



# FDA Tobacco Regulation: History of the 1996 Rule and Related Legislative Activity, 1998-2008

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## Summary

The 111<sup>th</sup> Congress may consider legislation giving the Food and Drug Administration (FDA) broad new authority to regulate the manufacture, distribution, advertising, promotion, sale, and use of cigarettes and smokeless tobacco products. Bipartisan FDA tobacco legislation passed the Senate in July 2004 and the House in July 2008 by wide margins, but the measures were opposed by the Bush Administration. The Obama Administration has signaled its support for the legislation.

In the mid-1990s, FDA claimed authority under the Federal Food, Drug, and Cosmetic Act (FFDCA) to regulate cigarettes and smokeless tobacco products as delivery devices for nicotine, an addictive drug. The agency's 1996 tobacco rule was struck down by the U.S. Supreme Court in March 2000 in *FDA v. Brown & Williamson Tobacco Corp.* The Court concluded that Congress had clearly intended to preclude FDA from regulating tobacco products. It found that because the FFDCA prohibits the marketing of products that have not been found to be safe and effective, the statute would have required FDA to ban such manifestly harmful products as cigarettes and smokeless tobacco if the agency had jurisdiction over them. Such a ban, argued the Court, would plainly contradict congressional intent. The Supreme Court's decision made it clear the Congress would have to enact legislation giving FDA statutory authority over tobacco products in order for the agency to assert jurisdiction. Lawmakers first drafted such language in the 105<sup>th</sup> Congress as part of an unsuccessful attempt to implement the 1997 proposed national tobacco settlement. Following the Supreme Court's decision, a bipartisan, bicameral group of lawmakers introduced the Family Smoking Prevention and Tobacco Control Act in the 108<sup>th</sup> Congress. The bill, which was reintroduced in the 109<sup>th</sup> and 110<sup>th</sup> Congresses, sought to balance the competing interests of public health groups and Philip Morris, the nation's leading cigarette company.

The Family Smoking Prevention and Tobacco Control Act would have required all tobacco product manufacturers to register annually with the FDA and provide the agency with a detailed product list. It would have mandated biennial inspection of all registered establishments and require premarket approval of new tobacco products unless they were determined to be substantially equivalent to other tobacco products already on the market. In addition, the legislation would have required manufacturers to obtain FDA approval in order to make reduced-risk and reduced-exposure claims for their products, including the use of descriptors such as "light," "mild," and "low." Finally, the measure would have authorized FDA to regulate the advertising and promotion of tobacco products in order to protect public health; given FDA the authority to modify the composition of tobacco products so as to protect public health (though it would have prohibited the agency from eliminating nicotine or banning tobacco products); and required FDA to develop new regulations for testing and reporting tobacco product ingredients and smoke constituents. This report provides some history and analysis of the 1996 FDA rule, including the agency's arguments for asserting jurisdiction over tobacco products, and summarizes the industry's legal challenge that overturned the rule. It then reviews the 1997 proposed national tobacco settlement, which would have codified the FDA rule and given the agency authority to regulate tobacco products as medical devices, and discusses the FDA provisions in the tobacco settlement legislation that was defeated in the 105<sup>th</sup> Congress. The report concludes with a summary of legislative activity on the Family Smoking Prevention and Control Act in the 108<sup>th</sup>, 109<sup>th</sup>, and 110<sup>th</sup> Congresses. A companion report will analyze FDA tobacco legislation in the 111<sup>th</sup> Congress.

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## Introduction

It is widely anticipated by public health officials and the tobacco companies that the 111<sup>th</sup> Congress will move to enact legislation giving the Food and Drug Administration (FDA) new authority to regulate the manufacture, distribution, advertising, promotion, sale, and use of cigarettes and smokeless tobacco products. Bipartisan FDA tobacco legislation passed the Senate in July 2004 and the House in July 2008 by wide margins, but the measures were opposed by the Bush Administration. The Obama Administration has signaled its support for the legislation.

Lawmakers first introduced FDA tobacco legislation over a decade ago, following the release of a 1996 final rule in which the agency asserted jurisdiction over tobacco products. FDA argued that the Federal Food, Drug, and Cosmetic Act (FFDCA) gave it the authority to regulate tobacco products based on its conclusion that cigarettes and smokeless tobacco are delivery devices for nicotine, an addictive drug. However, in 2000, the U.S. Supreme Court invalidated the FDA tobacco rule. In a 5-4 decision, the Court held in *FDA v. Brown & Williamson Tobacco Corporation* that FDA does not have the authority under the FFDCA to regulate cigarettes and smokeless tobacco products as drug-delivery devices.<sup>1</sup> The Court based its ruling on the finding that Congress has precluded the FDA from asserting jurisdiction over tobacco products. According to the Court, such authority would be inconsistent with the congressional intent clearly expressed in the FFDCA's overall regulatory scheme and in other tobacco-related legislation. For example, the Court concluded that if the FDA asserted jurisdiction under the FFDCA, 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, which permits tobacco companies to market their products with limited oversight by the Federal Trade Commission (FTC). In addition, the Court noted that Congress had, in enacting other tobacco-specific legislation, repeatedly rejected proposals to grant the FDA authority over tobacco, thereby demonstrating the intent to deny the agency such jurisdiction.

The Supreme Court's decision ended a four-year legal challenge by the tobacco industry to overturn the FDA regulation. The ruling made it clear that Congress would have to enact legislation giving FDA explicit statutory authority over tobacco products in order for the agency to assert jurisdiction. Lawmakers had initially drafted such language in the 105<sup>th</sup> Congress and included it in legislation to implement the 1997 proposed national tobacco settlement. That legislation was debated and rejected by the Senate in 1998. Following the Supreme Court's ruling, several FDA tobacco bills were introduced in the 107<sup>th</sup> Congress though none saw any legislative action.<sup>2</sup>

In the 108<sup>th</sup> Congress, Representatives Davis (R-VA) and Waxman (D-CA) and Senators DeWine (R-OH) and Kennedy (D-MA) introduced the Family Smoking Prevention and Tobacco Control Act (H.R. 4433, S. 2461). 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. The Senate voted 78-15 to add S. 2461 as an amendment to a corporate tax package, but the language was subsequently removed in conference. The Family Smoking Prevention and

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<sup>1</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

<sup>2</sup> H.R. 1044 (Waxman); H.R. 1097 (Ganske); H.R. 2180 (Davis); S. 190 (Frist); S. 247 (Harkin); and S. 2626 (Kennedy).

Tobacco Control Act was reintroduced in the 109<sup>th</sup> Congress (H.R. 1376, S. 666) and again in the 110<sup>th</sup> Congress (H.R. 1108, S. 625), during which it was reported out of the House Committee on Energy and Commerce, as amended, as well as ordered to be reported out of the Senate Committee on Health, Education, Labor, and Pension (HELP), as amended. The full House passed H.R. 1108 in July 2008 by a vote of 326-102.

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) would result in some additional decline in smoking prevalence, more substantial and enduring reductions in tobacco use would only come from stronger federal regulation.

In anticipation of renewed debate on comprehensive FDA tobacco legislation in the 111<sup>th</sup> Congress, this report provides some history and analysis of the 1996 FDA rule, including the agency's arguments for asserting jurisdiction over tobacco products, and summarizes the industry's successful legal challenge to overturn the rule. It then reviews the 1997 proposed national tobacco settlement, which would have codified the FDA rule and given the agency explicit authority to regulate tobacco products as medical devices, and discusses the FDA provisions in the McCain tobacco bill. That measure was introduced and debated in the 105<sup>th</sup> Congress in an attempt to implement the proposed settlement. The report concludes with a summary of legislative activity on the Family Smoking Prevention and Control Act in the 108<sup>th</sup>, 109<sup>th</sup>, and 110<sup>th</sup> Congresses. A companion report will examine FDA tobacco legislation in the 111<sup>th</sup> Congress.

