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FDA Regulation of Tobacco Products: A Policy and Legal Analysis

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Summary

On October 6, 2004, congressional conferees for the American Jobs Creation Act of 2004 (H.R. 4520, P.L. 108-357) rejected a Senate amendment that would have given the Food and Drug Administration (FDA) broad new authority to regulate cigarettes and smokeless tobacco products. The amendment incorporated the text of FDA tobacco legislation (S. 2461) introduced by Senators DeWine (R-OH) and Kennedy (D-MA). Identical legislation (H.R. 4433) had been introduced in the House by Representatives Tom Davis (R-VA) and Henry Waxman (D-CA). On October 10, 2004, following its rejection by the conference committee, the Senate passed the DeWine-Kennedy FDA tobacco bill by voice vote.

S. 2461/H.R. 4433 was the product of months of negotiations in which lawmakers sought to balance the competing interests of public health groups and Philip Morris, the nation's leading cigarette company. Both sides supported the legislation, which would create a new Chapter IX in the Federal Food, Drug, and Cosmetic Act (FFDCA) solely for the regulation of tobacco products. Among its many provisions, S. 2461/H.R. 4433 would authorize FDA to: restrict tobacco advertising and promotions, especially to children; develop standards that require changes in tobacco product composition and design, such as the reduction or elimination of toxic chemicals; and require manufacturers to obtain agency approval in order to make reduced-risk and reduced-exposure claims for their products.

In the mid-1990s, FDA claimed authority under the FFDCA to regulate cigarettes and smokeless tobacco products as delivery devices for nicotine, an addictive drug. The agency's 1996 tobacco regulation was invalidated by the U.S. Supreme Court in March 2000. 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 105th Congress as part of legislation to implement the 1997 proposed national tobacco settlement. Several FDA tobacco bills were introduced in the 107th Congress following the Supreme Court's decision, though none saw any legislative action.

Under S. 2461/H.R. 4433, FDA would be authorized to regulate tobacco product marketing and impose mandatory design changes on tobacco products if it determined that such actions were appropriate for the protection of public health, based on a consideration of the risks and benefits to individual consumers and to the population as a whole. But the legislation would also place certain restrictions on that authority, permitting most existing products to remain on the market (at least in the near term) and reserving for Congress the power to ban tobacco products.

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FDA Regulation of Tobacco Products: A Policy and Legal Analysis

Introduction

On October 6, 2004, congressional conferees for the American Jobs Creation Act of 2004 (H.R. 4520, P.L. 108-357) rejected a Senate amendment that would have given the Food and Drug Administration (FDA) broad new authority to regulate cigarettes and smokeless tobacco products. The amendment, offered by Senators DeWine (R-OH) and Kennedy (D-MA), incorporated the text of the Family Smoking Prevention and Tobacco Control Act (S. 2461), which the two Senators introduced on May 20, 2004. A companion House bill (H.R. 4433) was introduced on the same date by Representatives Tom Davis (R-VA) and Henry Waxman (R-CA). On October 10, 2004, following its rejection by the conference committee, the Senate passed the DeWine-Kennedy FDA tobacco bill by voice vote.

S. 2461/H.R. 4433 would create a new Chapter IX in the Federal Food, Drug, and Cosmetic Act (FFDCA)¹ giving the FDA broad authority to regulate the manufacture, distribution, advertising, promotion, sale, and use of cigarettes and smokeless tobacco (i.e., snuff and chewing tobacco). The legislation would:

- require all tobacco product manufacturers to register annually with the FDA and provide the agency with a detailed product list;
- mandate biennial inspection of all registered establishments;
- require premarket approval of new tobacco products unless they were determined to be substantially equivalent to other tobacco products already on the market;
- require 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”;
- authorize FDA to regulate the advertising and promotion of tobacco products in order to protect public health;
- give FDA the authority to modify the composition of tobacco products in order to protect public health (though it would reserve for Congress the authority to reduce nicotine yields to zero or ban tobacco products);
- require FDA to develop new regulations for the testing, reporting, and public disclosure of tobacco product ingredients and smoke constituents;

¹ 21 U.S.C. §§ 301 et seq.

- preserve the authority of states and localities to take additional measures to restrict the distribution, advertising, promotion, sale, access to, and use of tobacco products;
- instruct FDA to issue new recordkeeping requirements to help counter the illicit trade of tobacco products; and
- assess user fees on manufacturers to pay for the cost of FDA tobacco regulation.

In addition, S. 2461 would require FDA to reissue most of its 1996 tobacco regulation as an interim final rule, subject to public comment and possible amendment. The agency had claimed jurisdiction over tobacco products under the FFDCa, based on its conclusion that cigarettes and smokeless tobacco products are delivery devices for nicotine, an addictive drug.

On March 21, 2000, the U.S. Supreme Court invalidated the FDA tobacco regulation. In a 5-4 decision, the Court ruled that FDA does not have the authority under the FFDCa to regulate cigarettes and smokeless tobacco products as drug-delivery devices. 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 first drafted such language in the 105th Congress and included it in legislation that would have implemented the 1997 proposed national tobacco settlement. That legislation was debated and rejected by the Senate in 1998. Following the Supreme Court's ruling, several lawmakers introduced FDA tobacco legislation in the 107th Congress without subsequent legislative action.²

The recent introduction of S. 2461 and the companion House bill (H.R. 4433), sponsored by Representatives Tom Davis (R-VA) and Henry Waxman (D-CA), followed months of negotiations in which lawmakers sought to balance the competing interests of public health groups and the tobacco industry. Both sides support giving FDA the authority to regulate cigarettes and smokeless tobacco

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

products, but they disagree on the central question of how much regulatory control the agency should be given.

Public health advocates want FDA to have broad authority to take whatever actions the agency considers necessary to protect public health. They argue that giving FDA limited authority would invite tobacco companies to mount a legal challenge to every proposed regulatory action. A weak FDA tobacco bill would, in their view, be worse than no bill at all. The tobacco companies, on the other hand, want to see certain restrictions placed on FDA's authority. They oppose giving FDA the authority to alter the composition of their products to the point that adult smokers reject them. The companies want to reserve for Congress — not the FDA — the authority to remove nicotine from tobacco products or take any other action that might lead to the elimination of tobacco products.

S. 2461/H.R. 4433 represents a compromise between those two competing positions. Leading public health groups and Philip Morris, the nation's largest cigarette manufacturer with 50% of the U.S. market, strongly support the bill's regulatory framework. The other major cigarette companies, however, have broken ranks with Philip Morris and are opposed to the legislation. While they continue in principle to support FDA regulation of their products, they fear that the sweeping new regulatory authority outlined in S. 2461/H.R. 4433, including tight restrictions on marketing, will help further consolidate Philip Morris's dominance over the U.S. market.

