Tobacco Legislation in the 105th Congress: Side-by-Side Comparison of S. 1415, S. 1530, S. 1638, S.1889, H.R. 3474, and H.R. 3868

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ABSTRACT

This report provides a summary of tobacco legislation in the 105th Congress, including a side-by-side comparison of two sets of bills introduced to implement the June 20, 1997, tobacco settlement or otherwise comprehensively limit tobacco use and marketing. Six bills are included: S. 1415, S. 1530, S. 1638, S. 1889, H.R. 3474 and H.R. 3868. The report also summarizes the provisions of the settlement and the FDA tobacco regulation. This product will be updated as additional bills are introduced. A list of CRS products on tobacco issues may be found in the Tobacco Electronic Briefing Book on the CRS home page. This site also includes briefing pages on a variety of tobacco issues.

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Summary

On June 20, 1997, a group of state attorneys general and tobacco industry lawyers announced a settlement that would grant the tobacco industry immunity from class-action lawsuits in return for annual industry payments to settle the states' Medicaid lawsuits, submission to strict federal regulation of its products, and funding for national tobacco control programs. The proposed settlement raises many complex issues and will require legislation if it is to take effect. House and Senate Committees have held numerous tobacco hearings as lawmakers consider development of legislation to implement settlement's provisions or otherwise comprehensively restrict tobacco use and marketing. Several comprehensive tobacco bills have been introduced, including S. 1415 (McCain), S. 1530 (Hatch), S. 1638 (Conrad), S. 1889 (Harkin), H.R. 3474 (Fazio), and H.R. 3868 (Hansen).

On April 1, the Senate Commerce Committee passed S. 1415 by a vote of 19–1. A modified version of the bill was subsequently debated and amended by the Senate before being recommitted to the Commerce Committee on a procedural vote. The modified bill, as amended, would raise cigarette prices by an estimated $1.10 a pack over 5 years and fines manufacturers up to $7 billion a year if youth smoking rates do not decline by 67 in 10 years. The bill grants FDA new legal authority to regulate tobacco products, gives states the option of settling their lawsuits in return for annual funding, prohibits addiction-based lawsuits, and caps the industry's legal liability at $8 billion a year. As amended, S. 1415 would use tobacco revenues to pay for tax cuts and boost funding for federal drug interdiction programs.

With the exception of the Hatch bill, which mirrors last year's settlement and grants the industry broad immunity from civil liability, the other bills provide the tobacco companies with little or no legal protection. For example, both the Conrad and Fazio bills would settle the state lawsuits but do not grant the industry any protection from class actions or addiction-based claims. Moreover, both bills would raise cigarette prices by about $1.50 a pack over 3 years and allocate the revenues to biomedical research and a variety of existing children's health, nutrition, and welfare programs. The Harkin bill would increase cigarette prices by about $1.50 in 2 years. It gives FDA broad authority to regulate tobacco products as devices, fines manufacturers up to $10 billion a year if youth reduction targets are not met, and caps the industry's legal liability at $8 billion a year.

Unlike the proposed settlement, which did not include any provisions on tobacco farmers, the comprehensive bills all include financial assistance for growers and tobacco-dependent communities. S. 1415 includes two competing proposals for assisting tobacco growers. One proposal would largely preserve the federal tobacco price support program and provide assistance to farm families and communities as the U.S. share of tobacco markets declines. The other proposal would terminate the price support program and buy out the farmers. Numerous other tobacco-related bills, more limited in scope, have been introduced in the 105th Congress.

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Overview

Since 1994, 41 states and Puerto Rico have filed lawsuits against the tobacco industry seeking reimbursement for the medical expenses they have paid to treat smoking-related illnesses under the Medicaid program. On June 20, 1997, a group of state attorneys general, together with private attorneys who had brought class-action lawsuits against tobacco companies, announced that they had reached a national settlement with the industry. Under the terms of the agreement, the industry would pay $368.5 billion over the first 25 years, and $15 billion a year thereafter, to reimburse states for their tobacco-related medical costs, pay for tobacco control programs to reduce tobacco use among teenagers, and extend health insurance to uninsured children.

The industry would also submit to regulation of its products by the Food and Drug Administration (FDA) and agree to substantial restrictions on tobacco product advertising and promotion. In return, the industry would gain protection from current and future civil lawsuits. In addition to settling all the state cases, the proposed settlement would terminate all pending class-action lawsuits and nicotine addiction claims, and provide the companies with immunity from such lawsuits in the future. Participating tobacco companies would be required to enter into legally binding and enforceable contracts with states, in which the companies would agree voluntarily to waive their First Amendment rights to advertise their products, in exchange for legal immunity.

The text box on page 2 briefly summarizes the major provisions of the settlement. Table 2 provides a more detailed outline of the settlement. Note that the citations that appear in parentheses in Title I of the settlement refer to section 897 of the FDA's tobacco regulation,[1] which is summarized in Table 3.

The proposed settlement raises many complex issues and will require federal legislation before taking effect. This report summarizes and provides a side-by-side comparison of 6 bills introduced to implement the settlement or otherwise comprehensively limit underage tobacco use and marketing. The report also summarizes many of the other, more limited tobacco bills that have been introduced

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[1] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents. *Federal Register*, v. 61, no. 168, Aug. 28, 1996. pp. 44396-45318.

in the 105th Congress. There are a number of key issues affecting possible legislation.

