proposal was appropriate for protecting public health, based on a consideration of the risks and benefits to the population as a whole.

Under the legislation, manufacturers would have to obtain FDA approval in order to market a new product. The same public health standard would apply to such applications. Thus, FDA could deny a new product application if, among other things, the company failed to demonstrate that marketing the product would be appropriate for protecting public health. For conventional tobacco products, it is difficult to imagine how a manufacturer seeking approval of a new product would be able to meet that standard. However, H.R. 1256/S. 982 provides two exceptions to the requirement that manufacturers obtain premarket approval for new products: (1) the manufacturer makes a claim and FDA, upon review, agrees that the new product is substantially equivalent (as defined in the bill) to a product already on the market; or (2) the new product is determined to be a minor modification of an existing product. For the first 21 months after the bill's enactment, manufacturers would be permitted to market a new product for which a substantial equivalence claim has been submitted, even if FDA has not reviewed and approved the claim. That final provision has attracted some criticism from public health officials. It was added to accommodate the industry's concern that it will take FDA some time to establish a tobacco regulatory program and have in place the necessary personnel and procedures to review industry submissions.

Finally, H.R. 1256/S. 982 would prohibit the use of descriptors such as "light" and "mild." Any product for which the manufacturer, explicitly or implicitly, wished to make a reduced-risk claim would have to provide evidence substantiating that claim and meet additional requirements in order to obtain FDA approval to market that product. **Table 1** provides a detailed summary of all the tobacco control provisions in H.R. 1256 (as passed by the House) and the key differences in S. 982 (as reported out of committee). Unlike S. 982, the House measure includes several provisions dealing with retirement benefits of federal employees. Those provisions, which are not included in **Table 1**, are intended to offset the projected loss in federal excise tax revenue due to enactment of H.R. 1256 and the resulting decline in tobacco consumption.

A more detailed discussion of some of the issues surrounding the regulation of reduced-risk tobacco products and FDA's authority to establish tobacco product standards follows. This section of the report concludes with a word about legislation's treatment of menthol cigarettes.

Reduced-Risk Tobacco Products

Both the tobacco industry and the public health community are eager to establish a regulatory scheme for "reduced-risk" tobacco products. In recent years Philip Morris and the other leading cigarette companies have test marketed a variety of products that are potentially less harmful to the individual user than traditional tobacco products. They include cigarettes made using genetically modified tobacco, and cigarette-like products that deliver nicotine using a combustion process that involves lower temperatures and a more controlled burn. The companies want FDA's approval to market these products without fear of the agency taking regulatory action against

them. FDA has in the past asserted jurisdiction when cigarette manufacturers have expressly promoted their products as beneficial to health.[10]

Public health advocates insist that FDA be given the authority not just to assess industry claims that a reduced-risk product is less harmful to the individual user under normal conditions of use, but also to weigh the risks and benefits to the wider population. They are concerned about recent efforts by the smokeless tobacco companies to market oral snuff and chewing tobacco as a safer alternative to smoking. The companies see the growing anti-smoking sentiment in the country and the spread of indoor (and outdoor) smoking restrictions as an opportunity to market their products to smokers who have trouble finding somewhere to smoke and who are considering alternative sources of nicotine. Epidemiological studies indicate that compared to smoking cigarettes, using smokeless tobacco products exposes an individual to less overall risk from a narrower range of diseases. But public health experts worry that promoting smokeless tobacco as a safer alternative to smoking will undermine efforts both to discourage youngsters from using smokeless tobacco and to encourage adult smokers to give up tobacco products altogether. As a consequence, there may be little if any overall improvement in the nation's health.

Public health officials often point to the introduction of low-tar cigarettes in the 1960s and 1970s to illustrate the challenges of regulating reduced-risk products. The companies were careful not to make any explicit health claims when they started to market "light" and "ultralight" cigarettes, but the implicit message was that these products provided a less harmful way of smoking and many smokers believed and continue to believe that they are safer than regular-strength cigarettes. Light cigarettes emit lower levels of tar and nicotine than regular-strength cigarettes, as measured by a standardized smoking machine test developed by the Federal Trade Commission and commonly referred to as the FTC method. However, the National Cancer Institute (NCI) concluded that there is "no convincing evidence" that the introduction of such low-yield products "resulted in an important decrease in the disease burden" among smokers.[11] Many smokers who switched to low-yield cigarettes changed the way they smoked so as to maintain the desired intake of nicotine. They smoked more intensely by inhaling more deeply and more often and by covering the ventilation holes at the base of the filter. This compensatory smoking behavior exposed them to higher amounts of tobacco toxins.[12]

H.R. 1256/S. 982 would prohibit manufacturers from marketing "modified risk tobacco products" without FDA prior approval. The legislation defines modified risk tobacco products as any product:

- whose labeling or advertising indicates, explicitly or implicitly, that the product is less risky than other tobacco products or reduces exposure to a substance in the product or its smoke;

[10] The FFDCA's definition of drug includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease ... " and "articles (other than food) intended to affect the structure or any function of the body.... (§ 201(g)(1)) During the 1950s, the agency took regulatory action against cigarettes advertised as effective in preventing respiratory and other diseases and cigarettes promoted as weight-reduction aids. The FDA regulates several nicotine replacement therapies to help tobacco users quit. These products include nicotine gum, transdermal nicotine patches, nicotine inhalers, and nicotine nasal spray.

[11] National Institutes of Health, National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph 13 (NIH Pub. No. 02-5074) (Oct. 2001).

[12] For a detailed discussion of the scientific and regulatory issues surrounding reduced risk tobacco products, see the Institute of Medicine's 2001 report, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, Washington, DC: National Academy Press.

- whose manufacturer has taken any action (other than through labeling or advertising) that "would be reasonably expected to result in consumers believing" that the product or its smoke reduces risk or exposure; or
- whose labeling or advertising uses descriptors such as "light," "mild," or "low" to characterize the level of a substance in the product.

In order to gain approval to market a modified risk tobacco product, a manufacturer would have two options. The first is to submit a *reduced-risk claim.* That would require the company to demonstrate to FDA that the product, "as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and benefit the health of the population as a whole.... " Alternatively, the manufacturer could assert that the product reduces exposure to a particular substance or substances. H.R. 1256/S. 982 sets out detailed criteria for approving such a *reduced-exposure claim* in the absence of scientific evidence to make a reduced-risk claim. Those criteria, based on recommendations of the Institute of Medicine,[13] include determining that the substance or substances are harmful; the exposure reduction is "substantial;" the reduced exposure is "reasonably likely" to lead to a "substantial and measurable and substantial reduction" in harm among individual users; and approval of such a product is "likely to benefit the health of the population as a whole." Applications for products that make exposure-reduction claims would be approved for five years at a time. All manufacturers of approved modified risk tobacco products, whether on the basis of a reduced-risk claim or a reduced-exposure claim, would be required to conduct postmarket surveillance and report their findings on an annual basis.

H.R. 1256/S. 982 would require manufacturers, within one year, to stop using terms such as "light" and "low-tar" on their low-yield brands. Those brands would be permitted to remain on the market provided the manufacturers made any other changes necessary to ensure that the products did not fall under the definition of a modified risk tobacco product. For example, manufacturers have for years reported tar and nicotine yields (as measured by the FTC method) on cigarette advertising and on some very low-tar cigarette packs. Because this information implies that the product reduces risk or exposure, it too would have to be removed. Under a separate provision in the legislation, FDA would be required to develop new regulations for the testing, reporting, and public disclosure of tobacco product ingredients and smoke constituents, including tar and nicotine levels (see **Table 1**). Those regulations would replace the current FTC method.[14]

It is difficult to imagine a company gaining FDA approval to market a modified risk tobacco product based on a reduced-risk claim, as least in the near term. Demonstrating that the product, as actually used by consumers, will reduce risk both to the individual user and to the population as a whole requires long-term epidemiological studies. However, gaining approval for a new product on the basis of a reduced-exposure claim in the absence of such studies does not require that the manufacturer meet such stringent requirements. For example, the company would have to show that the reduced exposure is "reasonably likely" to lead to a reduction in harm and that the product is "expected" to benefit the health of the population as a whole. Approving modified risk

[13] *Id*.

[14] Over the past several decades, cigarette design changes have led to substantial reductions in tar and nicotine yields as measured by the FTC method. However, these machine-measured yields do not provide a reliable measure of the amount of tar and nicotine a smoker inhales. Smokers alter their smoking behavior (e.g., increasing puff volume and frequency, covering the ventilation holes with fingers or lips) to obtain sufficient nicotine to satisfy their addiction. For more information, see National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine* (Oct. 2001).

tobacco products under such criteria makes postmarket surveillance all the more important as a means of monitoring the product's actual impact on public health.