## **FDA's 1996 Tobacco Regulation**

On August 28, 1996, the FDA issued a final rule aimed at reducing underage smoking and use of smokeless tobacco products.<sup>3</sup> The FDA rule included three sets of provisions: restrictions on the sale and distribution of tobacco products to minors; limits on tobacco-product marketing and advertising; and new labeling requirements for packaging and advertising (see box on next page). The agency said that the purpose of the rule was to reduce the easy access to tobacco products by minors. It also hoped to reduce the amount of positive advertising imagery used by manufacturers to make their products appealing to minors. While the rule did not directly address adult tobacco use, data from the National Survey on Drug Use and Health (NSDUH) suggest that over time it would help reduce adult tobacco consumption. NSDUH data indicate that most smokers take up the habit as teenagers. Thus, reducing the number of new teenage smokers, who are needed to replace adult smokers that quit or die, is expected to lower overall tobacco consumption in the future.

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<sup>3</sup> 61 Fed. Reg. 44396-45318; 21 C.F.R. Parts 801, 803, 804, 807, 820, and 897.

## **Summary of FDA's 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 Requirements**

- Required cigarette and smokeless tobacco packaging to include the statement: “Nicotine-Delivery Device for Persons 18 and Older.”
- Required cigarette and smokeless tobacco 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.<sup>a</sup>
- 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 items and services identified with a cigarette or smokeless tobacco brand name (e.g., promotional 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.

a. The FDA rule defined significant youth readership as having 2 million or more readers under age 18, or having readers under age 18 constitute more than 15% of the total readership.

## **FDA's Assertion of Jurisdiction over Tobacco Products**

Under the FFDCRA, drug and device manufacturers must demonstrate that their products are both safe and effective in order to gain FDA marketing approval.<sup>4</sup> The safety and effectiveness standard poses a difficult challenge for regulating tobacco products, which are manifestly unsafe when used as intended. Critics of FDA's rule argued that in asserting regulatory authority over tobacco products, the agency would have no choice but to ban them because of their harmful and addictive effects. In commenting on the rule, the FDA conceded that tobacco products are “unsafe” as that term is generally understood, but concluded that banning tobacco products was not a realistic option because the health care system would be overwhelmed by more than 40

<sup>4</sup> See CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams.

million nicotine addicts seeking assistance for withdrawal symptoms. Moreover, the agency argued, banning cigarettes would create an enormous black market, which might lead to the use of unregulated and potentially even more dangerous products.

The FDA asserted jurisdiction over cigarettes and smokeless tobacco by concluding that nicotine is a drug and that cigarettes and smokeless tobacco are drug-delivery devices under the FFDCA's definitions. The statute defines a drug, in relevant part, as "... articles (other than food) *intended* to affect the structure or any function of the body."<sup>5</sup> In its rulemaking, the FDA drew on the extensive scientific literature documenting nicotine's pharmacologic effects on the body, including satisfaction of addiction, stimulation, and sedation. The agency also concluded that cigarettes and smokeless tobacco are devices that deliver nicotine into the body. As with drugs, the FFDCA's definition of medical devices includes articles that are intended by the manufacturer to affect the structure and function of the body.<sup>6</sup> Unlike a drug, however, a device is defined, in part, as an article "which does not achieve its primary intended purpose through chemical action."<sup>7</sup>

In the absence of direct claims by the manufacturers about the intended use of tobacco products, the FDA relied on other lines of evidence in order to meet this key definitional criterion for drugs and devices. For example, the agency considered evidence of foreseeability (i.e., a reasonable manufacturer would foresee that consumers will use the product to satisfy nicotine addiction) and actual consumer use (i.e., consumers use the product because they are addicted). FDA officials combed through thousands of pages of internal tobacco company documents before concluding that the manufacturers intended their products to be addictive.

Having made the determination that tobacco products fall under the statutory definitions of drugs and devices, the FDA further concluded that these products are combination products because they have components that are both a drug and a device. Under the FFDCA, the FDA is authorized to regulate products that "constitute a combination of a drug, device, or biologic product."<sup>8</sup> The agency has interpreted this provision as giving it the discretion to regulate combination products as drugs, as devices, or as biologic products.<sup>9</sup> In its final rule, the FDA chose to regulate tobacco products under the device provisions of the FFDCA because they offer the agency greater regulatory flexibility than do the drug provisions of the act.<sup>10</sup>

The device authorities of the act present a range of regulatory controls that apply to all devices. The FDA stated in its rule that these mandatory controls would apply to cigarettes and smokeless tobacco products. They include, among others, adulteration and misbranding provisions, labeling requirements, establishment registration, device listing and premarket notification, recordkeeping and reporting requirements, and good manufacturing practices. In addition, the FFDCA gives the agency inspection and recall authority for devices. The act also requires the agency to classify each device based upon the degree of risk it poses to the user as well as other regulatory concerns and unique qualities of the device. The FDA indicated in the final rule that it would classify

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<sup>5</sup> 21 U.S.C. § 321(g)(1)(C); FFDCA § 201(g)(1)(C) (emphasis added).

<sup>6</sup> 21 U.S.C. § 321(h)(3); FFDCA § 201(h)(3).

<sup>7</sup> 21 U.S.C. § 321(h); FFDCA § 201(h).

<sup>8</sup> 21 U.S.C. § 353(g); FFDCA § 503(g).

<sup>9</sup> 61 Fed. Reg. 44396, 44400 (1996).

<sup>10</sup> *Id.* at 44403. In 2005, FDA published a final rule setting forth definitions and an algorithm the agency uses to assign combination products to an agency component for regulatory oversight. 69 Fed. Reg. 49848 (2005).

cigarettes and smokeless tobacco at some point in the future.<sup>11</sup> The agency further stated that when classification was determined, it would impose any additional requirements that were appropriate.

In addition to mandatory controls, the FFDCA contains various discretionary provisions that apply to devices under certain circumstances. The FDA predicated its authority to regulate tobacco products on one such provision regarding restricted devices. The act's restricted device provision states, in relevant part, that "[t]he Secretary may by regulation require that a device be restricted to sale, distribution, or use ... upon such other conditions as the Secretary may prescribe in such regulation, if, *because of its potentiality for harmful effect or the collateral measures necessary for its use*, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness."<sup>12</sup>

In the final tobacco rule, the FDA relied on the FFDCA's restricted device provision when it concluded that, because of the harmful effects of cigarettes and smokeless tobacco and in the absence of a reasonable assurance of the safety and effectiveness of such products, it needed to implement additional restrictions on tobacco access and advertising in order to prevent new users from becoming addicted.<sup>13</sup> As a result, the FDA used its restricted device authority to limit youth access to tobacco products. Agency officials also concluded that the authority under the FFDCA's restricted device provision was broad enough to permit the FDA to restrict tobacco-product marketing and advertising. It reasoned that without advertising restrictions, the access restrictions would be substantially diminished if manufacturers were "free to entice children and adolescents to circumvent the access restrictions."<sup>14</sup>

## **Court Challenge to the FDA Tobacco Rule**

The tobacco companies filed a lawsuit against the FDA and sought summary judgment on the grounds that the FDA lacked the authority to regulate tobacco products when such products are marketed and sold without explicit claims of therapeutic benefit. The lawsuit further charged that the FDA exceeded its statutory authority because the FFDCA does not authorize the FDA to regulate tobacco products as drugs or devices.<sup>15</sup> Finally, the companies argued that the rule's advertising restrictions, which limited advertisements to which children are exposed to a black-on-white, text-only format, violated the First Amendment protection of commercial speech.

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<sup>11</sup> Class I devices (e.g., elastic bandages, manual surgical instruments) present minimal harm to the user and are only subject to general controls, such as manufacturer registration and labeling. Class II devices (e.g., cardiac pressure monitors, powered surgical instruments) are those for which general controls alone are insufficient to assure safety and effectiveness. In addition to complying with general controls, Class II devices are also subject to special controls, such as additional labeling requirements, mandatory performance standards, and postmarket surveillance. Class III devices (e.g., replacement heart valves, breast implants) present the greatest potential for risk of illness or injury and are subject to the most stringent regulatory control. They require premarket approval by FDA—a process that involves a comprehensive agency review of their safety and effectiveness—unless they are substantially equivalent to a device already on the market.

<sup>12</sup> 21 U.S.C. § 360j(e); FFDCA § 520(e) (emphasis added).

<sup>13</sup> 61 Fed. Reg. 44396, 44405.

<sup>14</sup> 61 Fed. Reg. 44406-07.