This report examines the legislative debate over giving FDA the authority to regulate tobacco products and provides some analysis of S. 2461/H.R. 4433. It begins with an overview of the FDA's 1996 tobacco rule that includes a summary of the agency's arguments for asserting jurisdiction over tobacco products. That is followed by an analysis of the U.S. Supreme Court decision in *FDA v. Brown & Williamson*, which overturned the FDA tobacco rule. The report 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. It includes a discussion of the FDA provisions in the McCain tobacco bill (see **Table 1**), which was introduced and debated in the 105th Congress in an attempt to implement the proposed settlement. The final section of the report summarizes the provisions in S. 2461/H.R. 4433 (see **Table 2**) and discusses some of the key issues, including preemption and the regulation of reduced-risk products.

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.³ 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

³ 61 *Federal Register* 44396-45318; 21 C.F.R. Parts 801, 803, 804, 807, 820, and 897.

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.

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.^a
- 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 FFDCA, drug and device manufacturers must demonstrate that their products are both safe and effective in order to gain FDA marketing approval. The safety and effectiveness standard poses a difficult challenge for regulating tobacco products, which are manifestly unsafe when used as intended. 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 its

rulemaking, 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 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 FFDCAs’ 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.”⁴ 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 FFDCAs’ definition of medical devices includes articles that are intended by the manufacturer to affect the structure and function of the body.⁵ Unlike a drug, however, a device is defined, in part, as an article “which does not achieve its primary intended purpose through chemical action.”⁶

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 since they have components that are both a drug and a device. Under the FFDCAs, the FDA is authorized to regulate products that “constitute a combination of a drug, device, or biologic product.”⁷ The agency has interpreted this provision as giving it the discretion to regulate combination products as drugs, as devices, or as biologic products.⁸ In its final rule, the FDA chose to regulate tobacco products under the device provisions of the FFDCAs because they offer the agency greater regulatory flexibility than do the drug provisions of the Act.⁹

⁴ 21 U.S.C. § 321(g)(1)(C); FFDCAs Section 201(g)(1)(C). Emphasis added.

⁵ 21 U.S.C. § 321(h)(3); FFDCAs Section 201(h)(3).

⁶ 21 U.S.C. § 321(h); FFDCAs Section 201(h).

⁷ 21 U.S.C. § 353; FFDCAs Section 503(g).

⁸ 61 *Federal Register* 44396, 44400 (1996).

⁹ *Id.* at 44403.

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. 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 cigarettes and smokeless tobacco as either Class I, II, or III devices at some point in the future. The agency further stated that when classification was determined, it would impose any additional requirements that were appropriate.¹⁰

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."¹¹

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.¹² 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

¹⁰ 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.

¹¹ 21 U.S.C. § 360j(e); FFDCA Section 520(e). Emphasis added.

¹² 61 *Federal Register* 44396, 44405.

manufacturers were “free to entice children and adolescents to circumvent the access restrictions.”¹³

Court Challenge of 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 FFDCFA does not authorize the FDA to regulate tobacco products as drugs or devices.¹⁴ 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.

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 FFDCFA when it classified nicotine as a drug and tobacco products as drug-delivery devices.¹⁵ 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.¹⁶ 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.¹⁷ 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.”¹⁸ The court’s decision was stayed pending further appeal.

¹³ 61 *Federal Register* 44406-07.

¹⁴ *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374 (M.D.N.C. 1997).

¹⁵ *Id.*

¹⁶ 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.

¹⁷ *Brown & Williamson Tobacco Corp. v. FDA*, 153 F. 3d. 155 (4th Cir. 1998).

¹⁸ *Id.* at 165.

On November 10, 1998, in a 6-3 decision, the full appellate court rejected the Administration's request to reconsider the ruling.¹⁹ 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.²⁰ 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]."²¹

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. v. NRDC* is the leading case on judicial review of agency interpretations of statutes.²² This case involved EPA's rules regulating emissions under the Clean Air Act. In *Chevron*, the Court enunciated a two-part 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?²³

Under the first part of the *Chevron* test, if Congress has spoken directly to the question at issue, then the Court "must give effect to the unambiguously expressed intent of Congress."²⁴ However:

If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation.... Sometimes the legislative delegation to an agency on a

¹⁹ *Brown & Williamson Tobacco Corp. v. FDA*, 161 F.3d 764 (4th Cir. 1998).

²⁰ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

²¹ *Id.* at 126.

²² 467 U.S. 837 (1984).

²³ *Id.* at 842-843.

²⁴ *Id.* at 843.

particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.²⁵

The second part of the *Chevron* test analyzes the reasonableness of an agency's interpretation.²⁶ If an agency's interpretation is reasonable, then a court may not substitute its own construction of the statutory provision. However, deference is not owed to an agency's decision if it construes a statute in a way that is contrary to congressional intent or frustrates congressional policy.²⁷ With regard to challenges based on statutory construction, the Court stated clearly in *Chevron*:

The judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent ... If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.²⁸

In *FDA v. Brown & Williamson*, the Court restated its view that when Congress has spoken to the precise question at issue, *Chevron* deference is not due. 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. 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.²⁹

²⁵ *Id.* at 843-844.

²⁶ *CHW West Bay v. Tommy G. Thompson*, 246 F.3d 1218, 1222 (9th Cir. 2001)(construction of statute not owed deference under *Chevron* because agency's actions contravened congressional intent and was unsupported by the substantial evidence from the regulations).

²⁷ *CHW West Bay*, 246 F.3d at 1223. See also *Anaheim Mem'l Hospital v. Shalala*, 130 F.3d 845, 849 (1997)(reiterating rule that deference is not owed to an agency construction of a statute that is contrary to congressional intent or frustrates congressional purpose).

²⁸ 467 U.S. at 843, cited in *INS v. Cardoza-Fonseca*, 480 U.S. 421, 447-448 (1987)(question concerning validity of an INS interpretation of the Immigration and Nationality Act relating to asylum was not due *Chevron* deference because it posed a question of statutory construction for the Court to decide).

²⁹ *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 Section 202, 42 U.S.C. § 300x-26).

Thus, the Court held that Congress had clearly “intended to exclude tobacco products from the FDA’s jurisdiction.”³⁰

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.³¹ 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.³² 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.³³

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.³⁴

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 105th 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.³⁵ 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

³⁰ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000).

³¹ 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. First Amended Complaint for Declaratory and Injunctive Relief at 6-11, *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374 (M.D.N.C. 1997) (No. 2:95CV00591).

³² These statutes, both of which are administered by the FTC, require health warnings on cigarette and smokeless tobacco packages and advertising, respectively.

³³ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, at 143-156.

³⁴ *Id.* at 161-164.

³⁵ 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>].

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 box on the next page.