H.R. 1256/S. 982 also would give FDA the authority to require the manufacturer of an approved modified risk tobacco product to comply with certain labeling and advertising requirements. Such authority could be used to place tight restrictions on the ability of manufacturers to market their modified risk products to individual tobacco users. Philip Morris and the other companies believe that they should be able to provide adult consumers with information about reduced-risk and reduced-exposure products, provided the information is accurate and not misleading, to help them make an informed choice.

Tobacco Product Design and Characteristics

H.R. 1256/S. 982 would not permit cigarettes to contain any additive that is a "characterizing flavor" of the product or the smoke, other than tobacco or menthol.[15] The legislation would give FDA the authority to develop product standards to reduce nicotine, reduce or eliminate other harmful constituents, or otherwise modify the composition and testing of tobacco products, if it determined that such regulation was appropriate to protect the public health. Once again, FDA would be required to make that determination based on a consideration of the risks and benefits to the population as a whole, which is the approach favored by public health officials. Unlike some of the previous FDA tobacco bills, there is nothing in H.R. 1256/S. 982 to prevent the agency from requiring changes in the composition of tobacco products that would render them "unacceptable for adult consumption." Placing that restriction on FDA's ability to modify tobacco products had been a key requirement for the industry.

Critics of the idea of reduced nicotine levels, including former FDA Commissioner Andrew von Eschenbach, argue that "if the FDA ordered a cut in nicotine levels, smokers would alter their smoking habits in order to maintain their current levels of the addictive substance."[16] Von Eschenbach said that such a decision could "ma[k]e the public health radically worse."[17] On the other hand, supporters of low-nicotine products say that smokers may not be able to compensate for sufficiently reduced nicotine levels by inhaling deeper or smoking more frequently. Rather, such reduced-nicotine products may help smokers quit altogether.[18]

The authority to set product standards would give FDA an important tool for modifying tobacco products already on the market so as to make them less harmful. However, developing such standards may be a long and difficult process. More than 4,000 chemical compounds have been identified in tobacco smoke, including about 60 known carcinogens. Researchers still know relatively little about the precise mechanisms by which individual compounds and groups of related compounds contribute to the overall health risks of smoking. It may take years to collect the data necessary to demonstrate that the reduction or elimination of a particular tobacco product constituent will lead to an improvement in public health.

As part of the standard-setting process, FDA would be required to take into account the technical feasibility of compliance, as well as the existence of any patents that might make it impossible to

[15] R.J. Reynolds reached an agreement with several states attorneys general regarding the adult-only marketing and sale of flavored cigarettes named after a fruit, candy, or alcoholic beverage. Press Release, R.J. Reynolds Tobacco Company, Attorneys General Agree on Flavored Cigarette Marketing Guidelines, Oct. 11, 2006, http://www.rjrt.com/newsroom/resourcesRJRTview.asp?postID=1178.

[16] *Lower Nicotine Levels in Cigarettes Could Backfire: FDA Chief*, Wash. Post, Mar. 6, 2007.

[17] *Id*.

[18] *Id*.

meet a compliance deadline. Also, the agency must consider whether a proposed standard might lead to a "significant demand for contraband or other tobacco products that do not meet the requirements of the [legislation]." Until more is learned about the nature of nicotine addiction, that requirement may pose a significant challenge to any proposed reduction in nicotine yield.

H.R. 1256/S. 982 does not permit FDA to ban tobacco products, or to require the reduction of nicotine yields to zero. As discussed earlier, the industry has argued strenuously in favor of placing such restrictions on FDA's regulatory authority. Companies are fearful that the agency, left unchecked, could achieve a de facto ban by eliminating nicotine and making tobacco products unacceptable to adults. The public health community maintains that FDA should have unrestricted authority to take whatever actions it feels are necessary to protect public health.

Menthol Cigarettes

H.R. 1256/S. 982 would ban the use of all artificial and natural flavors in cigarettes, except menthol. Menthol cigarettes are an important component of the U.S. cigarette industry, accounting for more than one-quarter of the approximately $70 billion domestic market. The exemption for menthol is widely viewed as an important compromise that was negotiated with Philip Morris in order to secure the company's support for the legislation. In June 2008, seven former HHS Secretaries from Democratic and Republican administrations wrote to members of the House and Senate urging them to ban the use of menthol in cigarettes.[19] Their concern mirrors that of many in the public health community who question why menthol—by far the most widely used flavoring in cigarettes—is receiving special treatment.

The menthol exemption is controversial because mentholated cigarettes are the most popular choice among African-American smokers. According to the Surgeon General, more than three-quarters of African American smokers smoke menthol cigarettes, as compared to about one-quarter of white smokers.[20] Public health officials hypothesize that the widespread use of mentholated cigarettes among African Americans may, in part, be the reason why they suffer from higher smoking-related health risks. Despite smoking fewer cigarettes per day and beginning smoking later in life, the years of potential life lost before the age of 65 is two times higher in black smokers than white smokers. Furthermore, African-American teen smokers have a greater risk of developing long-term consequences from smoking than other ethnic groups, and are in danger of experiencing the negative effects of tobacco earlier in their lifetimes. Researchers point to studies suggesting that menthol smokers may be exposed to higher levels of dangerous compounds than smokers of regular cigarettes. Some menthol brands, including top-selling Newport, contain among the highest levels of nicotine among leading cigarettes. There is also evidence that it is harder to quit smoking menthol products. Tobacco companies, while acknowledging the health risks of smoking, contend that menthol does nothing to worsen those risks.

Sponsors of H.R. 1256/S. 982 argue that under FDA's broad new authority to promulgate tobacco product standards to reduce or eliminate harmful constituents, or otherwise modify the

[19] The full text of the letter is at http://www.nytimes.com/2008/06/05/business/05TobaccoLetter.html?_r=1&scp=5&sq=menthol&st=cse&oref=slogin.

[20] For information on smoking among African Americans and the characteristics and health impact of menthol cigarettes, see (i) U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, *Tobacco Use Among U.S. Racial/Ethnic Minority Groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General*, 1998, at http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_1998/index.htm; and (ii) U.S. Dept. of Health and Human Services, National Institutes of Health, National Cancer Institute, *The First Conference on Menthol Cigarettes: Setting the Research Agenda*, Executive Summary, 2002, at http://dccps.cancer.gov/tcrb/MentholExecSumRprt4_10-16.pdf.

characteristics of tobacco products, the agency could ban menthol if it determined that such action was appropriate to protect the public health. Meeting that standard might perhaps require more definitive scientific evidence than is currently available. H.R. 1256/S. 982would require the Tobacco Products Scientific Advisory Committee, established by the legislation to advise the Secretary on nicotine addiction and other issues, to study and report on the public health impact of menthol cigarettes.

Legal Issues

This section of the report addresses First Amendment concerns with the requirement in H.R. 1256/S. 982 that the HHS Secretary publish as a final rule the FDA's 1996 rule on cigarettes and smokeless tobacco and, in particular, the rule's ban on outdoor advertising for cigarettes or smokeless tobacco within 1,000 feet of a school or playground. In *Lorillard Tobacco Co. v. Reilly*, the Supreme Court held a similar provision unconstitutional. Unlike H.R. 1256, the Senate version of the FDA tobacco legislation contains a provision, discussed below, that is designed to address these First Amendment concerns. This section also examines federal preemption of state law in the context of the FDA tobacco legislation, the Federal Cigarette Labeling and Advertising Act, and three Supreme Court cases.

Restrictions on Advertising and Promotion; First Amendment Issues

H.R. 1256/S. 982 would give FDA broad authority to regulate tobacco product marketing if it determined that such regulation was appropriate to protect the public health. The HHS Secretary would be required to make that determination based on a consideration of the "risks and benefits to the population as a whole," including whether the agency's actions would discourage current users from quitting or encourage others to start using tobacco products.[21]

This section will review briefly the U.S. Supreme Court's decisions on government regulation of advertising and other forms of commercial speech, before analyzing the FDA's 1996 rule in the context of such decisions.[22] In *Central Hudson Gas & Electric Corp. v. Public Service Commission* (1980), the Court established a four-part test for deciding the constitutionality of commercial speech regulation.[23] First, in order to be protected by the First Amendment, the commercial speech must concern lawful activity and not be false or misleading. Second, the government must demonstrate that by restricting such speech, it is seeking to further a substantial government interest. Third, the restrictions must directly advance that interest. Fourth, there has

[21] H.R. 1256, § 101 (to be codified at § 906(d)(1)). In the past, Philip Morris criticized that approach and preferred the language of H.R. 140 in the 108th Congress, which would have permitted FDA to regulate tobacco advertising and promotion based on a determination that such regulation was "appropriate for the prevention of, or decrease in, the use of tobacco products by [minors]." Anti-tobacco groups believed that such a standard would make it virtually impossible for FDA to act. They argued that because the industry denied that any of its advertising is directed at children, it would have challenged every regulatory proposal by the agency. Philip Morris defended the language, arguing that it was simply a recognition of the fact that the First Amendment, as currently interpreted by the U.S. Supreme Court, "prevents the FDA from prohibiting advertising directed at adults." The company contended that giving the agency broader authority to regulate the marketing of its products would be inefficient because it would have encouraged FDA to develop regulations that would never survive a constitutional challenge.