<sup>15</sup> *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374 (M.D.N.C. 1997).



### **U.S. District Court (*Coyne Beahm, Inc. v. FDA*)**

On April 25, 1997, a North Carolina federal district court ruled in favor of the FDA, holding that the agency had acted appropriately under the FFDCA when it classified nicotine as a drug and tobacco products as drug-delivery devices.<sup>16</sup> However, while the court upheld the rule's access restrictions and labeling requirements, it ruled that the FDA did not have the authority to restrict tobacco advertising and promotion. The court permitted the two youth access provisions that had taken effect prior to its ruling to remain in effect, but delayed implementation of the rule's other provisions, pending further action by the court.<sup>17</sup> Both sides appealed the district court's ruling.

### **Federal Court of Appeals (*Brown & Williamson Tobacco Corp. v. FDA*)**

On August 14, 1998, a three-judge panel of the U.S. Court of Appeals for the Fourth Circuit overturned the lower court's decision and ruled that the FDA lacked the statutory authority to regulate tobacco products.<sup>18</sup> The court held that the decision to regulate cigarettes as a restricted device rather than as a drug, in order to avoid having to ban them, was "... obvious sophistry, [which] reinforces the conclusion that regulation of tobacco products under the Act was not intended by Congress."<sup>19</sup> The court's decision was stayed pending further appeal.

On November 10, 1998, in a 6-3 decision, the full appellate court rejected the Administration's request to reconsider the ruling.<sup>20</sup> The Justice Department filed a Petition for a Writ of Certiorari with the U.S. Supreme Court on January 19, 1999, requesting that the court review the Fourth Circuit ruling and find that the FDA has full statutory authority both to regulate tobacco products and to issue all the provisions of the 1996 tobacco rule. The Supreme Court accepted the case and ultimately upheld the Fourth Circuit's decision.

### **U.S. Supreme Court (*FDA v. Brown & Williamson Tobacco Corp.*)**

On March 21, 2000, the U.S. Supreme Court, in a 5-4 decision written by Justice Sandra Day O'Connor, affirmed the ruling of the appeals court that the FDA does not have the authority to regulate tobacco products as drug-delivery devices.<sup>21</sup> Although the majority opinion acknowledged the public health threat posed by tobacco use, the Court concluded that "Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the [FFDCA's] overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the [FFDCA]."<sup>22</sup>

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<sup>16</sup> *Id.*

<sup>17</sup> The two youth access provisions were: (i) no sales to individuals under age 18; and (ii) photo ID required as a condition of sale for all individuals under age 27.

<sup>18</sup> *Brown & Williamson Tobacco Corp. v. FDA*, 153 F. 3d. 155 (4<sup>th</sup> Cir. 1998).

<sup>19</sup> *Id.* at 165.

<sup>20</sup> *Brown & Williamson Tobacco Corp. v. FDA*, 161 F. 3d. 764 (4<sup>th</sup> Cir. 1998).

<sup>21</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

<sup>22</sup> *Id.* at 126.

In reaching its decision, the Court examined the FDA tobacco rule in light of the precedents that govern cases involving an agency's construction of a statute that it administers. As part of such a review, the Court must determine whether an agency's interpretation of its statute is entitled to deference and presents a reasonable or permissible construction of the law. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* is the leading case on judicial review of agency interpretations of statutes.<sup>23</sup> This case involved the Environmental Protection Agency's rules regulating emissions under the Clean Air Act. In *Chevron*, the Court enunciated a two-step test for judicial review of an agency's interpretation of its statute: (1) has Congress spoken directly to the precise question at issue? and (2) if Congress has not done so and the statute is silent or ambiguous with respect to the specific issue, is the agency's answer based on a permissible construction of the statute?<sup>24</sup>

Under *Chevron* step one, if Congress has spoken directly to the question at issue, then *Chevron* deference is not due and the Court "must give effect to the unambiguously expressed intent of Congress."<sup>25</sup> In this case, the Court examined both the FFDCA and other tobacco-related statutes, ultimately concluding that Congress had clearly intended to preclude the FDA from regulating tobacco. As a result, the Court did not need to reach step two of *Chevron*. In reaching its decision, the Court relied on a number of factors. First, the Court found that, because tobacco is a dangerous product and because the FFDCA prohibits the marketing of products that have not been found to be safe and effective, the statute would require the FDA to ban tobacco products if the agency did indeed have jurisdiction over such products. Such a ban, argued the Court, would plainly contradict the congressional intent reflected in the enactment of several pieces of legislation that clearly contemplate the continued marketing of tobacco products.<sup>26</sup> Thus, the Court held that Congress had clearly "intended to exclude tobacco products from the FDA's jurisdiction."<sup>27</sup>

In addition, the Court found that the FDA had repeatedly denied that it had jurisdiction over tobacco and that Congress had repeatedly rejected bills that would have granted the agency such authority.<sup>28</sup> Instead, Congress had demonstrated its intent to create a distinct regulatory scheme for tobacco by enacting other tobacco-related regulatory statutes, such as the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act.<sup>29</sup> The Court cited these tobacco-related statutes as additional evidence in support of its conclusion that Congress had intended to preclude the FDA from regulating tobacco.<sup>30</sup>

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<sup>23</sup> 467 U.S. 837 (1984).

<sup>24</sup> *Id.* at 842-43.

<sup>25</sup> *Id.* at 843.

<sup>26</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134-43 (2000). Examples of such tobacco-related legislation include the Federal Cigarette Labeling and Advertising Act (P.L. 89-92, 15 U.S.C. §§ 1331 et seq.); the Public Health Cigarette Smoking Act of 1969 (P.L. 91-222, 15 U.S.C. §§ 1331 et seq.); the Comprehensive Smoking Education Act (P.L. 98-474, 15 U.S.C. §§ 1331 et seq.); the Comprehensive Smokeless Tobacco Health Education Act of 1986 (P.L. 99-252, 15 U.S.C. §§ 4401 et seq.); and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (P.L. 102-321, § 202, 42 U.S.C. § 300x-26).

<sup>27</sup> *Brown & Williamson*, 529 U.S. at 143.

<sup>28</sup> According to the tobacco companies, beginning in 1906 and as recently as 1993, Congress rejected any legislation designed to give the FDA jurisdiction over tobacco. *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374 (M.D.N.C. 1997) (No. 2:95CV00591), at 6-11 (First Amended Complaint for Declaratory and Injunctive Relief).

<sup>29</sup> These statutes, both of which are administered by the FTC, require health warnings on cigarette and smokeless tobacco packages and advertising, respectively.

<sup>30</sup> *Brown & Williamson*, 529 U.S. at 143-156.

Writing in dissent, Justice Stephen Breyer argued that cigarettes and other tobacco products clearly fall within the plain meaning of the statutory definition of drugs and devices because such products are intended to affect the structure and function of the body. In addition, the dissent argued that the purpose of the FFDCA—to protect the public health—also supported the conclusion that the FDA was authorized to regulate tobacco products. For these reasons, the dissent would have upheld the FDA’s jurisdiction over such products.<sup>31</sup>

The Supreme Court’s decision clarifies that the FDA cannot assert jurisdiction over cigarettes and other tobacco products unless Congress enacts legislation to give the agency unambiguous statutory authority over such products. Lawmakers first drafted such language during the 105<sup>th</sup> Congress and included it in the comprehensive tobacco legislation that was introduced in an effort to implement the 1997 proposed national tobacco settlement.

## **1997 Proposed National Tobacco Settlement**

On June 20, 1997, a group of state attorneys general announced that they had reached an agreement with the tobacco companies to settle the state tobacco lawsuits.<sup>32</sup> Forty-one states and Puerto Rico had sued the tobacco industry seeking to recover the costs, primarily Medicaid expenditures, of treating smoking-related diseases. Under the proposed national settlement, the industry agreed to pay \$368.5 billion over the first 25 years, and \$15 billion a year thereafter, to reimburse states for their tobacco-related medical costs and pay for tobacco-control programs to reduce tobacco use among teenagers. In addition to settling the state lawsuits, the proposed settlement would have terminated all pending class-action lawsuits and nicotine addiction claims, and provided the companies with immunity from such lawsuits in the future.