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.³⁶ 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.

³⁶ 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. Formal rulemaking, by contrast, is a more rigorous and time-consuming process that tends to place a greater burden of proof on the agency promulgating the rule. Under the proposed national settlement, the FDA would have had to show "substantial evidence" in support of its cigarette performance standards, which is a more stringent standard than the arbitrary, capricious, and abuse of discretion standard.

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 rule making 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.^a

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.

McCain Tobacco Bill (105th 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 105th Congress to pass legislation to implement the settlement ended when the McCain bill (S. 1415) was defeated on a pair of procedural votes on June 17, 1998, after an extended floor debate. Following the demise of 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.³⁷ The MSA did not address FDA’s authority over tobacco products (see box below).

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 costs. The MSA required the companies to pay approximately \$206 billion over the first 25 years. 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).

Table 1, beginning on page 29, provides a summary of the major provisions of the McCain tobacco bill. Although the measure was intended to implement the proposed national settlement, it was 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 included stiffer financial penalties if the decline in underage tobacco use did not meet the reduction targets, and it also provided the industry with fewer legal protections than those negotiated in the June 1997 agreement.

The McCain bill also added a new Chapter IX to the FFDCA solely for the regulation of tobacco products. That language, which was provided by Senator Frist, drew extensively on the Act’s existing drug and device provisions in Chapter V, but with modifications.³⁸ By establishing new legal authority within the FFDCA for

³⁷ The full text of the MSA is available on the website of the National Association of Attorneys General (NAAG), at [<http://www.naag.org/issues/issue-tobacco.php>]. NAAG is responsible for implementing and enforcing the MSA.

³⁸ The Frist language incorporated, with modifications, the following FFDCA drug and device provisions: adulterated drugs and devices (Section 501); misbranded drugs and devices (Section 502); device manufacturer registration (Section 510); performance standards (Section 514); premarket approval (Section 515); judicial review (Section 517); notification and recall (Section 518); records and reports (Section 519); general provisions (continued...)

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 be required to demonstrate that any proposed tobacco regulation was appropriate for the protection of public health. Such a determination would involve a consideration of the risks and benefits to the population as a whole.

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, have established a comprehensive regulatory scheme that is appropriate for regulating tobacco products.

Several other comprehensive tobacco bills were introduced in the 105th Congress, though none of them saw any legislative activity.³⁹ 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. For more details, see CRS Report 98-6, *Tobacco Legislation in the 105th Congress*.

FDA Tobacco Bills in the 107th & 108th Congress

This section of the report includes a brief description of the tobacco legislation introduced in the 107th Congress (2001-2002) in the wake of the Supreme Court

³⁸ (...continued)

respecting control of devices intended for human use (Section 520); preemption of state and local requirements (Section 521); and postmarket surveillance (Section 522).

³⁹ S. 1492 (Kennedy); S. 1530 (Hatch); S. 1638 (Conrad); S. 1889 (Harkin); H.R. 3028 (DeLauro); H.R. 3474 (Fazio); H.R. 3868 (Hansen).

decision, followed by a summary and some analysis of S. 2461/H.R. 4433. Because some of the legislation introduced during these sessions was drafted, at least in part, in response to Philip Morris's new position on FDA tobacco regulation, the section begins by comparing Philip Morris's position on FDA tobacco regulation with that of the leading anti-tobacco organizations.

Competing Views on FDA Regulatory Authority

Philip Morris USA. In March 2001, Philip Morris, the nation's leading cigarette company with about 50% of the U.S. market, issued a white paper in support of legislation giving FDA authority to regulate cigarettes.⁴⁰ The company explained that its support for such legislation did not signal a reversal of its earlier opposition to the FDA's attempt to regulate cigarettes as restricted medical devices. Philip Morris opposed the FDA rule on the grounds that it would have left the agency with no choice but to ban the sale of cigarettes. The company argued that cigarettes simply cannot be found to be safe and effective as required under the FDCA's existing drug and device provisions, a position with which the Supreme Court agreed in *FDA v. Brown & Williamson*.

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

Philip Morris set out in the white paper some fundamental principles for FDA tobacco legislation:

- Tobacco regulation should reflect the unique health, social and economic issues associated with such products. Cigarettes should be regulated as cigarettes, not as a medical device.
- Regulation should not equal prohibition. Adults should be able to make their own decision whether to smoke. The government should continue to inform the public about the dangers of tobacco products and discourage their consumption, but should not restrict an adult's ability to make a decision about smoking.
- Regulation should build on the framework of the MSA in working to prevent youth smoking.
- FDA should require that ingredients added by the manufacturers do not increase the inherent risks or addictiveness of smoking. The agency should have the authority to impose mandatory design

⁴⁰ The Philip Morris white paper on FDA tobacco regulation is available online at [http://www.pmusa.com/policies_practices/legislation_regulation/fda_tobacco.asp].

changes to cigarettes to help reduce harm, provided the changes do not significantly diminish adult smokers' enjoyment of the product.

- Regulation should define reduced exposure and reduced risk products and establish guidelines for communications about such products in a way that is consistent and accurate and does not encourage smoking or discourage quitting.
- FDA should continue to address the broad issues of disclosure (e.g., the content of warning labels, information about ingredients and smoke constituents) so that adults smokers remain informed about health risks.

The overarching concern for Philip Morris is that any new legislation must recognize cigarettes as legal products and respect the decision of adults to smoke. The company has indicated that it opposes any proposals that would give FDA the authority to ban cigarettes outright or to achieve a de facto prohibition by imposing ever-lower tar and nicotine yields that would render the product unpalatable to adult smokers. Such product changes, argues the company, would drive smokers towards illicit, unregulated products, where there are no standards for ingredients or tar and nicotine levels. Interestingly, FDA used a similar line of reasoning in developing the tobacco rule when it concluded that banning tobacco products under the FFDCA's drug and device provisions was not a realistic option. The agency reasoned that a ban on cigarettes would encourage cigarette smuggling and the development of a black market supplying smokers with unregulated and potentially more dangerous products.