[22] For more information on the First Amendment and commercial speech, see CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by Henry Cohen.

[23] 447 U.S. 557 (1980).

to be a reasonable fit between the type of restrictions imposed and the government's objectives—in other words the regulation cannot be "more extensive than is necessary to service that interest."[24]

The U.S. Supreme Court has issued a series of decisions striking down government restrictions on commercial speech, including tobacco product advertising.[25] In the 2001 case, *Lorillard Tobacco Co. v. Reilly* (2001), the Court found a number of Massachusetts state regulations restricting outdoor and point-of-sale advertising for cigars and smokeless tobacco products to be unconstitutional.[26] The Court determined that the regulations restricted speech more than was reasonable to advance the state's interest in reducing underage (i.e., illegal) use of tobacco products and, thus, failed to meet the fourth part of the *Central Hudson* test. Banning all outdoor tobacco advertisements within 1,000 feet of a school or playground, in conjunction with other zoning restrictions, argued the Court, "would constitute a nearly complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers."[27] The Court found that the restrictions on outdoor advertising of cigars and smokeless tobacco were overbroad in that they prohibited advertising "in a substantial portion of the major metropolitan areas of Massachusetts," included oral communications, and imposed burdens on retailers with limited advertising budgets.[28] The Court also upheld challenges by smokeless tobacco and cigar companies to the outdoor advertising restrictions on the grounds that adults have a right to information and the tobacco industry has a right to communicate truthful speech on legal products.[29]

H.R. 1256/S. 982 would require the HHS Secretary to publish the agency's 1996 rule as a final rule, with some changes, within 180 days after enactment. In developing the 1996 tobacco rule, FDA created a set of advertising restrictions aimed at reducing underage smoking and smokeless tobacco use that it hoped would withstand a constitutional challenge. Whether the FDA's 1996 rule would have passed the *Central Hudson* test remains unclear. In *FDA v. Brown & Williamson*, the Supreme Court confined itself to a review of the agency's interpretation of its authority under the FFDCA. The Court did not address the constitutionality of the rule's marketing restrictions. The FDA's 1996 rule would have limited advertisements in publications with a significant teen audience to black text on a white background.[30] The 1996 rule also included a ban on outdoor advertising within 1,000 feet of a school or playground. As noted, in *Lorillard*, the Court found a

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[24] 447 U.S. at 566.

[25] Ronald Beyer et al., "Tobacco Advertising in the United States: A Proposal for a Constitutionally Acceptable Form of Regulation," *Journal of the American Medical Association*, vol. 287, no. 22 (June 2002), pp. 2990-95.

[26] 533 U.S. 525 (2001).

[27] *Id*. at 562.

[28] *Id*. at 562, 564-65.

[29] *Id*. at 564.

[30] If H.R. 1256 passes and the FDA's 1996 final rule becomes law, 21 C.F.R. § 897.32 will permit labeling or advertising for cigarettes or smokeless tobacco with "only black text on a white background," except in facilities "where vending machines and self-service displays are permitted ... provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility" or in an adult publication. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 FR 44617 (Aug. 28, 1996). An adult publication would be defined under 21 C.F.R. § 897.32(a)(2) as:

> a newspaper, magazine, periodical, or other publication: (i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence and (ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

61 Fed. Reg. 44617.

similar provision in the Massachusetts regulations unconstitutional.[31] S. 982 addresses this concern, as discussed below.

Analyzing this restriction on outdoor advertising in the context of *Central Hudson*, it does not appear that the 1996 rule's restriction on advertisements within 1,000 feet of a school or playground would survive the fourth step of the *Central Hudson* test—that the regulation cannot be "more extensive than is necessary" to serve the substantial government interest.[32] In *Lorillard*, the Court stated that "[t]he broad sweep of the regulations indicates that the Attorney General did not 'carefully calculate the costs and benefits associated with the burden on speech imposed' by the regulations."[33] The Supreme Court further explained that a "careful calculation of the costs of a speech regulation does not mean that a State must demonstrate that there is no incursion on legitimate speech interests, but a speech regulation cannot unduly impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information about products."[34]

First, the Court noted that "the Attorney General did not seem to consider the impact of the 1,000 foot restriction on commercial speech in major metropolitan areas."[35] Rather, the Attorney General imposed a 1,000 foot restriction that was identical to the FDA's restriction in the 1996 rule. The Court noted that suppression of speech or limits on speech tend to be case-specific. However, "the FDA's regulations would have had widely disparate effects nationwide. ... The uniformly broad sweep of the geographical limitation demonstrates a lack of tailoring."[36] In the FDA's final 1996 rule, the agency took note of comments that focused on the impact of the rule in major metropolitan areas, including a survey that "showed that outdoor tobacco advertising would be prohibited in 94 percent and 78 percent of the respective land mass of Manhattan and Boston under the [1,000 foot] proposal."[37] However, the FDA attributed "the possibility that its restrictions effectively outlaw outdoor advertising in most urban areas" to population density in cities.[38] The agency then stated that its intent in establishing the 1,000 foot restriction was "to restrict the accessible and intrusive communications of information about cigarettes and smokeless tobacco to children and adolescents at school and at play."[39] The rule explained that the FDA "considered the cost of its [1,000 foot] restriction but conclude[d] that a narrower restriction would not adequately advance its purpose of protecting young people from unavoidable advertising."[40] The *Lorillard* Court's declaration that a 87 to 91 percent ban on tobacco advertising "would constitute nearly a complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers" and the Court's statement

[31] At the House Committee on Energy and Commerce markup of the Family Smoking Prevention and Tobacco Control Act in the 110th Congress (H.R. 1108), Members of Congress debated whether the Court's holding in *Lorillard* would impact the 1996 rule's restriction on advertisements within 1,000 feet of a school or playground, which H.R. 1108 would have required to be published as a final rule. H.R. 1108, § 102(a). The committee report on H.R. 1108 similarly addresses this debate in the section-by-section analysis and the dissenting views. H.Rept. 110-762, at 72-73, 159 (2008).

[32] 447 U.S. at 566.

[33] *Id*. at 561 (quoting Cincinnati v. Discovery Network, Inc., 507 U. S. 410, 417 (1993)).

[34] *Id*. at 565-66.

[35] *Id*. at 562.

[36] *Id*. at 563.

[37] 61 Fed. Reg. 44506.

[38] *Id*.

[39] *Id*.

[40] *Id*.

that the 1,000 foot restrictions' "breadth and scope ... [did] not demonstrate a careful calculation of the speech interests involved," appear to indicate that Court would strike the 1,000 foot restriction if the 1996 final rule became effective.[41]

Second, the Court stated that tailored restrictions on tobacco advertising and promotion "would involve targeting those practices [that appeal to children] while permitting others."[42] The FDA stated in its responses to comments on the rulemaking:

> The prohibition on outdoor advertising within 1,000 feet of schools and playgrounds is designed to address a different problem. The concern is not the appeal of the advertising. If the problem were only appeal, the 1,000 foot restriction would not be necessary because the text-only requirement would eliminate this concern. The concern is the nature of the billboards themselves. Billboards near schools and playgrounds ensure that children are exposed to their messages for a prolonged period of time.[43]

Therefore, it does not seem likely that the Supreme Court would uphold the 1,000 foot restriction if, as the agency stated, it was not meant to target practices that appeal to children. Based on the Court's discussion in *Lorillard*, it does not appear likely that the 1996 FDA final rule's 1,000 foot restriction would survive a *Central Hudson* analysis.[44] One approach would be for Congress to exclude the 1,000 foot restriction in the new final rule that would be published 180 days after the FDA tobacco legislation is enacted.