The proposed settlement incorporated all the provisions of the FDA tobacco rule and included additional restrictions on marketing and advertising, as well as new warning labels. It also proposed amending the FFDCA to classify tobacco products as Class II devices and give FDA the authority to reduce or eliminate harmful compounds added to tobacco products or found in smoke. A summary of the key provisions in the proposed national settlement is provided in the text box below.

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<sup>31</sup> *Id.* at 161-64.

<sup>32</sup> The full text of the June 1997 proposed national tobacco settlement is available online at <http://www.stic.neu.edu/settlement/6-20-settle.htm>.

### **Summary of Proposed National Tobacco Settlement (June 20, 1997)**

**FDA Regulation.** Incorporated the following provisions of FDA's 1996 tobacco rule (21 CFR 897): prohibited sale of tobacco products to persons under age 18; required photo ID to verify age; limited advertising to which children are exposed to black-on-white, text-only format; prohibited the sale or distribution of promotional non-tobacco items such as hats and tee shirts; prohibited brand-name sponsorship of sporting and other events; required explicit warning labels. Extended the FDA's regulation by banning all vending machines and outdoor advertising, and prohibiting the use of human and cartoon images in advertising and packaging. Established strict regulatory requirements for reducing or eliminating nicotine from tobacco products, including formal rulemaking with judicial review and demonstrating that the modified product reduces health risks and does not create a black market for unmodified products.

**Retailer Licensing.** Set federal standards for licensing retailers who sell tobacco products. Retailers caught selling to minors would be fined or risk license revocation.

**Industry Documents.** Established a public depository of industry documents and created a three-judge arbitration panel to settle disputes over documents that are determined by the industry to be privileged against disclosure.

**Non-Tobacco Ingredients.** Required companies to disclose annually to FDA the amounts of all non-tobacco ingredients added to each brand, and to demonstrate that each ingredient is not harmful under the intended conditions of use.

**Reduction of Youth Tobacco Use.** Set targets for reducing the number of underage smokers: 30% reduction in five years; 60% in 10 years. Fined industry up to \$2 billion a year if targets are not met.

**State Youth Access Laws.** Required states to enforce their minimum-age-of-sale laws for tobacco products or risk losing settlement funds. The provisions expanded on those of the Synar Amendment.<sup>a</sup>

**Environmental Tobacco Smoke.** Restricted smoking in public buildings entered by 10 or more individuals at least once a week to separately ventilated smoking rooms. Exempted restaurants (except fast food), bars, private clubs, and prisons.

**Industry Annual Payments.** Required industry to pay \$10 billion up front and annual payments beginning at \$8.5 billion in the first year, increasing to \$15 billion in the fifth year, and remaining at \$15 billion a year thereafter. Payments would be adjusted for inflation and volume of sales, and would be tax deductible. Total estimated payments over first 25 years = \$368.5 billion.

**Tobacco Control Programs and Research.** Allocated funds to states to reimburse Medicaid programs and provide health insurance to uninsured children. Provided funds for tobacco cessation programs, counter advertising, biomedical research, FDA regulation, and federal, state, and local tobacco control programs.

**Civil Liability.** Terminated all pending state Medicaid and class-action lawsuits and prohibits such lawsuits in the future. Preserved the right of individuals to bring personal injury claims, but prohibited punitive damages in claims arising from past industry conduct. Limited the total damages paid by the industry in any one year to 33% of the annual payment.

a. The Synar Amendment (42 U.S.C. § 300x-26) requires states to enforce their laws prohibiting the sale of tobacco products to minors or risk losing 40% of their federal substance abuse block grant funding. States conduct annual random, unannounced inspections of retail outlets to ensure compliance with the laws. The Synar Amendment is administered by the Substance Abuse and Mental Health Services Administration, part of the Department of Health and Human Services. For more information, go to <http://prevention.samhsa.gov/tobacco/>.

Public health officials criticized the restrictions the proposed settlement would have placed on FDA's ability to regulate nicotine. For example, any proposal by the agency to reduce nicotine yields or eliminate other harmful ingredients in cigarettes would have required formal rulemaking with judicial review, instead of the informal, notice-and-comment rulemaking that is typically used by federal agencies to promulgate regulations. Formal rulemaking, which is seldom used today, involves trial-type hearings before an administrative judge, at which parties present evidence and conduct cross-examinations. It is a rigorous and lengthy process that places a

considerable burden of proof on the agency.<sup>33</sup> The FDA also would have been required to show that the proposed modification significantly reduced health risks and did not create a black market for unmodified products. Finally, the FDA would have to wait 12 years before proposing to eliminate nicotine from tobacco products. The tobacco companies defended those restrictions on FDA's authority by claiming that they represented reasonable constraints on an agency that was seeking to eliminate its products.

## **McCain Tobacco Bill (105<sup>th</sup> Congress)**

The proposed national settlement was presented to Congress as a blueprint for a comprehensive tobacco-control policy. Because the proposal included changes to the FFDCA and other federal statutes, it would have required congressional legislative action in order to take effect. Attempts by the 105<sup>th</sup> Congress to pass legislation to implement the settlement ended when a bill sponsored by Senator McCain (R-AZ) was defeated on a pair of procedural votes on June 17, 1998, after an extended floor debate. Following the demise of the McCain bill, S. 1415, the major cigarette companies resumed negotiations with the states and, in November 1998, signed a contractual agreement—the Master Settlement Agreement, or MSA—to settle the state lawsuits.<sup>34</sup> The MSA did not address FDA's authority over tobacco products (see box below).

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<sup>33</sup> Most federal regulations are issued under the notice-and-comment procedure established by the Administrative Procedure Act (5 U.S.C. §§ 551 et seq.). The agency publishes a notice of proposed rulemaking in the *Federal Register*, solicits public comment, and incorporates in the final rule a concise statement about the rule's basis and purpose. Courts review such rules under the "arbitrary, capricious, and abuse of discretion" standard, generally upholding an agency's action if it is found to be rational, based on a consideration of the relevant factors, and within the scope of the authority designated to the agency by Congress. *See* 5 U.S.C. § 706(2)(A). Formal rulemaking, by contrast, is a more rigorous and time-consuming process. Under the proposed national settlement, the FDA would have had to show "substantial evidence" in support of its cigarette performance standards. *See* 5 U.S.C. § 706(2)(E).

<sup>34</sup> The full text of the MSA is available on the website of the National Association of Attorneys General (NAAG) at [http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/1109185724\\_1032468605\\_cigmsa.pdf](http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/1109185724_1032468605_cigmsa.pdf). NAAG is responsible for implementing and enforcing the MSA.

### **Tobacco Master Settlement Agreement (MSA)**

On November 23, 1998, 46 states, the District of Columbia, and five U.S. territories signed a comprehensive agreement with the four major cigarette companies (Philip Morris Inc., R.J. Reynolds Tobacco Company, Brown & Williamson Tobacco Corp., and Lorillard Tobacco Company). The companies agreed to make annual payments to the states in perpetuity as reimbursement for past tobacco-related medical expenses.<sup>a</sup> The MSA required the companies to pay approximately \$206 billion over the first 25 years.<sup>b</sup> The four states that were not party to the MSA had reached earlier, individual settlements with the industry that called for payments totaling \$40 billion over 25 years (MS, 7/3/1997; FL, 8/25/1997; TX, 1/16/1998; MN, 5/8/1998). Although it bore a superficial resemblance to the 1997 proposed national settlement, the MSA was considerably narrower in scope and did not require congressional action for its implementation. It settled only the state and local government lawsuits. Unlike the proposed national settlement, the MSA did not provide the industry with any legal protection from class-action lawsuits and claims brought by individuals, labor unions, and private health care insurers. While the companies agreed to some restrictions on cigarette advertising and marketing (similar to provisions in the FDA tobacco rule), the MSA lacked the broader tobacco-control initiatives that were included in the proposed national settlement and the McCain bill (e.g., retailer licensing, ingredient disclosure, youth tobacco use targets and penalties, and indoor smoking restrictions).

a. In 1999, Congress enacted legislation allowing the states to keep all the MSA funds. Section 3031 of the FY1999 Emergency Supplemental Appropriations Act (P.L. 106-31) amended the Medicaid statute by waiving any federal claim to a portion of those funds. Generally, under Medicaid law, states that pursue third-party recoveries are required to provide the federal government its share of any recovered funds.

b. The Government Accountability Office (GAO) has issued a series of reports on the states' allocations and use of MSA funds. GAO's most recent testimony, summarizing state MSA-related activities for FY2000 through FY2005, is at <http://www.gao.gov/new.items/d07534t.pdf>. In addition, the Campaign for Tobacco-Free Kids, the nation's leading anti-tobacco lobby, is tracking how much of the MSA funds and other tobacco-related revenue (e.g., excise taxes) states are spending on tobacco control. The Campaign's most recent MSA report, released in November 2008 on the 10<sup>th</sup> anniversary of the agreement, is at <http://www.tobaccofreekids.org/reports/settlements/>.