While Philip Morris has been actively lobbying for FDA tobacco legislation, the other three major cigarette companies—R. J. Reynolds, Brown & Williamson, and Lorillard—have criticized the various legislative proposals. Like Philip Morris, R. J. Reynolds and Lorillard both support “reasonable” FDA regulation of cigarettes, provided they are regulated as cigarettes under new legal authority, and not as drugs and devices under existing law. The companies believe that any new regulation must preserve the rights of adults to choose and purchase a wide range of cigarettes brands. But they also stress the importance of maintaining a level playing field upon which manufacturers can compete for the business of adult smokers. This final point appears to lie at the heart of their opposition to the proposed legislation. All three companies, which together account for about 43% of the U.S. cigarette market, fear that sweeping new regulation of their products, including tight restrictions on marketing, will be to Philip Morris's advantage, allowing the nation's number one cigarette manufacturer to lock in its leading market share. They worry that new restrictions on advertising would force consumers to rely on brand recognition and product placement, which would give industry-leader Philip Morris an advantage.⁴¹

Campaign for Tobacco-Free Kids. Working in partnership with the nation's leading anti-tobacco organizations, including the American Lung Association and the American Cancer Society, the Campaign for Tobacco-Free Kids

⁴¹ For a discussion of company positions on FDA regulation, go to each company's website: R. J. Reynolds Tobacco Company [http://www.rjrt.com/TI/TIregulation_Position.asp]; Brown & Williamson Tobacco Corporation [http://www.bw.com/Index_sub2.cfm?ID=4]; Lorillard Tobacco Company [<http://www.lorillard.com>].

has developed its own set of core elements that it believes must be incorporated in legislation giving FDA authority to regulate tobacco products.⁴² While the Campaign and Philip Morris appear to be in general agreement on several areas over which FDA should be granted authority (e.g., youth access and marketing, ingredient testing and disclosure, good manufacturing practice, and reduced risk products), they fundamentally disagree on whether any limitations should be placed on that authority. Speaking for the anti-tobacco community at large, the Campaign argues that FDA should be granted broad and unrestricted regulatory authority to take those actions it deems necessary to protect the public health. In contrast to Philip Morris's position on FDA regulatory authority, the Campaign insists on the following:

- New FDA authority to regulate tobacco products should, as much as possible, be comparable to the agency's existing authority over other consumer products.
- Tobacco products should be regulated based on a "protection of public health standard" that aims to reduce tobacco-related health risks to the population as a whole. This standard would require a determination of the impact of a product change or new rule on overall tobacco use, including whether it encourages tobacco use or discourages quitting.
- FDA should have the authority to evaluate scientifically and, through a notice-and-comment rulemaking process, decide whether to reduce or eliminate harmful and addictive components of all tobacco products in order to protect the public health.

107th Congress

Philip Morris released its white paper early in the 107th Congress. Several FDA tobacco bills were introduced in that Congress, none of which 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 FFDCIA 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 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 or, 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.

⁴² The Campaign's list of key elements of any legislation giving FDA authority to regulate tobacco products is available online at [<http://tobaccofreekids.org/research/factsheets/pdf/0181.pdf>].

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 107th 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 FFDCa. This approach was favored by some public health advocates, but strongly opposed by the industry. As with the earlier versions introduced during the 105th 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.

108th Congress

At the beginning of the 108th 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 (R-OH) and Kennedy (D-MA) and Representatives Tom Davis (R-VA) and Henry Waxman (D-CA) announced the introduction of bipartisan, bicameral FDA tobacco legislation (S. 2461, H.R. 4433). Both Philip Morris and the Campaign for Tobacco-Free Kids announced their "enthusiastic" support for the legislation. **Table 2**, beginning on page 32, summarizes the key provisions in S. 2461/H.R. 4433. Where applicable, the comparable drug and device provisions in FFDCa Chapter V are noted in the table.

Issues

S. 2461/H.R. 4433 represents an attempt to balance the competing interests of Philip Morris and leading anti-tobacco groups. The legislation would grant FDA the authority to:

- restrict tobacco advertising and promotions, especially to children;
- stop illegal sales of tobacco products to children;

- develop performance standards that require changes in the composition and design of tobacco products, such as the reduction or elimination of harmful chemicals;
- prohibit claims about reduced-risk and reduced-exposure tobacco products that are not scientifically substantiated or that would discourage current tobacco users from quitting or encourage new users to start;
- prohibit terms such as “light,” “mild,” or “low tar” that can mislead consumers into believing that certain products are safer than others;
- require larger and more explicit health warnings on tobacco products.

At the same time, S. 2461/H.R. 4433 explicitly states that one of its purposes is “to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers.” The legislation states that FDA may not prohibit the sale of tobacco products to individuals age 18 and over. Moreover, it provides that only Congress may impose a new standard that would ban tobacco products or require the “reduction of nicotine yields of a tobacco product to zero.” The following provides more discussion and analysis of these and other provisions in the bills.

Restrictions on Advertising and Promotion. S. 2461/H.R. 4433 would give FDA broad authority to regulate tobacco product marketing if it determined that such regulation was appropriate to protect the public health. The agency would be required to make that determination based on a consideration of the “risks and benefits to the population as a whole,” including whether the agency’s actions would discourage current users from quitting or encourage others to start using tobacco products.

Philip Morris has in the past criticized that approach. The company prefers the language in H.R. 140, which would permit FDA to regulate tobacco advertising and promotion based on a determination that such regulation was “appropriate for the prevention of, or decrease in, the use of tobacco products by [minors].” Anti-tobacco groups believe that such a standard would make it virtually impossible for FDA to act. They argue that because the industry denies that any of its advertising is directed at children, it would challenge every regulatory proposal by the agency. Philip Morris defends the language, arguing that it is simply a recognition of the fact that the First Amendment, as currently interpreted by the U.S. Supreme Court, “prevents the FDA from prohibiting advertising directed at adults.” The company contends that giving the agency broader authority to regulate the marketing of its products would be inefficient because it would encourage FDA to develop regulations that would never survive a constitutional challenge.

In order to place these arguments in context, it is helpful to review briefly the U.S. Supreme Court’s decisions on government regulation of advertising and other

forms of commercial speech.⁴³ In *Central Hudson Gas & Electric Corp. v. Public Service Commission* (1980), the Court established a four-part test for deciding the constitutionality of commercial speech regulation.⁴⁴ First, in order to be protected by the First Amendment, the commercial speech must concern lawful activity and not be false or misleading. Second, the government must demonstrate that by restricting such speech, it is seeking to further a substantial interest. Third, the restrictions must directly advance that interest. Fourth, there has to be a reasonable fit between the type of restrictions imposed and the government's objectives.

Over the past 10 years the U.S. Supreme Court has issued a series of decisions striking down government restrictions on commercial speech, including tobacco product advertising.⁴⁵ In *Lorillard Tobacco Co. v. Reilly* (2001), the Court found a number of Massachusetts state regulations restricting outdoor and point-of-sale advertising for cigars and smokeless tobacco products to be unconstitutional.⁴⁶ The Court determined that the regulations restricted speech more than was reasonable to advance the state's interest in reducing underage (i.e., illegal) use of tobacco products and, thus, failed to meet the fourth part of the *Central Hudson* test. Banning all outdoor tobacco advertisements within 1,000 feet of a school or playground, in conjunction with other zoning restrictions, argued the Court, "would constitute a nearly complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers."⁴⁷

Some public health law experts believe that the Supreme Court in its recent decisions on the regulation of commercial speech has left public health authorities with little room to craft tobacco advertising restrictions that meet both the third (effectiveness) and fourth (extensiveness) parts of the *Central Hudson* test.⁴⁸ On the one hand, tobacco advertising restrictions that are narrowly tailored may not provide clear evidence of effectiveness, thus failing the third part of *Central Hudson* test. On the other hand, more sweeping (and potentially effective) restrictions may be viewed as too extensive and not reasonably related to the government's asserted interest, thus failing the fourth part of the *Central Hudson* test.