The House version of the Family Smoking Prevention and Tobacco Control Act specifies (in §102(a)(2) of H.R. 1256) the portions of the new final rule that will be different from the 1996 rule. The House's specified alterations do not include a change to the part of the FDA 1996 final rule that addressed the 1,000 foot restriction, which would be codified at 21 C.F.R. § 897.30(b). On the other hand, the Senate bill (§ 102(a)(2)(E) of S. 982) states that the new version of the FDA 1996 final rule must "include such modifications of section 897.30(b), if any, that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court of the United States in *Lorillard Tobacco Co. v. Reilly*."[45]

Some public health law experts believe that the Supreme Court in its decisions on the regulation of commercial speech has left public health authorities with little room to craft tobacco advertising restrictions that meet both the third (effectiveness) and fourth (extensiveness) parts of the *Central Hudson* test.[46] On the one hand, tobacco advertising restrictions that are narrowly tailored may not provide clear evidence of effectiveness, thus failing the third part of *Central Hudson* test. On the other hand, more sweeping (and potentially effective) restrictions may be viewed as too extensive and not reasonably related to the government's asserted interest, thus failing the fourth part of the *Central Hudson* test.

In the event that the advertising restrictions are challenged, H.R. 1256 contains a severability clause that states:

> If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of this

[41] 447 U.S. at 562.

[42] *Id*. at 563.

[43] 61 Fed. Reg. 44506.

[44] 61 Fed. Reg. 44507-08.

[45] S. 982, § 102(a)(2)(E) (italicized text added).

[46] Beyer et al., *supra* n. 25.

> Act to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.[47]

Preemption of State and Local Regulation Regarding Labeling, Advertising, and Promotion

This section examines federal preemption of state law in the context of the FDA tobacco legislation. The Federal Cigarette Labeling and Advertising Act (FCLAA),[48] which mandates health warnings on cigarette packaging and advertising, includes the following preemption provision:

> (a) ADDITIONAL STATEMENTS. No statement relating to smoking and health, other than the statement required by [the labeling provisions] of this Act, shall be required on any cigarette package.
>
> (b) STATE REGULATIONS. No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.[49]

The FCLAA's introductory declaration of policy indicates that Congress did not want "commerce and the national economy ... impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations.... "[50] To that end, the act's preemption provision (1) prohibits additional health-related statements on the labels of cigarette packages that are properly labeled in accordance with the act, and (2) prevents states and localities from imposing any other "requirement or prohibition based on smoking and health" regarding the advertising and promotion of cigarettes.

The U.S. Supreme Court has issued three decisions regarding the FCLAA preemption provision. In these cases, the Court explored the constitutional questions that are raised when state statutes or common law causes of action impose requirements that conflict with federal laws that may preempt such state action (see box below).

In *Cipollone v. Liggett Group Inc.*, the U.S. Supreme Court held that certain types of tort actions that are brought against cigarette manufacturers under state common law are preempted by the FCLAA.[51] In the case, the son of a woman who died of lung cancer caused by smoking cigarettes sued cigarette manufacturers for causing his mother's death. His claims were based on New Jersey common (i.e., court-made) law. The plaintiff claimed, among other things, that the defendants had failed to provide adequate warnings of the health consequences of smoking

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[47] H.R. 1256, § 5. Section 5 of S. 982 contains a slightly modified severability clause referencing regulations promulgated under the Act: "If any provision of this Act, of the amendments made by this Act, or of the regulations promulgated under this Act (or under such amendments), or the application of any such provision to any person or circumstance is held to be invalid, the remainder of this Act, such amendments and such regulations, and the application of such provisions to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible."

[48] 15 U.S.C. §§ 1331-41, 4402.

[49] 15 U.S.C. § 1334. The FCLAA requires the following four rotating Surgeon General's health warnings on all cigarette packages and advertising: (1) Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy; (2) Quitting Smoking Now Greatly Reduces Serious Risks to Your Health; (3) Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight; and (4) Cigarette Smoke Contains Carbon Monoxide. *Id*. at § 1333.

[50] *Id*. at § 1331.

[51] 505 U.S. 504 (1992). This summary of *Cipollone* was written by Henry Cohen, Legislative Attorney. *Supreme Court Allows Cigarette Manufacturers to Be Sued*, CRS Supreme Court Review: 1991-92 Term, at 19-20.

cigarettes, had made and breached express warranties that their cigarettes did not present any significant health consequences, had fraudulently—through their advertising—attempted to neutralize the federally mandated warning labels, had fraudulently concealed medical and scientific data indicating that cigarettes were hazardous to health, and had conspired to deprive the public of such medical and scientific data. The defendant cigarette manufacturers argued that the FCLAA preempted state law claims. In other words, the defendants argued that, having complied with the federal warning requirements, they could not be held liable for the plaintiff's mother's death, even if everything the plaintiff asserted was true.

The FCLAA contains two preemption provisions. It prohibits states from (1) requiring any statement, other than the warnings prescribed by the Act, to appear on any cigarette packages, and (2) imposing any requirement or prohibition based on smoking and health with respect to the advertising or promotion of cigarettes that are labeled in conformity with the federal statute. The Supreme Court treated the two preemption provisions separately. It construed the first, prohibiting the states from requiring additional *statements* on cigarette *packages*, to supersede "only positive enactments by legislatures or administrative agencies that mandate particular warning labels."[52] In other words, the first provision did not preempt state courts from awarding damages and thereby in effect requiring additional warning labels. However, the Court construed the second provision, prohibiting states from imposing any *requirement or prohibition* with respect to cigarette *advertising or promotion*, as broader, and as intended to preempt some common law claims.

The Court then delineated which state law claims are preempted and which may be brought. Failure-to-warn claims are preempted to the extent that they would require additional, or more clearly stated, warnings in cigarette advertising or promotions, but are not preempted to the extent that they rely on the defendants' "testing or research practices or other actions unrelated to advertising or promotion."[53] Breach of express warranty claims are not preempted because express warranties, whether set forth in advertisements or elsewhere, are not imposed by the state but arise from the manufacturer's voluntary statements. Fraudulent misrepresentation claims are preempted to the extent they are predicated on advertising statements that tended to neutralize the federally mandated warning labels, because the federal statute prohibits states from imposing *prohibitions*, not just requirements, with respect to cigarette advertising or promotion. However, fraudulent misrepresentations claims, and conspiracy claims, based on concealment of the hazards of smoking are not preempted insofar as they rely on a state law duty to disclose such facts through channels of communication other than advertising or promotion.

[52] 505 U.S. at 519.

[53] Cipollone v. Liggett Group Inc., 505 U.S. 504, 520, 524-25, 530-31 (1992).

Federal Preemption of State Law

The preemption doctrine derives from the Supremacy Clause of the U.S. Constitution, which establishes that the laws of the United States "shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any State to the contrary notwithstanding."[54] In applying this constitutional mandate, courts have recognized both express and implied forms of preemption, which are "compelled whether Congress' command is explicitly stated in the statute's language, or implicitly contained in its structure and purpose."[55] Both types of preemption may apply to state legislation, regulations, and common law. As the Supreme Court held in *Gade v. National Solid Wastes Management Association*, "the question whether a certain state action is pre-empted by a federal law is one of congressional intent. The purpose of Congress is the ultimate touchstone. To discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute."[56]

In the **express preemption** context, a federal statute will be deemed to supplant existing state law to the extent that it contains an explicit provision to that effect, the scope of which is determined by interpreting the language of the provision and analyzing the legislative history as necessary.[57] Where express preemption provisions are not present, federal law may preempt state law implicitly. There are several different ways to conceptualize the doctrine of **implied preemption**, but it is often subdivided into three general categories for purposes of analysis: (1) federal occupation of the entire field of regulation; (2) actual conflict between federal and state requirements; and (3) state requirements that frustrate congressional purpose.[58]

These standards, however, are highly speculative in their application. Indeed, the U.S. Supreme Court itself has noted that "none of these expressions provide an infallible constitutional test or an exclusive constitutional yardstick. In the final analysis, there can be no crystal clear distinctly marked formula."[59] Thus, cases involving federal preemption of state law often hinge on the particular factual circumstances of a given case.

The Supreme Court next addressed FCLAA preemption in *Lorillard Tobacco Co. v. Reilly*.[60] In addition to finding Massachusetts' regulations on smokeless tobacco and cigar advertising unconstitutional (discussed earlier), the Court in *Lorillard* ruled that the state's restrictions on cigarette advertising were preempted by the FCLAA. Specifically, the Court concluded that the regulations did relate to the "advertising or promotion" of cigarettes. It further concluded that the regulations, targeted at youth exposure to cigarette advertising, were "based on smoking and health" within the meaning of the FCLAA because "concern about youth exposure to cigarette advertising is intertwined with the concern about ... smoking and health."[61] The fact that the regulations governed location rather than content of advertising did not remove them from the preemption language, which covers "all 'requirements' and 'prohibitions' imposed under state law."[62] The *Lorillard* decision clarified that while the FCLAA preempts the ability of states to

[54] U.S. CONST. art. VI, cl. 2.