**Table 1** provides a summary of the major provisions of the McCain tobacco bill. Although the measure was intended to implement the proposed national settlement, it would have been tougher on the industry in several key respects. S. 1415 would have cost the companies \$516 billion over the first 25 years, an amount significantly higher than the figure agreed to in the proposed settlement (i.e., \$368.5 billion). It would have included stiffer financial penalties if the decline in underage tobacco use did not meet the reduction targets, and it also would have provided the industry with fewer legal protections than those negotiated in the June 1997 agreement.

The McCain bill also would have added a new Chapter IX to the FFDCAs solely for the regulation of tobacco products. That language, which was provided by Senator Frist (R-TN), drew extensively on the act's existing drug and device provisions in Chapter V, but with modifications.<sup>35</sup> By attempting to establish a new legal authority within the FFDCAs 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 been required to demonstrate that any proposed tobacco regulation was appropriate for the protection of public health. Such a determination would have involved a consideration of the risks and benefits to the population as a whole.

<sup>35</sup> The Frist language incorporated, with modifications, the following FFDCAs drug and device provisions: adulterated drugs and devices (§ 501); misbranded drugs and devices (§ 502); device manufacturer registration (§ 510); performance standards (§ 514); premarket approval (§ 515); judicial review (§ 517); notification and recall (§ 518); records and reports (§ 519); general provisions respecting control of devices intended for human use (§ 520); preemption of state and local requirements (§ 521); and postmarket surveillance (§ 522).

The tobacco companies opposed S. 1415 and launched a \$40 million advertising campaign that helped defeat it. They portrayed the legislation as nothing more than a massive tax increase to pay for new government spending. During the Senate floor debate, which stretched over four weeks (May 18-June 17, 1998), lawmakers focused on where the bill's revenues should go, how to compensate tobacco growers, and whether to limit the fees of private attorneys who were retained by the states. Amendments were added to the bill to eliminate the so-called marriage income tax penalty, boost funding for anti-drug programs, and cap attorneys' fees. There was no debate on the bill's FDA provisions.

Public health officials supported many of the McCain bill's tobacco-control provisions, but were critical of the measure's FDA provisions. They feared that the agency's attempts to implement the new law would be blocked at every turn by lengthy legal challenges from the industry. Instead, they sided with the FDA's arguments for asserting jurisdiction under existing law (i.e., FFDCA's Chapter V device provisions). In its rulemaking the agency concluded that the device provisions, which have been interpreted in case law, regulation, and agency practice for over two decades, established a comprehensive regulatory scheme that was appropriate for regulating tobacco products.

Several other comprehensive tobacco bills were introduced in the 105<sup>th</sup> Congress, though none of them saw any legislative activity.<sup>36</sup> The bills, which were supported by the public health community and opposed by the industry, would have given FDA explicit authority to regulate tobacco products under the FFDCA's Chapter V drug and device provisions. In each case, the legislation amended the act's definitions of drugs and devices to include nicotine and tobacco products, respectively, and authorized the agency to regulate tobacco products using a standard of protecting the public health. By avoiding having to regulate tobacco products based on safety and effectiveness, the agency would have been able to keep such unhealthful products on the market.

## **FDA Tobacco Legislation from the 107<sup>th</sup> to the 110<sup>th</sup> Congresses**

This section of the report includes a brief description of the tobacco legislation introduced in the 107<sup>th</sup> Congress (2001-2002) in the wake of the Supreme Court decision, followed by a summary of FDA tobacco legislative activity in the 108<sup>th</sup>, 109<sup>th</sup>, and 110<sup>th</sup> Congresses.

### **107<sup>th</sup> Congress**

Several FDA tobacco bills were introduced in the 107<sup>th</sup> Congress, most in response to the Supreme Court's ruling. None of the bills saw any legislative action. Four bills (i.e., S. 190 (Frist), S. 2626 (Kennedy), S. 2764 (Miller), and H.R. 2180 (Tom Davis)) adopted the same approach as the McCain legislation. They would have created a new FFDCA Chapter IX solely for the regulation of tobacco products. Senator Kennedy's bill (S. 2626) was almost identical to the FDA provisions in the McCain bill. The three other bills included many of the same provisions. However, they contained a few small but significant changes that were intended to

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<sup>36</sup> S. 1492 (Kennedy); S. 1530 (Hatch); S. 1638 (Conrad); S. 1889 (Harkin); H.R. 3028 (DeLauro); H.R. 3474 (Fazio); H.R. 3868 (Hansen).

address industry concerns over the extent of FDA's regulatory control. For example, all three measures specified that FDA could not compel the industry to change the composition of its products in ways that would render them "unacceptable for adult consumption." They also required the agency to show that any proposal to restrict the sale, distribution, advertising, and promotion of tobacco products was based on a determination that such regulation "would be appropriate for the prevention of, or decrease in, the use of tobacco products by children...." Finally, all three measures reserved for Congress—not FDA—the authority to eliminate nicotine or ban tobacco products.

In addition to giving FDA new regulatory authority over tobacco products, H.R. 2180 also contained restrictions on youth access, advertising, and marketing that were broadly similar to those included in the McCain bill. The provisions in H.R. 2180 were subsequently incorporated into Representative McIntyre's bill (H.R. 3940) to eliminate tobacco quotas and the price support loan program and compensate quota owners and active growers. S. 2764 also contained substantially similar buyout provisions.

The three remaining FDA tobacco bills introduced in the 107<sup>th</sup> Congress (i.e., S. 247 (Harkin), H.R. 1044 (Waxman), and H.R. 1097 (Ganske)), rather than creating new legal authority for regulating tobacco products, would have given FDA the authority to regulate tobacco products as drug-delivery devices under Chapter V of the FFDCAs. This approach was favored by some public health advocates, but strongly opposed by the industry. As with the earlier versions introduced during the 105<sup>th</sup> Congress, each of these bills merely amended the definitions of drugs and devices to include nicotine and tobacco products, respectively, and specified that tobacco regulation would be based on a general standard of protecting the public health. Additionally, the three measures would have made effective all the provisions of the 1996 FDA tobacco rule.

## **108<sup>th</sup> Congress**

At the beginning of the 108<sup>th</sup> Congress, Representatives McIntyre and Tom Davis reintroduced their tobacco legislation (H.R. 140). The measure combined a buyout for quota owners and active growers with FDA regulatory authority. H.R. 140 was supported by Philip Morris but opposed by the public health community. In the Senate, negotiations among members of the Committee on Health, Education, Labor, and Pension (HELP) to draft a compromise bill that had the support of both sides came to a standstill in October 2003. Anti-smoking advocates and their congressional supporters criticized the draft legislation for failing to give FDA sufficient authority to protect public health.

Negotiations resumed in early 2004 and on May 20 Senators DeWine and Kennedy and Representatives Tom Davis and Henry Waxman introduced the Family Smoking Prevention and Tobacco Control Act (S. 2461, H.R. 4433). Both Philip Morris and the Campaign for Tobacco-Free Kids announced their "enthusiastic" support for the legislation. On July 15, Senator DeWine introduced the text of S. 2461 as an amendment to the American Jobs Creation Act of 2004 (H.R. 4520, P.L. 108-357), which was under consideration on the Senate floor. The amendment passed by a vote of 78-15. However, during the conference on H.R. 4520, the House conferees on October 6 rejected the DeWine amendment. Following its rejection by the conference committee, Senators DeWine and Kennedy reintroduced the legislation with a new bill number (S. 2974) on October 10. The measure was passed on the Senate floor that same day without amendment by unanimous consent. No further action was taken by either chamber.