In developing the 1996 tobacco rule, FDA created a set of advertising restrictions aimed at reducing underage smoking and smokeless tobacco use that it hoped would withstand a constitutional challenge. Whether the FDA rule would have passed the *Central Hudson* test remains unclear. In *FDA v. Brown &*

⁴³ For more information on the First Amendment and commercial speech, see CRS Report 95-815A, *Freedom of Speech and Press: Exceptions to the First Amendment*, by Henry Cohen.

⁴⁴ 447 U.S. 557 (1980).

⁴⁵ Ronald Beyer et al., "Tobacco Advertising in the United States: A Proposal for a Constitutionally Acceptable Form of Regulation," *Journal of the American Medical Association*, vol. 287, no. 22 (Jun. 2002), pp. 2990-2995.

⁴⁶ 533 U.S. 525 (2001).

⁴⁷ *Id.* at 562.

⁴⁸ Ronald Beyer et al., *supra* n. 45.

Williamson, the Supreme Court confined itself to a review of the agency's interpretation of its authority under the FFDCFA. The Court did not address the constitutionality of the rule's marketing restrictions. It should be noted, however, that the FDA rule included a ban on outdoor advertising within 1,000 feet of a school or playground. In *Lorillard*, the Court found unconstitutional a similar provision in the Massachusetts regulations.

Product Design and Composition. S. 2461/H.R. 4433 would not permit cigarettes to contain any additive that is a "characterizing flavor" of the product or the smoke, other than tobacco or menthol. The legislation would give FDA the authority to develop product standards to reduce nicotine, reduce or eliminate other harmful constituents, or otherwise modify the composition and testing of tobacco products, if it determined that such regulation was appropriate to protect the public health. Once again, FDA would be required to make that determination based on a consideration of the risks and benefits to the population as a whole, which is the approach favored by public health officials. Unlike some of the FDA tobacco bills introduced in the 107th Congress, there is nothing in S. 2461/H.R. 4433 to prevent the agency from requiring changes in the composition of tobacco products that would render them "unacceptable for adult consumption." Placing that restriction on FDA's ability to modify tobacco products had been a key requirement for the industry.

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

As part of the standard-setting process, FDA would also be required to consider whether a proposed standard might lead to a "significant demand for contraband products and other tobacco products that do not meet the requirements of the [legislation]." Until more is learned about the nature of nicotine addiction, that requirement may pose a significant challenge to any proposed reduction in nicotine yield.

S. 2461/H.R. 4433 does not permit FDA to ban tobacco products, or to require the reduction of nicotine yields to zero. The authority to take those specific actions is reserved for Congress. As discussed earlier, the industry has argued strenuously in favor of placing such restrictions on FDA's regulatory authority. Companies are fearful that the agency, left unchecked, could achieve a de facto ban by eliminating nicotine and making tobacco products unacceptable to adults. The public health community maintains that FDA should have unrestricted authority to take whatever actions it feels are necessary to protect public health.

Reduced Risk Products. Both the tobacco industry and the public health community are eager to establish a regulatory scheme for "reduced-risk" tobacco products. In recent years Philip Morris and the other leading cigarette companies

have test marketed a variety of products that are potentially less harmful to the individual user than traditional tobacco products. They include cigarettes made using genetically modified tobacco, and cigarette-like products that deliver nicotine using a combustion process that involves lower temperatures and a more controlled burn. The companies want FDA's approval to market these products without fear of the agency taking regulatory action against them. FDA has in the past asserted jurisdiction when cigarette manufacturers have expressly promoted their products as beneficial to health.⁴⁹

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

Public health officials often point to the introduction of low-tar cigarettes in the 1960s and 1970s to illustrate the challenges of regulating reduced-risk products. The companies were careful not to make any explicit health claims when they started to market "light" and "ultralight" cigarettes, but the implicit message was that these products provided a less harmful way of smoking and many smokers believed and continue to believe that they are safer than regular-strength cigarettes. Light cigarettes emit lower levels of tar and nicotine than regular-strength cigarettes, as measured by a standardized smoking machine test developed by the Federal Trade Commission and commonly referred to as the FTC method. However, the National Cancer Institute (NCI) concluded that there is "no convincing evidence" that the introduction of such low-yield products "resulted in an important decrease in the disease burden" among smokers.⁵⁰ Many smokers who switched to low-yield cigarettes changed the way they smoked so as to maintain the desired intake of

⁴⁹ The FDCA's definition of drug includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease...." (Section 201(g)(1)(B)) During the 1950s, the agency took regulatory action against cigarettes advertised as effective in preventing respiratory and other diseases and cigarettes promoted as weight-reduction aids. Note: The FDA regulates several nicotine replacement therapies to help tobacco users quit. These products include nicotine gum, transdermal nicotine patches, nicotine inhalers, and nicotine nasal spray.

⁵⁰ National Institutes of Health, National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph 13 (NIH Pub. No. 02-5074) (Oct. 2001).

nicotine. They smoked more intensely by inhaling more deeply and more often and by covering the ventilation holes at the base of the filter. This compensatory smoking behavior exposed them to higher amounts of tobacco toxins.⁵¹

S. 2461/H.R. 4433 would prohibit manufacturers from marketing “modified risk tobacco products” without FDA prior approval. The legislation defines modified risk tobacco products as any product:

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

In order to gain approval to market a modified risk tobacco product, a manufacturer would have two options. The first is to submit a *reduced-risk claim*. That would require the company to demonstrate to FDA that the product, “as actually used by consumers,” will reduce the risk of tobacco-related disease to individual users and “benefit the health of the population as a whole.” Alternatively, the manufacturer could assert that the product reduces exposure to a particular substance. S. 2461/H.R. 4433 sets out detailed criteria for approving such a *reduced-exposure claim*. Those criteria, based on recommendations of the Institute of Medicine,⁵² include determining that the exposure reduction is “substantial;” the substance to which exposure is reduced is harmful; the reduced exposure is anticipated to lead to a “measurable and substantial reduction” in harm among individual users; and approval of such a product is “expected to benefit the health of the population as a whole.” Applications for products that make exposure-reduction claims would be approved for five years at a time. All manufacturers of approved modified risk tobacco products, whether on the basis of a reduced-risk claim or a reduced-exposure claim, would be required to conduct postmarket surveillance and report their findings on an annual basis.