[55] *Gade v. National Solid Wastes Management Association*, 505 U.S. 88, 97 (1992) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

[56] *Id.* at 96 (internal quotation marks and case citations omitted).

[57] *Jones v. Rath*, 430 U.S. at 525.

[58] *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002); *see also Hines v. Davidowitz*, 312 U.S. 52, 61, 77 (1941) (regarding field and frustration of purpose preemption); *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963) (regarding conflict preemption).

[59] *Hines v. Davidowitz*, 312 U.S. at 67.

[60] 533 U.S. 525 (2001).

[61] *Id*. at 548.

[62] *Id*. (emphasis omitted).

regulate the advertising and promotion of cigarettes, states retain the authority to regulate other aspects of tobacco use and sales. The FCLAA, for example, does not preempt state laws that prohibit sales to minors or restrict smoking in public places.[63]

The Supreme Court examined the scope of the FCLAA once again in *Altria Group, Inc. v. Good*.[64] In this case, the Court addressed whether the FCLAA preempted a state law claim that Philip Morris USA and its parent company Altria Group violated the Maine Unfair Trade Practices Act (MUTPA) by using "light" and "low tar" descriptors on cigarettes, thereby delivering the message that "light" cigarettes deliver less tar and nicotine to consumers than regular brands, while knowing such message to be untrue. The MUTPA makes it unlawful to use "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."[65] To determine whether the respondents' claims under the MUTPA were preempted by the FCLAA, the Court used the "predicate-duty" test it developed in *Cipollone*. This test asks "whether the legal duty that is the predicate of the common law damages action constitutes a 'requirement or prohibition based on smoking and health ... with respect to ... advertising or promotion.'"[66] The Court held that the respondents' claims were not expressly preempted by the FCLAA because their claims under the MUTPA were predicated on the general duty not to deceive.

The Court further rejected Philip Morris's argument that the state law claims were impliedly preempted because of its contention that the FTC has for decades promoted the development and consumption of low tar cigarettes and has encouraged consumers to rely on representations of tar and nicotine content in choosing among cigarette brands. In rejecting Philip Morris's implied preemption argument, the Court stated, "[i]n short, neither the handful of industry guidances and consent orders on which [Philip Morris] relies nor the FTC's inaction with regard to 'light' descriptors even arguably justifies the preemption of state deceptive practices rules like the MUTPA."[67] While holding that lawsuits accusing cigarette-makers of fraudulent conduct under state law could proceed, the Court noted that the respondents "still must prove that the petitioners' use of 'light' and 'lowered tar' descriptors in fact violated the state deceptive practices statutes."[68]

The public health community strongly supports the elimination of the FCLAA preemption language so that states could impose their own restrictions on tobacco labeling and advertising. The tobacco companies, on the other hand, oppose any such change, in part to preserve the uniform national standards currently in effect. However, the industry also is anxious to preserve the FCLAA's preemption provision in light of the U.S. Supreme Court's ruling in *Cipollone.* If Congress were to amend that provision, such legislation, depending on the language, could either increase or restrict the types of lawsuits that currently may be brought against cigarette manufacturers on the basis of the warning contained on cigarette packages.

H.R. 1256/S. 982 appears to attempt to accommodate both sides by preserving the current language in the FCLAA preemption provision, while adding at the end the following:

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[63] The FCLAA preemption provisions apply only to cigarettes and do not cover state regulation of smokeless tobacco and cigars. As discussed in an earlier section of the report, Massachusetts' outdoor advertising and point-of-sale restrictions on smokeless tobacco and cigars were found to be in violation of the First Amendment.

[64] *Altria Group, Inc. v. Good,* 128 S. Ct. 538 (2008). This paragraph and the subsequent paragraph were written by Vivian Chu, Legislative Attorney, CRS.

[65] Me. Rev. Stat. Ann., Tit. 5 §207 (Supp. 2008).

[66] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 , 524 (1992).

[67] *Altria*, 128 S. Ct. at 551.

[68] *Id*.

> (c) Exception. Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health ... imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.[69]

Thus, states would continue to be prohibited from adding their own warning labels to cigarette packages, but would be permitted to regulate certain aspects of cigarette advertising and promotion, subject to any First Amendment challenge. For the tobacco companies, the language in subsection (b) underlying *Cipollone* would remain intact.[70] In addition to amending the FCLAA preemption provision, H.R. 1256/S. 982 § 916 would include a general preemption provision in the new FFDCA language that would place certain restrictions on states (for example, with regard to tobacco product standards, adulteration, and misbranding) while allowing them to regulate the sale, advertising, and promotion of tobacco products (see **Table 1**).

[69] H.R. 1256/S. 982, § 203.

[70] *See* Letter from Steven C. Parrish, Senior Vice President, Corporate Affairs, Altria Group, Inc., to Senators Edward M. Kennedy and John Cornyn (February 15, 2007), http://www.altria.com/download/pdf/SCP_FDA_Endorsement_Senate.pdf.

Table 1. Family Smoking Prevention and Tobacco Control Act

Summary of H.R. 1256 (As Passed, Excluding Non-Tobacco Provisions in Division B)—Key Differences in S. 982 (As Reported) in Italics

FDA Tobacco Regulatory Authority (FFDCA Chapter IX)	
FDA authority over tobacco products	Creates a new FFDCA Chapter IX for regulating tobacco products, excluding any such product intended for the diagnosis, treatment, or prevention of disease, or a product for which a health claim has been made (unless the product is a modified risk product – discussed below). Does not give the Secretary regulatory authority over: (1) tobacco leaf, unless in the possession of a manufacturer; or (2) tobacco growers and warehouses. Requires the Secretary, within 90 days of enactment, to establish a Center for Tobacco Products at FDA to implement Chapter IX. Requires the Secretary to establish within FDA an office to assist small tobacco product manufacturers (i.e., companies employing fewer than 350 employees) in complying with the FFDCA. Specifies that each rulemaking under this Chapter must be in accordance with 5 U.S.C. § 5, and that prior to rulemaking the Secretary must endeavor to consult with other appropriate federal agencies. [FFDCA Sec. 901]
Adulterated tobacco products	Specifies the conditions under which tobacco products are deemed adulterated, including: (1) contamination by any poisonous or deleterious substance; (2) preparation, packaging, or storage under unsanitary conditions; (3) failure of a manufacturer to pay user fees (see below); (4) failure to conform to good manufacturing practice requirements (see below); (5) failure to meet required tobacco product standards (see below); or (6) the product is in violation of the requirements for modified risk products (see below). [FFDCA Sec. 902]
Misbranded tobacco products	Specifies the conditions under which tobacco products are deemed misbranded, including: (1) product labeling and advertising that is false or misleading in any particular; (2) failure to include in the package labeling the name and place of business of the manufacturer and a statement of the percentage of domestic and foreign-grown tobacco in the product; (3) distribution and sale in violation of tobacco product regulations issued pursuant to this Act; and (4) failure of the products' manufacturer to register with FDA, as required under the Act. Authorizes the Secretary to require, by regulation, the prior approval of statements made on tobacco product labels. Prohibits the Secretary from requiring the prior approval of the content of tobacco product advertising, except for modified risk products (see below). [FFDCA Sec. 903]
Submission of data and research documents	Requires each tobacco product manufacturer or importer to submit: (1) within six months of enactment, a list of the amounts of all added ingredients, by brand and sub-brand; (2) a description of the content, yield, and form of nicotine in each product; (3) beginning three years after enactment, a list of the amounts of all potentially harmful smoke constituents, by brand and sub-brand; and (4) beginning six months after enactment, all documents developed after the date of enactment relating to the health impact of current or future products. Requires any and all documents (including scientific, financial, and marketing research) about a new product that are requested by the Secretary to be submitted at least 90 days prior to the product's release. Requires similar disclosure of information about a new (or changes in the quantity of an existing) additive. Within three years of enactment and annually thereafter, requires the Secretary to publish (in a format understandable to a lay person) and publicly display a list of the amounts of potentially harmful constituents, by brand and sub-brand. Requires the Secretary to conduct periodic consumer research to ensure that the list is not misleading to the public and, after five years, to report the results of such research to Congress with recommendations for modifying or discontinuing the list. [FFDCA Sec. 904]
Registration and inspection	Requires annual registration of all tobacco product manufacturers (and others engaged in the preparation, compounding, and processing of tobacco products) and provides for public access to registration information. Requires manufacturers at the time of registration to provide a detailed product list, including copies of consumer information and product labeling. Requires registrants to file a biannual report of any changes in their product list. Mandates biennial inspection of all registered establishments. Requires foreign manufacturers and other establishments seeking to import tobacco products into the United States to register. [FFDCA Sec. 905]