## 109<sup>th</sup> Congress

Senators DeWine and Kennedy and Representatives Davis and Waxman reintroduced the Family Smoking Prevention and Tobacco Control Act on March 17, 2005 (S. 666, H.R. 1376). There was no legislative action taken on either measure during the 109<sup>th</sup> Congress.

## 110<sup>th</sup> Congress

On February 15, 2007, Senators Kennedy and Cornyn and Representatives Waxman and Davis once again introduced the Family Smoking Prevention and Tobacco Control Act (S. 625, H.R. 1108). On August 1, 2007, the Senate HELP Committee adopted a handful of amendments to S. 625 and approved the measure (as amended) by a vote of 13-8. On April 2, 2008, the House Committee on Energy and Commerce took up a manager's amendment to H.R. 1108, which included several provisions intended to address the concerns of various stakeholder groups. The Committee then adopted three additional amendments before approving the bill (as amended) by a vote of 38-12. The House passed H.R. 1108 on July 30, 2008, by a vote of 326-102.

The Bush administration and the FDA Commissioner, Andrew von Eschenbach, indicated concerns regarding the legislation, specifically that the bill would be “creating a false impression that regulated tobacco products were safe,”<sup>37</sup> and “that this will actually encourage individuals to smoke more rather than less.”<sup>38</sup> Additionally, the Secretary of Health and Human Services stated in a July 21, 2008 letter that the Bush Administration “would strongly oppose this legislation.”

**Table 2** summarizes the provisions in S. 625, as reported, and highlights the key differences between that measure and H.R. 1108, as passed by the House.

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<sup>37</sup> Stephanie Saul, *Bill to Regulate Tobacco as a Drug Is Approved by a House Committee*, N.Y. Times, Apr. 3, 2008, at C3.

<sup>38</sup> H.R. 1108, Family Smoking Prevention and Tobacco Control Act, Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 110<sup>th</sup> Cong. (Oct. 3, 2007) (written statement of Andrew C. von Eschenbach, Commissioner of Food and Drugs, FDA), <http://www.fda.gov/ola/2007/tobacco100307.html>.

**Table I. Summary of McCain Tobacco Bill (105<sup>th</sup> Congress)**

Topic	S. 1415 (McCain)
<b>Amendment of Federal Food, Drug, and Cosmetic Act (FFDCA)</b>	Creates new FFDCA Chapter IX for regulating tobacco products. Defines adulterated and misbranded tobacco products. For each brand, requires manufacturers to submit annually a list of the amounts of all added ingredients and a description of the content, yield, and form of nicotine. Requires notification of modified products or release of new products. Requires annual registration of all manufacturers and biennial inspection of facilities. Authorizes regulation of the sale, distribution, advertising, promotion, and use of tobacco products in order to protect public health. Provides for good manufacturing practice regulation, subject to a tobacco product advisory committee's recommendations. Authorizes adoption (and revocation) of performance standards to reduce/eliminate nicotine or otherwise modify the composition of the product in order to protect public health; mandates notice and comment rulemaking, including consideration of impact of performance standard on consumption and development of a black market. Requires a one-year delay before new standards take effect. Requires two-year congressional review of any proposal to eliminate nicotine or ban tobacco products. Authorizes the recall of products that contain out-of-the-ordinary defects that pose serious health risks. Provides for the establishment of industry reporting requirements. Requires premarket approval of new products. Provides for judicial review of regulatory actions to issue or revoke performance standards. Provides for postmarket surveillance. Defines reduced risk product and permits marketing of such products. Permits state and local authorities to adopt more stringent public health controls. [Section 101]
<b>Marketing and advertising restrictions</b>	Prohibits outdoor tobacco product advertising; prohibits use of human or cartoon images in advertising; prohibits Internet advertising unless site is inaccessible to minors; prohibits paying for placement of tobacco products in movies, TV, or video games; prohibits paying to glamorize tobacco use in media that appeal to minors; prohibits promotional non-tobacco merchandise bearing brand names; prohibits brand-name sponsorship of sporting and cultural events; prohibits use of recent non-tobacco trade or brand names for tobacco products. Limits size and placement of point-of-sale advertising. Requires black-on-white format for point-of-sale advertising in facilities that are accessible to minors and for advertising in publications with a significant youth readership. <sup>a</sup> Limits advertising in audio format to words with no music. Limits advertising in video format to static black-on-white text. [Sections 1403-1405]
<b>Warnings, labeling, and packaging</b>	Amends existing federal labeling laws to require new, explicit health warning labels in bold type. <sup>b</sup> Authorizes DHHS to revise warning labels in order to promote a greater public awareness of the risks of tobacco use. Exempts tobacco-product exports from the new labeling requirements. Mandates regulations for the testing, reporting, and public disclosure of ingredients and tobacco smoke constituents to protect the public health. [Sections 301-305, 311, 1106]
<b>Youth access restrictions</b>	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machines; restricts self-service displays to adult-only facilities; allows mail-order sales subject to FDA review. [Sections 231, 1162]
<b>Retailer licensing and registration</b>	Requires states to license tobacco retailers. Establishes penalties for noncompliance, including license suspension and revocation. [Section 231]
<b>State enforcement of youth access laws</b>	Requires states to enforce (using federal drug abuse block grant funds) laws prohibiting the sale or distribution of tobacco products to minors, and to conduct monthly unannounced inspections. States must achieve 80% compliance by year four and 90% by year seven or risk losing federal block grant funds. Repeals Synar Amendment. <sup>c</sup> [Sections 231-233]
<b>Underage tobacco-use targets</b>	Mandates an annual survey to determine the percentage of individuals under age 18 who used a tobacco product in the past 30 days, and the percentage who used each brand in the past 30 days. Sets reduction targets for underage use of cigarettes (by 40% in five years and 67% in 10 years) and smokeless tobacco products (by 25% in five years and 45% in 10 years). [Sections 201-204]

Topic	S. 1415 (McCain)
<b>Industry penalties</b>	Mandates industry-wide and manufacturer-specific penalties (not tax-deductible) if reduction targets for underage use are not met. Industry-wide penalties capped at \$2 billion a year; manufacturer-specific penalties capped at \$5 billion a year. [Sections 205-206]
<b>Smoking restrictions in public facilities</b>	Restricts smoking in public facilities (i.e., those entered by 10 or more individuals at least one day a week), including federally owned or leased buildings, to enclosed, separately ventilated, designated smoking areas. Specifies that employees may not be required to enter smoking areas. Exempts restaurants (other than fast food), bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco outlets, and prisons. States may opt out if they have a similar or more stringent law of their own. Allows state and local governments to enact stricter laws. [Sections 501-507]
<b>Industry payments to National Tobacco Trust Fund</b>	Establishes National Tobacco Trust Fund. Mandates tax-deductible industry payments into Trust Fund. Annual payments subject to inflation adjustment beginning in the sixth year, and subject to a volume-of-sales adjustment beginning in 2002. Total net revenue over first 25 years = \$516 billion (estimated by Congressional Budget Office). [Sections 401-406]
<b>State reimbursement and allocation of trust funds</b>	Allocates 40% of the amount in the Trust Fund to reimburse states for smoking-related medical costs, 22% for tobacco-control programs, 22% for biomedical research, and 16% to provide financial assistance to tobacco farmers. [Sections 451-455]
<b>Consent decree</b>	Requires manufacturers, states, and the federal government to enter into voluntary, but legally binding consent decrees to enforce many of the provisions of the act (e.g., FDA regulatory authority, document disclosure, advertising and point-of-sale restrictions, annual payments). Excludes from annual liability cap (see below) any company that violates the provisions of the act. [Sections 1402-1405]
<b>Attorneys' fees</b>	Establishes a three-person arbitration panel to determine and award plaintiff attorneys' fees and expenses. Awards to be paid by participating manufacturers. Limits fees to \$4,000/hr. [Section 1413]
<b>Legal immunity</b>	Allows states to settle their lawsuits in return for funding from the Trust Fund, or opt to continue with their lawsuits and forgo payments from the Trust Fund. Settles smokers' class-action lawsuits and prohibits addiction claims. Caps total annual liability at \$8 billion. Modifies rule of evidence to establish an evidentiary presumption that nicotine is addictive and certain diseases are caused by tobacco use. [Sections 1406-1412]
<b>Industry documents</b>	Establishes a public tobacco document depository. Requires manufacturers to submit to FDA all documents specified in the act. Requires manufacturers to make a separate submission (with accompanying detailed log) to a three-judge panel of all documents for which they assert attorney-client privilege or trade secrecy. Requires panel to settle disputes over making such privileged documents public. [Sections 901-909, 1403]
<b>Tobacco farmers</b>	Incorporates two competing titles: (1) Establishes a \$28.5 billion fund to provide financial assistance to tobacco farmers and their communities, maintains burley tobacco price support program, replaces flue-cured quotas with nontransferable permits. [Title X] (2) Terminates the federal tobacco price support program, establishes an \$18 billion fund to buy out quota owners and compensate tenants. [Title XV]
<b>Native Americans</b>	Provides that the requirements of this Act relating to the manufacture, distribution, and sale of tobacco products apply on tribal lands. Exempts tribal religious and traditional tobacco uses from the requirements of the Act. Requires licensing of tribal tobacco retailers. [Sections 601-603]
<b>Preemption of state and local actions</b>	Allows state and local governments to adopt and enforce any additional tobacco-product control measures. [Section 5]