If enacted into law, the modified risk provisions in S. 2461/H.R.4433 would produce immediate changes in cigarette marketing. Manufacturers would be required to stop using terms such as “light” and “low-tar” on their low-yield brands. Those brands would be permitted to remain on the market provided the manufacturers made any other changes necessary to ensure that the products did not fall under the definition of a modified risk tobacco product. For example, manufacturers have for

⁵¹ For a detailed discussion of the scientific and regulatory issues surrounding reduced risk tobacco products, see the Institute of Medicine’s 2001 report, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, Washington, DC: National Academy Press.

⁵² *Id.*

years reported tar and nicotine yields (as measured by the FTC method) on cigarette advertising and on some very low-tar cigarette packs. Because this information implies that the product reduces risk or exposure, it too would have to be removed. Under a separate provision in the legislation, FDA would be required to develop new regulations for the testing, reporting, and public disclosure of tobacco product ingredients and smoke constituents, including tar and nicotine levels (see **Table 2**). Those regulations would replace the current FTC method.⁵³

It is difficult to imagine a company gaining FDA approval to market a modified risk tobacco product based on a reduced-risk claim, as least in the near term. Demonstrating that the product, as actually used by consumers, will reduce risk both to the individual user and to the population as a whole requires long-term epidemiological studies. However, gaining approval for a new product on the basis of a reduced-exposure claim does not require that the manufacturer meet such stringent requirements. For example, the company would have to show that the reduced exposure is “anticipated” to lead to a reduction in harm and that the product is “expected” to benefit the health of the population as a whole. Approving modified risk tobacco products under such criteria makes postmarket surveillance all the more important as a means of monitoring the product’s actual impact on public health.

S. 2461/H.R. 4433 would also give FDA the authority to require the manufacturer of an approved modified risk tobacco product to comply with certain labeling and advertising requirements. Such authority could be used to place tight restrictions on the ability of manufacturers to market their modified risk products to individual tobacco users. Philip Morris and the other companies believe that they should be able to provide adult consumers with information about reduced-risk and reduced-exposure products, provided the information is accurate and not misleading, to help them make an informed choice.

Preemption of State and Local Regulation. Another key issue in the debate surrounding FDA tobacco legislation involves federal preemption of state law. The Federal Cigarette Labeling and Advertising Act (FCLAA), which mandates health warnings on cigarette packaging and advertising, includes the following preemption provision:

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

⁵³ Over the past several decades, cigarette design changes have led to substantial reductions in tar and nicotine yields as measured by the FTC method. However, these machine-measured yields do not provide a reliable measure of the amount of tar and nicotine a smoker inhales. Smokers alter their smoking behavior (e.g., increasing puff volume and frequency, covering the ventilation holes with fingers or lips) to obtain sufficient nicotine to satisfy their addiction. For more information, see National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine* (Oct. 2001).

promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.⁵⁴

The FCLAA's introductory declaration of policy indicates that Congress did not want "commerce and the national economy ... impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations...."⁵⁵ To that end, the Act's preemption provision (1) prohibits additional health-related statements on the labels of cigarette packages that are properly labeled in accordance with the Act, and (2) prevents states and localities from imposing any other "requirement or prohibition based on smoking and health" regarding the advertising and promotion of cigarettes.

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

In *Cipollone v. Liggett Group Inc.*, the U.S. Supreme Court held that certain types of tort actions that are brought against cigarette manufacturers under state common law are preempted by the FCLAA.⁵⁶ The case was brought on behalf of Rose Cipollone, a lifelong smoker who developed lung cancer at age 57. She filed a lawsuit against the Liggett Group and two other cigarette companies, accusing them, among other things, of failing to warn her adequately of the health risk of smoking and its addictive nature. In 1988, a jury awarded \$400,000 in damages to Cipollone's family after finding Liggett negligent for its failure to warn smokers prior to 1966 when the federal labeling law went into effect, and for advertising that could be interpreted as a warranty for safety. On appeal, the U.S. Court of Appeals for the Third Circuit ordered a new trial after affirming in part and reversing in part some of the district court's pre-trial rulings.⁵⁷ The Supreme Court granted certiorari to review whether or not the petitioner's state law claims were preempted by the FCLAA.⁵⁸

In 1992, the U.S. Supreme Court concluded that failure-to-warn claims are preempted by the FCLAA because they require a showing that the cigarette manufacturers' advertising and promotions should have included additional, and more clearly stated, warnings.⁵⁹ Such a finding "constitutes a requirement ... based on smoking and health imposed under State law with respect to advertising or

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

⁵⁵ *Id.* at § 1331.

⁵⁶ 505 U.S. 504 (1992).

⁵⁷ *Cipollone v. Liggett Group Inc.*, 893 F.2d 541 (3rd Cir. 1990).

⁵⁸ *Cipollone v. Liggett Group Inc.*, 499 U.S. 935 (1991).

⁵⁹ *Cipollone v. Liggett Group Inc.*, 505 U.S. 504 (1992).

promotion,” which the FCLAA prohibits.⁶⁰ However, the Court found that other types of claims that are not based on smoking and health, including fraudulent misrepresentation and conspiracy to defraud, are not preempted even though they might relate to advertising or promotion.

Federal Preemption of State Law

The preemption doctrine derives from the Supremacy Clause of the U.S. Constitution, which establishes that the laws of the United States “shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any State to the contrary notwithstanding.”^a In applying this constitutional mandate, courts have recognized both express and implied forms of preemption, which are “compelled whether Congress’ command is explicitly stated in the statute’s language, or implicitly contained in its structure and purpose.”^b Both types of preemption may apply to state legislation, regulations, and common law.

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

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

a. U.S. CONST. art. VI, cl. 2.

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

c. *Jones v. Rath*, 430 U.S. at 525

d. *Sprietsma v. Mercury Marine*, 123 S. Ct. 518, 527 (2002). See also: *Hines v. Davidowitz*, 312 U.S. 52, 61, 77 (1941) (regarding field and frustration of purpose preemption); and *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963) (regarding conflict preemption).

e. *Hines v. Davidowitz*, 312 U.S. at 67.

The Supreme Court also addressed FCLAA preemption in *Lorillard Tobacco Co. v. Reilly*.⁶¹ In addition to finding Massachusetts’ regulations on smokeless tobacco and cigar advertising unconstitutional (discussed earlier), the Court in *Lorillard* ruled that the state’s restrictions on cigarette advertising were preempted by the FCLAA. Specifically, the Court concluded that the regulations did relate to the “advertising or promotion” of cigarettes. It further concluded that the regulations, targeted at youth exposure to cigarette advertising, were “based on smoking and health” within the meaning of the FCLAA because “concern about youth exposure to cigarette advertising is intertwined with the concern about ... smoking and

⁶⁰ *Id.* at 524.