Substantial equivalence	Requires a manufacturer at least 90 days prior to introducing a product that was not commercially marketed as of February 15, 2007, to provide to the Secretary (in a manner prescribed by regulation) its determination that such product is substantially equivalent (within the meaning of Sec. 910, below) to another tobacco product that was in interstate commerce as of that date, and that such product is in compliance with the requirements of this Act. Manufacturers that introduced a product after February 15, 2007, and prior to the date that is 21 months following enactment have until that date (i.e., 21 months after enactment) to submit their report documenting substantial equivalence to a product commercially marketed as of February 15, 2007. Permits the Secretary, pursuant to regulations issued within 15 months of enactment, to exempt from having to demonstrate substantial equivalence certain modified tobacco products that have only minor differences from existing products. [FFDCA Sec. 905]
General regulatory controls on tobacco products	Authorizes the Secretary, by regulation, to restrict the sale, distribution, advertising and promotion of tobacco products, and access to such products, if the Secretary determines that such regulation is appropriate to protect the public health. Requires that such a determination be based on a consideration of the risks and benefits to the population as a whole, including users and nonusers of tobacco products. Requires that notices of proposed rulemaking and other published notices pursuant to authorities created under this Act be made accessible to the public, and that interested persons be given at least 60 days to comment. Prohibits limiting the sale and distribution of tobacco products to the written or oral authorization of a medical practitioner. Prohibits restricting the sale of tobacco products in face-to-face transactions by specific type of retail outlet, and prohibits establishing a minimum age of sale to persons older than 18 years of age. Requires the Secretary, within 18 months of enactment, to issue regulations regarding the sale and distribution of tobacco products other than by a retailer in a face-to-face exchange (e.g., Internet and mail-order sales), in order to prevent underage access to such products. Further requires the Secretary, within two years of enactment, to issue regulations regarding the promotion and marketing of tobacco products that are sold or distributed other than by a retailer in a face-to-face exchange, in order to protect minors. Requires the Secretary, by regulation, to establish good manufacturing practice (GMP) requirements (which may include testing raw tobacco for pesticide chemical residues) subject to the recommendations of the Tobacco Products Scientific Advisory Committee (see below). Manufacturers have three years to comply with GMP requirements (small manufacturers, as defined in the Act, have four years to comply). Provides the authority to grant temporary or permanent exemptions or variances to the GMPs in response to petitions. Protects trade secrets obtained by FDA from Freedom of Information Act requests. [FFDCA Sec. 906]
Tobacco product standards	Beginning three months after enactment (and subject to subsequent revision by rulemaking), prohibits a cigarette from containing: (1) an artificial or natural flavor, other than tobacco or menthol; or (2) an herb or spice. Authorizes the Secretary to promulgate tobacco product standards to reduce nicotine, reduce or eliminate other harmful constituents, or otherwise modify the design and characteristics of tobacco products, if it is determined that such regulation is appropriate to protect the public health. Requires that such a determination be based on a consideration of the risks and benefits to the population as a whole, including users and nonusers of tobacco products. Requires the involvement of other federal agencies and informed persons in setting product standards, and periodic evaluation of such standards. Further requires that the Secretary take into account (1) the technical feasibility of compliance with a proposed standard, and (2) the impact of the proposed standard on the creation of a black market for products that do not meet the requirements of this Chapter. Mandates notice and comment rulemaking, with a comment period of at least 60 days, and requires a one-year period before new standards take effect unless the Secretary determines an earlier effective date is necessary to protect public health. If, based on information submitted by manufacturers and growers regarding the technical feasibility of compliance and the existence of patents, the Secretary determines that the standard can be met only by substantial changes to tobacco farming methods, then the effective date must be at least two years following publication of the standard. Any party objecting to a proposal to reduce or eliminate a tobacco constituent because it is or may be harmful, may provide for the Secretary's consideration evidence that the proposal will not reduce or eliminate the health risk. Prohibits the Secretary from banning tobacco products or reducing nicotine yields to zero. Provides for the amendment and revocation of existing standards. The Secretary may refer a proposal to establish, amend, or revoke a product standard to the Tobacco Products Scientific Advisory Committee (see below), based on her own initiative, or upon the request of an interested person who demonstrates good cause. Within 60 days of the referral, the Advisory Committee is required to report with recommendations. Requires the Advisory Committee, within one year of its establishment, to report to the Secretary on the public health impact of menthol cigarettes. [FFDCA Sec. 907]

Tobacco Product Standards (cont'd)	*S. 982 requires the Advisory Committee, within two years of its establishment, to report to the Secretary on the public health impact of dissolvable tobacco products, including their use among children.*
Notification and recall	In the event that the Secretary determines that a tobacco product presents an unreasonable risk of substantial harm to the public health and that notification is necessary to eliminate such risk, the Secretary is authorized to issue an order to ensure adequate notification of all appropriate persons. Compliance with such an order does not relieve persons from liability under other federal or state law. Authorizes the Secretary to order the appropriate persons to cease distribution and, subject to an informal hearing, to recall a tobacco product that contains an out-of-the-ordinary defect that poses serious health risks. [FFDCA Sec. 908]
Records and reports	Requires tobacco product manufacturers and importers to establish and maintain such records and provide such information as the Secretary may, by regulation, reasonably require to assure that products are not adulterated or misbranded and to otherwise protect public health. For example, the Secretary may require a report from a manufacturer that becomes aware of information that reasonably suggests that one of its products may have caused or contributed to a serious unexpected adverse experience associated with the use of that product. Requires tobacco product manufacturers and importers to report any product removal from the market or other corrective action taken to reduce a health risk or remedy a violation of this Chapter. [FFDCA Sec. 909]
Premarket review	Requires FDA premarket approval of all new tobacco products introduced after February 15, 2007 (even if only test-marketed), unless: (1) the manufacturer has submitted a report pursuant to Sec. 905 claiming substantial equivalence to an existing product and the FDA has approved the claim; or (2) under regulations promulgated pursuant to Sec. 905, the new product is determined to be a minor modification of an existing product. Within 21 months of enactment, a new product for which a substantial equivalence claim has been submitted may be marketed before FDA reviews the claim. Defines substantial equivalence and specifies the information that must be provided under Sec. 905 to establish substantial equivalence. Specifies the information that must be provided in an application for premarket review, including a listing of components and ingredients, a description of manufacturing methods, the product's proposed labeling, and all information published, known, or which should have been known about the health risks of the product. Permits the Secretary, on her own initiative or upon the request of an applicant, to refer the application to the Tobacco Products Scientific Advisory Committee (see below). Requires the Secretary, within 180 days, to deny an application for premarket approval if: (1) the applicant has failed to show that permitting the marketing of the new tobacco product would be appropriate for protecting public health, taking into consideration the risks and benefits to the population as a whole, including users and nonusers; (2) the product fails to conform to GMPs; (3) the labeling is false or misleading; or (4) the product fails to conform to applicable tobacco product standards. Authorizes the Secretary to withdraw or suspend premarket approval, after due notice and an opportunity for an informal hearing, for a number of reasons including that continued marketing of the product is no longer appropriate for protecting public health. Investigational tobacco products may, under conditions prescribed in regulation, be exempted from the provisions of this Chapter. [FFDCA Sec. 910]
Modified risk tobacco products	Requires manufacturers to obtain FDA approval in order to market modified risk tobacco products. Defines a modified risk tobacco product as: (1) a product whose labeling/advertising includes descriptors such as "light," "mild," or "low," or that claims explicitly or implicitly that the product reduces the risk of tobacco-related disease or reduces exposure to a substance; or (2) a product for which the manufacturer has taken any other action directed at consumers such that they would be reasonably expected to believe that the product reduces risk or exposure. Products labeled/advertised with such descriptors may continue to be manufactured for 12 months after enactment. Use of the phrase "smokeless tobacco" and similar phrases on smokeless tobacco products does not constitute a reduced risk claim. Modified risk product applications must include a product description, the conditions for using the product, product formulation, sample product labels, all research documents, information on how consumers actually use the product, and any other information required by the Secretary. Authorizes FDA to approve a modified risk product claim if the manufacturer demonstrates that the product, as it is actually used by consumers, will significantly reduce harm to individual tobacco users and benefit the health of the population as a whole, including users and nonusers of tobacco products. Requires FDA to make modified risk product applications available for public comment and to refer them to the Tobacco Products Scientific Advisory Committee (see below) for review.