Topic	S. 1415 (McCain)
<b>International tobacco control</b>	Provides funding for international tobacco-control efforts (\$350 million/yr). Prohibits use of federal funds to promote U.S. tobacco exports or to seek removal of nondiscriminatory restrictions on tobacco by foreign countries. [Sections 1101-1107]
<b>Smuggling</b>	Requires all manufacturers, importers, exporters and wholesalers of tobacco products to be licensed. Mandates serial numbers and export labels on packages. Requires manufacturers and distributors to submit a report for all tobacco-product export shipments. Strengthens and amends Contraband Cigarette Trafficking Act to include all tobacco products. [Sections 1131-1140]
<b>Veterans</b>	Provides \$600 million/yr for five years from the Trust Fund for tobacco-related veterans' health care. [Section 1301]

**Source:** Table prepared by the Congressional Research Service, based on the text of the modified committee substitute bill, as amended during Senate floor debate, May 18 - June 17, 1998.

- a. Significant youth readership is defined as having at least 2 million readers under age 18, or that readers under age 18 constitute more than 15% of the total readership.
- b. (i) Federal Cigarette Labeling and Advertising Act (15 U.S.C. §§1331 et seq.), (ii) Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. §§ 4401 et seq.).
- c. The Synar Amendment to the Public Health Service Act (42 U.S.C. § 300x-26; 45 C.F.R. 96.130) requires states to enforce their laws prohibiting the sale of tobacco products to individuals under age 18. States must conduct random, unannounced inspections of retail outlets to ensure compliance with the law. States risk losing federal substance abuse block grant funds for failure to comply.

## Table 2. Family Smoking Prevention and Tobacco Control Act (110<sup>th</sup> Congress)

Summary of S. 625 (as reported) and Key Differences in H.R. 1108 (as passed)

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### FDA Tobacco Regulatory Authority (Federal Food, Drug, and Cosmetic Act, Chapter IX)

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<b>FDA authority over tobacco products</b>	<p>Creates a new FFDC 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 manufacturers in complying with the FFDC. [FFDC Sec. 901]</p> <p><i>H.R. 1108 includes the additional requirements that each rulemaking under this Chapter shall be in accordance with 5 U.S.C. Chapter 5, and that prior to rulemaking the Secretary shall endeavor to consult with other appropriate federal agencies. Also, unlike S. 625, the House version includes a definition of small tobacco product manufacturers (i.e., companies employing fewer than 350 employees).</i></p>
<b>Adulterated tobacco products</b>	<p>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); and (5) the product is in violation of the requirements for modified risk products (see below). [FFDC Sec. 902]</p>
<b>Misbranded tobacco products</b>	<p>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 the 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). [FFDC Sec. 903]</p>
<b>Submission of data and research documents</b>	<p>Requires each tobacco product manufacturer or importer to submit: (1) within 6 months of enactment, a list of the amounts of all added ingredients, by brand; (2) a description of the content, yield, and form of nicotine in each product; (3) a list of the amounts of all potentially harmful smoke constituents, by brand; and (4) beginning 6 months after enactment, all documents developed after the date of enactment of this act relating to the health impact of current or future products. Requires information about a new product to be submitted at least 90 days prior to its release, and requires prompt disclosure of information about a new (or changes in the quantity of an existing) additive. At the request of the Secretary, requires each manufacturer or importer to submit any or all research documents. Within three years 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. 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. [FFDC Sec. 904]</p> <p><i>H.R. 1108 specifies that the submission of the amounts of all potentially harmful constituents, by brand (see #3 above), must begin three years after enactment.</i></p>

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**FDA Tobacco Regulatory Authority  
(Federal Food, Drug, and Cosmetic Act, Chapter IX)**

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**Annual registration**

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.

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, to exempt from these requirements certain tobacco products that have only minor differences from preexisting 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 person 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 in specific types of retail outlets and prohibits establishing a minimum age of sale to persons older than 18 years of age. Authorizes the Secretary, by regulation, to establish good manufacturing practice (GMP) requirements, including testing raw tobacco for pesticide chemical residues, subject to the recommendations of the Tobacco Products Scientific Advisory Committee (see below). 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]

*H.R. 1108 requires (as opposed to authorizes) the Secretary to issue GMP regulations, which may provide for the testing of raw tobacco for pesticide residues. It also specifies that small manufacturers (as defined in the bill) are not required to comply with such regulations until four years after they take effect. H.R. 1108 also requires the Secretary, within 18 months, 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. It further requires the Secretary, within two years, 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.*

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**FDA Tobacco Regulatory Authority  
(Federal Food, Drug, and Cosmetic Act, Chapter IX)**

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**Tobacco product standards**

Subject to subsequent revision by rulemaking, prohibits cigarettes 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 composition and testing of tobacco products, if it 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 the involvement of other federal agencies and informed persons in setting product standards, and periodic evaluation of such standards. Mandates notice and comment rulemaking, with a comment period of at least 60 days, and requires a one-year delay before new standards take effect unless the Secretary determines an earlier effective date is necessary to protect public health. In any proposed standard that determines a tobacco product constituent to be harmful, a party challenging such a determination must prove that the proposal will not reduce or eliminate health risk. Reserves for Congress the authority to ban tobacco products or reduce nicotine yields to zero. Provides for the amendment and revocation of existing standards. Permits the Secretary to refer a proposal to establish, amend, or revoke a product standard to the Tobacco Products Scientific Advisory Committee (see below). The Secretary may make such a referral 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. [FFDCA Sec. 907]

*H.R. 1108 prohibits tobacco products containing foreign-grown tobacco with pesticide levels that exceed U.S. standards or that was grown using unapproved pesticides. It also requires the Secretary to consider the following types of information submitted in connection with a proposed tobacco product standard: (1) the technical feasibility of compliance with the standard; and (2) the impact of the standard on the creation of a black market for products that do not meet the requirements of this Chapter. Instead of reserving for Congress the authority to ban tobacco products or eliminate nicotine, H.R. 1108 prohibits the Secretary from taking such action.*

**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 FDA may by regulation reasonably require to assure that products are not adulterated or misbranded and to otherwise protect public health. For example, FDA 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 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 types of information to be included in an application for premarket review. Requires the Secretary, on his or her own initiative or upon the request of an applicant, to refer the application to the Tobacco Products Scientific Advisory Committee (see below). Establishes procedures for denying an application for premarket approval, and for withdrawing or temporarily suspending such approval. Specifies that a denial shall be based on a finding that permitting the marketing of the new tobacco product is inconsistent with the protection of public health, taking into consideration the risks and benefits to the population as a whole, including users and nonusers. Investigational tobacco products

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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. 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. In the case of a product for which the modified risk application is limited to an explicit or implicit reduced-exposure claim, authorizes FDA 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; and (3) the proposed labeling and market of the product will not mislead consumers into believing that it has been demonstrated to be less harmful. 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 that the modified risk claim is no longer valid. Requires FDA, within two years 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 judicial 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. [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]