⁶¹ 533 U.S. 525 (2001).

health.”⁶² The fact that the regulations governed location rather than content of advertising did not remove them from the preemption language, which covers “all ‘requirements’ and ‘prohibitions’ imposed under state law.”⁶³ The *Lorillard* decision clarified that while the FCLAA preempts the ability of states to regulate the advertising and promotion of cigarettes, states retain the authority to regulate other aspects of tobacco use and sales. The FCLAA, for example, does not preempt state laws that prohibit sales to minors or restrict smoking in public places.⁶⁴

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

S. 2461 appears to attempt to accommodate both sides by preserving the current language in the FCLAA preemption provision, while adding at the end the following:

(C) EXCEPTION. Notwithstanding subsection (b), a state or locality may enact statutes and promulgate regulations, based on smoking and health ... imposing specific bans or restrictions on the time and place, and manner, but not content, of the advertising or promotion of any cigarettes.

Thus, states would continue to be prohibited from adding their own warning labels to cigarette packages, but would be permitted to regulate certain aspects of cigarette advertising and promotion, subject to any First Amendment challenge. For the tobacco companies, the language in subsection (b) underlying *Cipollone* would remain intact. In addition to amending the FCLAA preemption provision, S. 2461 includes a general preemption provision in the new FFDCa language that would place certain restrictions on states while allowing them to regulate the sale, advertising, and promotion of tobacco products (see **Table 2**).

FDA’s 1996 Tobacco Rule. S. 2461/H.R. 4433 would require FDA to reissue the youth access and marketing—but not the labeling—provisions from its 1996 regulation as an interim final rule, subject to agency review and possible amendment. The interim final rule would become effective after one year. Anti-tobacco groups have criticized this provision, preferring language in other bills that would reinstate the 1996 tobacco rule without delay. Tobacco companies, noting that

⁶² *Id.* at 548.

⁶³ *Id.* Emphasis omitted.

⁶⁴ The FCLAA preemption provisions apply only to cigarettes and do not cover state regulation of smokeless tobacco and cigars. As discussed in an earlier section of the report, Massachusetts’ outdoor advertising and point-of-sale restrictions on smokeless tobacco and cigars were found to be in violation of the First Amendment.

the advertising and marketing provisions of the rule have not been subjected to constitutional review by the courts, may consider a First Amendment challenge.

Health Warnings. S. 2461/H.R. 4433 would replace the existing Surgeon General's health warnings on cigarette and smokeless tobacco packaging and advertising with several new and more explicit messages (see **Table 2**). FDA would be given the authority to revise those warnings, add new ones, and alter their format, including, but not limited to, changing their size, location, and color. The legislation would result in an immediate change in the design and appearance of tobacco product packaging. Cigarette packaging, for example, would carry health warnings that covered at least 30% of the front and back of the pack. As previously noted, states would not be permitted to add additional health warnings.

Table 1. Summary of McCain Tobacco Bill (105th Congress)

Topic	S. 1415 (McCain) ^a
Amendment of Federal Food, Drug, and Cosmetic Act (FFDCA)	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]
Marketing and advertising restrictions	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. ^b Limits advertising in audio format to words with no music. Limits advertising in video format to static black-on-white text. [Sections 1403-1405]
Warnings, labeling, and packaging	Amends existing federal labeling laws to require new, explicit health warning labels in bold type. ^c 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]
Youth access restrictions	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]
Retailer licensing and registration	Requires states to license tobacco retailers. Establishes penalties for noncompliance, including license suspension and revocation. [Sections 231]

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Topic	S. 1415 (McCain) ^a
State enforcement of youth access laws	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. ^d [Sections 231-233]
Underage tobacco-use targets	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]
Industry penalties	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]
Smoking restrictions in public facilities	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]
Industry payments to National Tobacco Trust Fund	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]
State reimbursement and allocation of trust funds	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]
Consent decree	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]
Attorneys' fees	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]
Legal immunity	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]

Topic	S. 1415 (McCain) ^a
Industry documents	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]
Tobacco farmers	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]
Native Americans	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]
Preemption of state and local actions	Allows state and local governments to adopt and enforce any additional tobacco-product control measures. [Section 5]
International tobacco control	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]
Smuggling	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]
Veterans	Provides \$600 million/yr for five years from the Trust Fund for tobacco-related veterans' health care. [Section 1301]

a. Modified committee substitute bill, as amended during debate on the Senate floor: May 18 — June 17, 1998.

b. 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.

c. (i) Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331), (ii) Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401).

d. 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. Summary of Family Smoking Prevention and Tobacco Control Act (S. 2461, H.R. 4433)

FDA Tobacco Regulatory Authority (Federal Food, Drug, and Cosmetic Act, Chapter IX)	
FDA authority over tobacco products	Creates a new FFDCa Chapter IX for regulating tobacco products, excluding any 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 reduced risk product — see below). Does not give FDA regulatory authority over: (1) tobacco leaf, unless in the possession of a manufacturer; or (2) tobacco growers and warehouses.
Adulterated tobacco products	Specifies the conditions under which tobacco products are deemed adulterated, including (1) contamination by any poisonous or deleterious substances; (2) preparation, packaging, or storage under unsanitary conditions; (3) failure to conform to good manufacturing practice requirements (see below); or (4) the product is in violation of the requirements for modified risk products (see below). [Note: These provisions are similar, with modifications, to the adulteration provisions in FFDCa Section 501.]
Misbranded tobacco products	Specifies the conditions under which tobacco products are deemed misbranded. For example, product labeling must not be false or misleading and must include a statement of the percentage of domestic and foreign-grown tobacco in the product. Authorizes FDA to require by regulation the prior approval of statements made on tobacco product labels. Prohibits FDA from requiring the prior approval of the content of tobacco product advertising, except for reduced risk products (see below). [Note: These provisions are similar, with modifications, to the misbranding provisions in FFDCa Section 502.]
Submission of data and research documents	Within six months, requires each tobacco product manufacturer or importer to submit: (1) 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) all documents developed after the date of enactment of this Act relating to the health impact of current or future products. At the request of the Secretary, requires each manufacturer or importer to submit any or all research documents. Requires prompt notification of modified existing products and the release of new products. 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 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.