Modified Risk Tobacco Products (cont'd)	In the case of a product for which the modified risk application is limited to an explicit or implicit **reduced-exposure** claim and the scientific evidence is not available to make a reduced risk claim without conducting long-term epidemiological studies, FDA is authorized to approve such a product for a five-year period (renewable) if the manufacturer demonstrates that: (1) the reduction in exposure to a harmful substance or substances is substantial; (2) the available scientific evidence shows a reasonable likelihood of a substantial reduction in risk among users; (3) testing of consumer perception shows that the proposed labeling and market of the product will not mislead consumers into believing that it has been demonstrated to be less harmful; and (4) use of the product is likely to benefit the health of the population as a whole, including users and nonusers of tobacco products. Establishes other conditions for approval of modified risk products, including the requirement that the advertising and labeling of such products enable the public to comprehend the product's risk in the context of all tobacco-related health risks. Permits FDA to require that manufacturers of approved modified risk products comply with other advertising and promotion requirements. Requires manufacturers of approved modified risk products to conduct postmarket surveillance. Permits FDA to withdraw approval, after an opportunity for an informal hearing, if it is determined among other things that the modified risk claim is no longer valid, or that the manufacturer failed to conduct postmarket surveillance. Requires FDA, within two years of enactment and in consultation with the Institute of Medicine and other experts, to issue regulations or guidance on the scientific evidence required for assessing modified risk tobacco products. Prohibits distributors from taking any action on a tobacco product that would reasonably be expected to result in consumers believing that the product is rendered less harmful or that it reduces or eliminates exposure to certain substances. Products for treating tobacco dependence, including cessation products, are not modified risk products if they have been approved as drugs/devices under FFDCA Chapter V. [FFDCA Sec. 911]
Judicial review	Establishes procedures for federal appellate court review of: (1) a regulation establishing, amending, or revoking a tobacco product standard; or (2) a denial of an application for premarket approval. Pursuant to 5 U.S.C. § 706(2)(A), specifies that the reviewing court will hold unlawful any agency action, findings, or conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Judgment by the appellate court is final, subject to review by the U.S. Supreme Court. [FFDCA Sec. 912]
Equal treatment of retail outlets	Requires FDA to issue regulations requiring retail outlets whose predominant business is selling tobacco products to comply with any advertising restrictions applicable to retail outlets accessible to individuals under age 18. [FFDCA Sec. 913]
Federal Trade Commission jurisdiction	Nothing in this Act (except where expressly provided) limits or diminishes the existing authority of the FTC to regulate the advertising, sale, or distribution of tobacco products. Requires the Secretary and the FTC Chairman to coordinate their tobacco regulatory activities. [FFDCA Sec. 914]
Ingredient and smoke constituent testing	Requires the Secretary, within three years of enactment, to issue new regulations mandating the testing and reporting of tobacco product ingredients and smoke constituents, by brand and sub-brand, that the Secretary determines should be tested to protect the public health. Such regulations may require the disclosure of testing results through, for example, labels and advertisements. Gives small tobacco product manufacturers (as defined in the bill) additional time to comply with the new testing and reporting requirements, including extensions for limited laboratory capacity. [FFDCA Sec. 915]
Preemption of state and local laws	Generally preserves state and local authority to regulate and tax tobacco products, but preempts all state and local requirements that relate to the following provisions in this Chapter: tobacco product standards; premarket approval; adulteration; misbranding; labeling; registration; GMPs; and modified risk products. Does not preempt state and local requirements relating to the sale, distribution, possession, use, access to, advertising, and promotion of tobacco products. Product liability actions under state law are not affected by this Act. [FFDCA Sec. 916]

Tobacco Products Scientific Advisory Committee	Within six months of enactment, requires the Secretary to establish a 12-member Tobacco Products Scientific Advisory Committee, subject to the Federal Advisory Committee Act (FACA). Specifies the Committee's membership, duties, and compensation. Instructs the Committee to provide advice and guidance to the Secretary on the effects of altering nicotine yield and whether there is a threshold at which nicotine becomes addictive, among other things. [FFDCA Sec. 917]
Nicotine replacement products	Instructs the Secretary to: (1) at the request of the applicant, designate nicotine replacement products as fast track products under FFDCA Sec. 506; (2) consider approving the extended use of nicotine replacement products; and (3) consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention. Within three years, requires the Secretary to submit to Congress a report on how best to regulate, promote, and encourage the development of innovative products and treatments for tobacco dependence. [FFDCA Sec. 918]
User fees	Instructs the Secretary to assess user fees (payable quarterly) on tobacco manufacturers and importers to pay for the cost of FDA tobacco regulation under this Chapter. Sets the amount of the assessment for each of the next 10 fiscal years, beginning at $85 million in FY2009 and increasing to $712 million in FY2019 and each subsequent fiscal year. Specifies that each class of tobacco products be assessed a percentage of the total assessment, based on the applicable percentages in subsection 625(c) of the Fair and Equitable Tobacco Reform Act of 2004 (P.L. 108-357). Specifies that the percentage share of fees paid by each manufacturer or importer of a particular class of tobacco products be based on that manufacturer's or importer's share of the domestic market, as determined by the Secretary of Agriculture pursuant to subsections 625(e)-(h) of P.L. 108-357. User fees may be collected and used only to the extent and in the amounts provided in advance in appropriations acts. Startup costs for FDA's tobacco regulatory activities may be paid out of other agency accounts, provided that such amounts are reimbursed through the user fees. [FFDCA Sec. 919] *S. 982 states that any startup costs must be reimbursed through the user fees.*
Illicit tobacco trade	Beginning one year after enactment, requires that the tobacco product labels, packaging, and shipping containers for products intended for domestic consumption must bear the statement: "Sale only allowed in the United States." Requires the Secretary to issue regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, packages, holds, exports, or imports tobacco products. Prohibits the Secretary from requiring retailers to maintain records of individual customer purchases. Grants the Secretary access to all records if there is reason to believe that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product. Requires tobacco product manufacturers and distributors with knowledge of illegal transactions to promptly notify the Attorney General. [FFDCA Sec. 920] Requires the GAO to study and, within 18 months of enactment, report on cross-border trade of tobacco products (including illicit trade). Cross-border trade is defined as both international and interstate trade, including trade with Indian tribes. The study is to include data on the health effects resulting from smuggled and counterfeit tobacco products, and from differing tax rates applicable to tobacco products.
1996 FDA Tobacco Regulations (21 CFR Part 897)	
Youth access and advertising restrictions	Requires the Secretary, within 180 days of enactment, to publish as a final rule the 1996 FDA tobacco rule (minus the labeling provisions in Subpart C, and with modified definitions of "cigarettes" and other terms, pursuant to the definitions used in this Act). Amends subsection 897.16(d) of the rule (i.e., prohibition on free samples of tobacco products) to permit free samples of smokeless tobacco products in a qualified adult-only facility (as defined). The published rule would be deemed to be in compliance with the Administrative Procedures Act and would take effect one year after enactment. Prior to making any amendments to the published final rule, the Secretary must promulgate a proposed rule. [For a list of the rule's provisions, see the text box on page 2 of this report.] *In addition, S. 982 requires the Secretary to modify subsection 897.30(b) of the FDA tobacco rule (i.e., ban on outdoor advertising within 1,000 feet of schools and playgrounds) to address First Amendment case law, including Lorillard Tobacco Co. v. Reilly (discussed earlier in this report).*