**Congressional review**

Provides for congressional review of any rule promulgated under this Chapter, pursuant to 5 U.S.C. § 801 et seq. [FFDCA Sec. 915]

*H.R. 1108 does not include this provision.*

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**Ingredient and smoke constituent testing**

Requires the Secretary, within two years, 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. [FFDCA Sec. 916; FFDCA Sec. 915 in H.R. 1108]

*H.R. 1108 requires the Secretary to issue new regulations within three years of enactment. The bill includes additional provisions relating specifically to small manufacturers (as defined in the bill) that provide additional time for compliance with the testing and reporting regulations, including extensions for limited testing laboratory capacity.*

**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, use, access to, advertising, and promotion of tobacco products. [FFDCA Sec. 917; FFDCA Sec. 916 in H.R. 1108]

**Tobacco Products Scientific Advisory Committee**

Within one year, requires the Secretary to establish an 12-member Tobacco Products Scientific Advisory Committee. Specifies the Committee's membership, duties, and compensation. [FFDCA Sec. 918; FFDCA Sec. 917 in H.R. 1108]

**Nicotine replacement products**

Instructs the Secretary to: (1) at the request of the applicant, designate nicotine replacement products as fast track products under FFDCA Section 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. 919; FFDCA Sec. 918 in H.R. 1108]

**User fees**

Establishes within the Treasury a Tobacco Product User Fee Fund. Instructs the Secretary to assess user fees (payable quarterly) on tobacco manufacturers and importers, to be deposited in the Fund, to pay for the cost of FDA tobacco regulation under this Chapter. Sets the amount of the assessment at \$85 million in FY2008, \$235 million in FY2009, and \$450 million in FY2010, adjusted in each subsequent fiscal year to reflect the greater of: (1) the percentage change in the Consumer Price Index; (2) the percentage change in base pay for federal workers in Washington DC; or (3) the average annual change in the cost, per FTE, of FDA personnel compensation and benefits. Requires an annual upward adjustment in the total amount of fees assessed, with these additional funds to be deposited in the general fund of the Treasury, to defray any net loss in general revenue due to changes in revenue and spending resulting from enactment of this Act.

*H.R. 1108 does not establish a fund within the Treasury and sets the amount of the assessment at \$90.1 million in FY2008, increasing to \$754.7 million in FY2018 and in each subsequent fiscal year (with no adjustments). Of the fees collected, it specifies a slightly lower amount available to the Secretary for tobacco regulation: \$85 million in FY2008, increasing to \$712 million in FY2018 and in 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. [FFDCA Sec. 920; FFDCA Sec. 919 in H.R. 1108]

*H.R. 1108, in addition, requires GAO, within three years, to report to Congress on underage tobacco use and the feasibility and impact of calculating user fees based in whole or in part on a manufacturer's youth market share.*

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**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. Requires the GAO to study and, within 18 months, report on cross-border trade of tobacco products (including illicit trade) and tobacco advertising that is broadcast, transmitted, or distributed from the United States to another country. [FFDCA Sec. 921; FFDCA Sec. 920 in H.R. 1108]

*H.R. 1108 requires the GAO study to include data on the health effects of: (1) smuggled and counterfeit tobacco products; and (2) differing tax rates applicable to tobacco products. It also defines cross-border trade as international and interstate trade, including trade with Indian tribes.*

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**FDA Final Tobacco Rule (August 28, 1996)**

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Requires the Secretary within 30 days 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). The rule shall become effective no later than one year after enactment of this Act.

*H.R. 1108 requires the Secretary to publish the final rule no sooner than 180 days after enactment. The bill also amends subsection 897.16(d) of the rule (prohibition on free samples of tobacco products) to permit free samples in a qualified adult-only facility (as defined).*

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**Tobacco Product Labeling and Advertising**

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**Cigarette health warning labels**

Amends the federal cigarette labeling and advertising law<sup>a</sup> to require new, rotating, explicit health warning labels in bold type on cigarette packages.<sup>b</sup> Specifies the placement and typography of the labels. 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 Act's cigarette labeling requirements 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 new labeling requirements will take effect one year after enactment. Instructs the Secretary, within two years, and through rulemaking, to require color graphics depicting the negative health consequences of smoking to accompany the label requirements. Thereafter, the Secretary may, by rulemaking, adjust the text, format, and type size of any of the label requirements in order to promote a greater public understanding of the risks of tobacco use. Permits states to regulate the time, place, and manner, but not the content, of cigarette advertising and promotion.

*Unlike S. 625, which requires the warning labels to occupy the top 50% of the front and rear panels of a cigarette package, H.R. 1108 requires the labels to occupy at least the top 30% of both panels. H.R. 1108 also has slightly modified requirements for the Secretary, through rulemaking, to change the required statements, require color graphics, and adjust the text, format, and type size of any other disclosures required under the FFDCA, in order to promote greater public understanding of the risks of tobacco use.*

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<b>Smokeless tobacco health warning labels</b>	<p>Amends the federal smokeless tobacco labeling and advertising law<sup>c</sup> to require new, rotating, explicit health warning labels in bold type on smokeless tobacco packages.<sup>d</sup> Specifies the placement and typography of the labels. 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, provided they do not sell or distribute such products. 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. Prohibits smokeless tobacco advertising on radio or television. Specifies that the new labeling requirements will take effect one year after enactment. Authorizes the Secretary, by rulemaking, to adjust the text, format, and type size of any of the label requirements, require color graphics, increase the required label area from 30% to 50% of a package's front and rear panels, and adjust the text, format, and type size of any other disclosures required under the FFCA, in order to promote a greater public understanding of the risks of smokeless tobacco use.</p> <p><i>H.R. 1108 states that retailers that are supplied with smokeless tobacco products in violation of these labeling requirements are not liable. It also specifies that retailers are liable if they publicly display an advertisement that is not labeled in accordance with this Act. Finally, H.R. 1108 includes an additional provision that authorizes the Secretary, through rulemaking, to make adjustments to the format and type size of the Act's smokeless tobacco labeling requirements or to the text, format, and type size of other required statements relating to tar, nicotine, and other constituents.</i></p>
<b>Tar, nicotine, and other smoke constituent disclosure</b>	<p>Amends the federal cigarette labeling and advertising law<sup>a</sup> 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. Retailers are liable if they sell or distribute tobacco products that do not bear the health warning labels required under this Act.</p> <p><i>H.R. 1108 does not include the provision making retailers liable if they sell or distribute products without the required health warning labels.</i></p>

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**Miscellaneous Provisions (H.R. 1108 only)**

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<b>Report on minimum purchase age</b>	<p><i>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.</i></p>
<b>Report on industry concentration</b>	<p><i>Requires FTC to study the causes and effects of concentration in the tobacco industry and report to Congress within five years and, again, within 10 years.</i></p>
<b>Indian tribes</b>	<p><i>Requires the Secretary to ensure that the provisions of this Act and its implementing regulations, including those that relate to retail sales of tobacco product, are enforced with respect to Indian Tribes.</i></p>

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**Source:** Table prepared by the Congressional Research Service, based on the text of S. 625, as reported by the Senate HELP Committee on August 1, 2007, and H.R. 1108, as passed by the House on July 30, 2008.

- a. Federal Cigarette Labeling and Advertising Act (15 U.S.C. §§ 1331 et seq.). The FTC administers the cigarette labeling law; the Justice Department enforces the law.
- b. The new labels read: (i) WARNING: Cigarettes are addictive; (ii) WARNING: Tobacco smoke can harm your children; (iii) WARNING: Cigarettes cause fatal lung disease; (iv) WARNING: Cigarettes cause cancer; (v) WARNING: Cigarettes cause strokes and heart disease; (vi) WARNING: Smoking during pregnancy can harm

your baby; (vii) WARNING: Smoking can kill you; (viii) WARNING: Tobacco smoke causes fatal lung disease in nonsmokers; and (ix) 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 and enforces the smokeless tobacco labeling law.
- d. The new labels read: (i) WARNING: This product can cause mouth cancer; (ii) WARNING: This product can cause gum disease and tooth loss; (iii) WARNING: This product is not a safe alternative to cigarettes; and (iv) WARNING: Smokeless tobacco is addictive.

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