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<p>Annual registration</p>	<p>Requires annual registration of all manufacturers 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.</p> <p>Requires a manufacturer within 90 days of introducing a product that was not commercially marketed as of June 1, 2003, to provide for FDA (in a manner prescribed by regulation) its determination that such product is substantially equivalent 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 June 1, 2003, and prior to a date that is 15 months following enactment of this Act have until that date (i.e., 15 months after enactment) to submit their report documenting substantial equivalence to a product commercially marketed as of June 1, 2003. (See Premarket Review below.) Permits the Secretary, by regulation, to exempt from these requirements certain tobacco products that have only minor differences from preexisting products. [Note: These provisions are similar, with modifications, to the registration provisions in FFDCA Section 510.]</p>
<p>General regulatory controls on tobacco products</p>	<p>Authorizes FDA by regulation to restrict the sale, distribution, advertising, promotion, and use 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.</p> <p>Prohibits limiting the sale and distribution of tobacco products to the written or oral authorization of a medical practitioner. Prohibits restrictions on: (1) sales of tobacco products in face-to-face transactions by a specific category of retail outlets; and (2) sales of tobacco products to adults. Authorizes FDA 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. Protects trade secret information obtained by FDA. [Note: The GMP provisions are comparable to FFDCA Section 520(f).]</p>
<p>Tobacco product standards</p>	<p>Subject to revision by FDA, prohibits cigarettes from containing: (1) an artificial or natural flavor, other than tobacco or menthol; or (2) an herb or spice. Authorizes FDA 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 the creation of a significant demand for contraband or other products that do not meet the requirements of this Chapter. 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 and requires a one year delay before new standards take effect unless FDA 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, not FDA, the authority to ban tobacco products or reduce nicotine yields to zero. Provides for the amendment and revocation of existing standards. Permits FDA to refer a proposal to establish, amend, or revoke a product standard to the Tobacco Products Scientific Advisory Committee (see below). Requires FDA to so refer a proposal upon the request of an interested person who demonstrates good cause. [Note: These provisions are similar, with modifications, to the performance standard provisions in FFDCA Section 514.]</p>

Notification and recall	Permits FDA to notify the public about a tobacco product that presents an unreasonable risk of substantial harm to the public health. Compliance with a notification does not relieve persons from liability under federal or state law. Authorizes FDA 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. [Note: These provisions are similar, with modifications, to subsections of FFDCA Section 518.]
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. [Note: These provisions are similar, with modifications, to subsections of FFDCA Section 519.]
Premarket review	Requires premarket review of any new tobacco product (including a product in test markets) that is found not to be substantially equivalent to products on the market as of June 1, 2003. Premarket review is not required if the new product has only minor modifications from a preexisting product (which exempts it from a substantial equivalence determination). Defines substantial equivalence and specifies the types of information to be included in an application for premarket approval. Requires the FDA, 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. [Note: These provisions are similar, with modifications, to the premarket approval provisions in FFDCA Section 515.]
Modified risk tobacco products	Requires manufacturers to obtain FDA approval in order to distribute and sell 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. In addition, FDA is authorized to approve a product that makes an exposure-reduction claim for a five-year period (renewable), based on an application containing certain specified types of information. 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. Establishes other conditions for approval, including the requirement that modified risk product advertising and labeling 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. [Note: Products for treating tobacco dependence, including cessation products, are not modified risk products and are subject to the requirements of FFDCA Chapter V.]

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Judicial review	Establishes procedures for judicial review of: (1) a regulation establishing, amending, or revoking a performance standard; or (2) a denial of an application for premarket approval. [Note: These provisions are similar, with modifications, to the judicial review provisions in FFDCCA Section 517. Under Section 517, FDA must demonstrate that its actions are supported by “substantial evidence on the record taken as a whole.” However, S. 2461 requires the agency to meet the less stringent standard of demonstrating that its actions are not “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”]
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.
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.
Congressional review	Provides for congressional review of any rule promulgated under the authority discussed above, pursuant to 5 U.S.C. 801 et seq.
Ingredient and smoke constituent testing	Mandates new FDA regulations for the testing, reporting, and public disclosure of tobacco product ingredients and smoke constituents, by brand and sub-brand, to protect the public health.
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: performance standards; premarket approval; adulteration; misbranding; registration; reporting; GMPs; and reduced risk products. Does not preempt state and local requirements relating to the sale, use, advertising, and promotion of tobacco products.
Tobacco Products Scientific Advisory Committee	Within one year, requires the Secretary to establish an 11-member Tobacco Products Scientific Advisory Committee.
Nicotine replacement products	Instructs FDA to: (1) at the request of the applicant, designate nicotine replacement products as fast track products under FFDCCA Section 506; (2) consider approving the extended use of nicotine replacement products for up to six months; (3) consider the evidence for additional indications for nicotine replacement products; and (4) consider relieving companies of premarket burdens under FFDCCA Section 505 if the requirement is redundant considering other nicotine replacement therapies already on the market.
User fees	Instructs the Secretary to assess user fees (payable quarterly) on tobacco manufacturers and importers to pay for the cost of FDA tobacco regulation under this Chapter. Establishes the percentage of total user fees assessed each fiscal year to be paid by the manufacturers and importers of each class of product (e.g., cigarettes, cigars, snuff). Caps the total assessment at \$85 million in FY2004, \$175 million in FY2005, and \$300 million in FY2006 (adjusted in each subsequent fiscal year to reflect inflation or the change in base pay for federal workers in Washington DC, whichever is greater). Requires each manufacturer and importer of a given class of tobacco product to pay an amount in proportion to its market share.

<p>Illicit tobacco trade</p>	<p>Requires tobacco product labels, packaging, and shipping containers to bear the statement: “Sale only allowed in the United States.” Within nine months, 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.</p>
<p>FDA Final Tobacco Rule (August 28, 1996)</p>	
	<p>Requires the Secretary within 30 days to publish the 1996 FDA tobacco regulations (minus the labeling provisions in Subpart C) as an interim final rule and provide an opportunity for public comment. The interim final rule shall become effective no later than one year after enactment of this Act.</p>
<p>Tobacco Product Label and Advertising Warnings</p>	
	<p>Amends the existing federal labeling laws for cigarettes and smokeless tobacco products^a to require new, explicit health warning labels in bold type.^b Authorizes the Secretary 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. Retailers that are supplied with tobacco products in violation of these labeling requirements are not liable, provided they do not sell or distribute such products. Authorizes the Secretary to determine whether cigarette advertising and package labels should include information on tar and nicotine yield, as well as the levels of other smoke constituents. Permits states to regulate the time, place, and manner, but not the content, of cigarette advertising and promotion.</p>

- a. (i) Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331), (ii) Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401). The Federal Trade Commission (FTC) administers the cigarette labeling law, and administers and enforces the smokeless tobacco labeling law. The Justice Department enforces the cigarette labeling law.
- b. For cigarette packaging and advertising, 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; (ix) WARNING: Quitting smoking now greatly reduces serious risks to your health. For smokeless tobacco packaging and advertising, 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; (iv) WARNING: Smokeless tobacco is addictive.