Tobacco Product Labeling and Advertising	
Cigarette health warning labels	Amends the federal cigarette labeling and advertising law[a] to require new, rotating, explicit health warning labels in bold type on cigarette packages.[b] Specifies the placement and typography of the labels (e.g., labels must occupy at least the top 30% of the front and rear panels of the package). Exempts cigarette exports from the package labeling requirements. Retailers that are supplied with cigarettes in violation of these labeling requirements are not liable. Further amends the existing cigarette labeling law to require the same health warnings in cigarette advertising, and specifies the placement and typography of such warnings (as well as other required statements relating to tar, nicotine, and other constituents) in press and poster ads. Authorizes the Secretary, through rulemaking, to make adjustments to the format and type size of the label statements, or to the text, format, and type size of other required statements relating to tar, nicotine, and other constituents. Retailers are liable if they publicly display an advertisement that is not labeled in accordance with this Act. Specifies that the Act's new labeling requirements will take effect one year after enactment. Permits the Secretary, by rulemaking, to revise the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30% to 50% of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under this Act, if the Secretary finds that such change would promote a greater public understanding of the risks of tobacco use. Amends the federal cigarette labeling and advertising law's preemption provisions to permit states to regulate the time, place, and manner, but not the content, of cigarette advertising and promotion. *S. 982 requires the warning labels to occupy the top 50% of the front and rear panels of the package. It also instructs the Secretary, within 24 months of enactment, to issue a rule requiring color graphics depicting the negative health consequences of smoking to accompany the label requirements. Authorizes the Secretary to issue a rule to revise the format, type size, color graphics, and text of the label requirements, or establish the format, type size, and text of any other disclosures required under this Act, if the Secretary finds that such change would promote a greater public understanding of the risks of tobacco use.*
Smokeless tobacco health warning labels	Amends the federal smokeless tobacco labeling and advertising law[c] to require new, rotating, explicit health warning labels in bold type on smokeless tobacco packages.[d] Specifies the placement and typography of the labels (e.g., labels must occupy at least 30% of the two principal display panels of the package). Exempts smokeless tobacco exports from the package labeling requirements. Retailers that are supplied with smokeless tobacco products in violation of these labeling requirements are not liable. Further amends the existing smokeless tobacco labeling law to require the same health warnings in smokeless tobacco advertising, and specifies the placement and typography of such warnings (as well as other required statements relating to tar, nicotine, and other constituents) in press and poster ads. Authorizes the Secretary, through rulemaking, to make adjustments to the format and type size of the label statements, or to the text, format, and type size of other required statements relating to tar, nicotine, and other constituents. Retailers are liable if they publicly display an advertisement that is not labeled in accordance with this Act. Specifies that the Act's new labeling requirements will take effect one year after enactment. Prohibits smokeless tobacco advertising on radio or television. Permits the Secretary, by rulemaking, to revise the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30% to 50% of a package's principal display panels, or establish the format, type size, and text of any other disclosures required under this Act, if the Secretary finds that such change would promote a greater public understanding of the risks of smokeless tobacco use.
Tar, nicotine, and other smoke constituent disclosure	Amends the federal cigarette labeling and advertising law[a] to require the Secretary, by rulemaking, to determine whether cigarette and other tobacco product packaging and advertising must disclose tar and nicotine yields. Requires the Secretary, by a memorandum of understanding, to resolve with the Federal Trade Commission (FTC) any differences between the tar and nicotine disclosure requirements established by the Secretary and those established by FTC under existing law. Additionally, the Secretary, by rulemaking, may require disclosure of the level of other tobacco product constituents (including smoke constituents), if such disclosure would benefit public health or otherwise increase awareness of the health risks of tobacco use, except that no such disclosure may be required on the face of any cigarette package or advertisement.

Prohibited Acts and Enforcement	
Prohibited Acts	Amends the existing provisions in FFDCA Sec. 301 ("Prohibited Acts") by prohibiting the introduction of adulterated or misbranded tobacco products into interstate commerce, among other things. Further amends Sec. 301 by prohibiting several types of activities with respect to tobacco products, including: (1) the sale of tobacco products in violation of a no-tobacco-sale order (see below); (2) the marketing of tobacco products in violation of the Act's modified risk tobacco product provisions; (3) the charitable distribution of tobacco products; and (4) marketing, labeling, or advertising that would reasonably be expected to result in consumers believing that the product is regulated, inspected, or approved by FDA or that it complies with FDA requirements, or that could result in consumers believing that the product is endorsed for use by FDA or in consumers being misled about the harmfulness of the product because of such regulation or compliance. *S. 982 amends (4) above to prohibit making any express or implied claim in labeling or through the media or advertising that would mislead consumers into believing that (i) the product is FDA approved, (ii) FDA deems the product safe, (iii) the product is FDA endorsed, or (iv) the product is safe or less harmful by virtue of its regulation or inspection by FDA, or its compliance with FDA regulatory requirements.*
Enforcement	Requires the Secretary, within six months of enactment, to publish an action plan to enforce restrictions adopted pursuant to this Act on the promotion and advertising of menthol and other cigarettes to youth. Requires the Secretary, within three months of enactment, to inform state, local, and tribal governments of the authority provided to them under this Act to regulate tobacco products. Amends FFDCA Sec. 303(f) authorizing the Secretary, after an opportunity for a hearing, to impose a no-tobacco-sale order on a retail outlet that repeatedly violates tobacco product restrictions promulgated under FFDCA Sec. 906 (as added by this Act). Requires the Secretary to issue guidance: (1) defining the term repeated violations as including at least five violations of particular requirements over a 36-month period; (2) providing for notice to the retailer of each alleged violation; (3) providing for a hearing for assessing civil money penalties; (4) providing that good faith reliance on false government-issued photo ID with date of birth does not constitute a violation of the minimum age requirement, provided the retailer has taken certain steps to prevent such violations; and (5) establishing a series of increasing civil money penalties based on the number of violations (as specified in the Act). Amends FFDCA Sec. 702 requiring the Secretary, to the extent feasible, to contract with states to carry out tobacco retailer inspections for the purpose of enforcing this Act. Requires the Secretary to ensure that the provisions of this Act and its implementing regulations, including those that relate to retail sales of tobacco products, are enforced with respect to Indian tribes. Exercising enforcement authority under this Act on Indian country requires the express written consent of the Indian tribe involved.
Minimum age	Requires the Secretary to convene an expert panel and, within five years, report to Congress on the public health implications of raising the minimum purchase age for tobacco products.

Source: Table prepared by the Congressional Research Service, based on the text of H.R. 1256, as passed by the House on April 2, 2009, and the text of S. 982, as amended and approved by the Committee on Health, Education, Labor and Pensions on May 20, 2009.

a. Federal Cigarette Labeling and Advertising Act (15 U.S.C. §§ 1331 et seq.). The FTC administers the cigarette labeling law.

b. The new labels read: (1) WARNING: Cigarettes are addictive; (2) WARNING: Tobacco smoke can harm your children; (3) WARNING: Cigarettes cause fatal lung disease; (4) WARNING: Cigarettes cause cancer; (5) WARNING: Cigarettes cause strokes and heart disease; (6) WARNING: Smoking during pregnancy can harm your baby; (7) WARNING: Smoking can kill you; (8) WARNING: Tobacco smoke causes fatal lung disease in nonsmokers; and (9) WARNING: Quitting smoking now greatly reduces serious risks to your health.

c. Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. §§ 4401 et seq.). The FTC administers the smokeless tobacco labeling law.

d. The new labels read: (1) WARNING: This product can cause mouth cancer; (2) WARNING: This product can cause gum disease and tooth loss; (3) WARNING: This product is not a safe alternative to cigarettes; (4) WARNING: Smokeless tobacco is addictive.

Appendix. Tobacco Master Settlement Agreement

On November 23, 1998, attorneys general from 46 states, the District of Columbia, and the U.S. territories signed a contractual agreement (the Master Settlement Agreement, or MSA) with the major cigarette companies to settle state lawsuits to recover the costs, borne by Medicaid and other public programs, of treating smoking-related illnesses.[71] The remaining four states — Mississippi, Florida, Texas, and Minnesota — had settled individually with the companies prior to the MSA. Under the terms of the MSA, the companies agreed to make annual payments totaling approximately $200 billion over the first 25 years and accept certain restrictions on tobacco product advertising, marketing, and promotion. Specifically, the MSA:

- prohibited tobacco companies from targeting youth in the advertising, promotion, or marketing of their products;
- banned the use of cartoons in advertising;
- limited each company to brand-name sponsorship of one sporting or cultural event a year, excluding concerts, team sports, events with a significant youth audience, or events with underage contestants;
- banned public transit advertising;
- banned outdoor billboard advertising, excluding billboard advertising for brand-name sponsored events;
- limited advertising outside retail stores to signs no bigger than 14 sq. ft;
- banned company payments to promote tobacco products in various media, including movies and TV;
- banned non-tobacco apparel with brand-name logos except at brand-name sponsored events;
- banned gifts of non-tobacco items to youth in exchange for tobacco products;
- restricted the use of nationally recognized non-tobacco brand names for tobacco products; and
- limited free samples of tobacco products to adult-only facilities.

Author Information

C. Stephen Redhead
Specialist in Health Policy

Vanessa K. Burrows
Legislative Attorney

[71] The full text of the MSA is available on the website of the National Association of Attorneys General, which is responsible for enforcing it, at http://www.naag.org/backpages/naag/tobacco/msa.

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