Summary of Proposed Tobacco Settlement (June 20, 1997)

FDA Regulation. Incorporates the following provisions of the FDA's August 28, 1996, tobacco regulation (21 CFR 897): prohibits sale of tobacco products to persons under age 18 and requires photo ID to verify age; limits advertising to which children are exposed to black-on-white, text only format; prohibits the sale or distribution of promotional non-tobacco items such as hats and tee shirts; prohibits brand-name sponsorship of sporting and other events; requires explicit warning labels. Extends 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. Establishes 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. Sets federal standards for licensing retailers who sell tobacco products. Retailers caught selling to minors would be fined or risk license revocation.

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

Non-Tobacco Ingredients. Requires 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. Sets targets for reducing the number of underage smokers: 30% reduction in 5 years; 60% reduction in 10 years. Fines industry up to $2 billion a year if targets are not met.

State Youth Access Laws. Requires states to enforce their minimum-age-of-sale laws for tobacco products or risk losing settlement funds. The provisions expand on those of the Synar Amendment.

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

Industry Annual Payments. Requires 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 would be tax deductible.

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

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

Legal Immunity. In the wake of damaging industry documents that have been made public in the past few months, lawmakers appear less inclined than previously to grant the industry protection from civil lawsuits. The industry has stated that the civil liability protections in the proposed settlement are a necessary precondition for it to agree voluntarily not to advertise and promote its products in media and venues to which children have access. In addition to protection from civil liability, the settlement also caps the amount the industry would have to pay in damages each year in personal injury lawsuits.

FDA Regulation. In August 1996, the FDA issued a regulation aimed at reducing tobacco use among children and adolescents. The agency concluded that cigarettes and smokeless tobacco products are delivery devices for nicotine, an addictive drug. Last year, a North Carolina federal judge agreed with FDA's position and ruled that cigarettes and smokeless tobacco products are both drugs and drug delivery devices within the meaning of the Federal Food, Drug, and Cosmetic Act (FFDCA). However, while the district court upheld all the regulation's youth access and labeling provisions, it found that the FDA did not have statutory authority under the FFDCA to restrict tobacco-product advertising and promotion. The court also delayed implementation of all but two of the regulation's provisions, pending further court action.[2]

On August 14, 1998, the Fourth U.S. Circuit Court of Appeals overturned the lower court's decision, ruling that the FDA lacks authority to regulate tobacco products. The appeals court ruled that Congress has never delegated such authority to FDA, and that the agency's argument for regulating as a medical device a substance as hazardous as tobacco was "obvious sophistry." The Clinton Administration has appealed the ruling to the full appellate court.

The proposed settlement would explicitly recognize the FDA's authority to regulate tobacco products and codify that authority into law. The settlement goes beyond the FDA's advertising restrictions, for example, by banning all outdoor tobacco product advertising and all brand-name advertising facing outside from retail stores. However, public health officials and some lawmakers have criticized the settlement on the grounds that it places undue restrictions on FDA's authority to regulate nicotine and other harmful tobacco-product constituents. They want to see FDA granted unrestricted authority to regulate tobacco products as combination drug/device products under the FFDCA.

Tobacco Use Reduction. The settlement sets reduction targets for underage use of tobacco products. For example, it mandates a 60% reduction over 10 years in the number of underage cigarette smokers. Manufacturers would be fined up to $2 billion a year if the reduction targets are not met. However, they could petition to recover 75% of the fine if they pursued all reasonably available measures to reduce underage tobacco use and did nothing to undermine the provisions of the settlement. Many lawmakers are pressing for greater reduction targets and larger penalties. Proposals include requiring manufacturers to pay a noncompliance fee of up to $2.00 per pack of cigarettes, and assessing penalties on a company-specific basis, as well as on the industry as a whole.

Annual Payments vs. Taxes. The proposed settlement mandates annual industry payments indefinitely. The industry would pay an up-front sum of $10 billion, and annual payments beginning at $8.5 billion in the first year and increasing to $15 billion by the fifth year. The payments would be tax-deductible and subject to a yearly adjustment for inflation and tobacco-product consumption. The industry

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[2] Two youth access provisions went into effect on February 28, 1997, prior to the North Carolina decision, which prohibit sales of tobacco products to anyone under age 18 and require retailers to check photo ID for anyone under age 27.

would have to increase cigarette prices by about 62 cents per pack to raise $15 billion in additional revenue, based on current cigarette sales. By itself, this price increase might reduce the number of underage cigarettes by as much as 20%.[3]

The President, the public health community, and many lawmakers argue that a much larger price increase, at least $1.50 per pack, is required in order to meet the youth tobacco use reduction targets in the settlement. Legislation to increase the federal tobacco excise tax by $1.50 per pack over three years has been introduced in the House and the Senate. For more information on the impact of the proposed tobacco settlement on prices, consumption, and income distribution, see CRS Report 97-995, *The Proposed Tobacco Settlement: Effects on Prices, Smoking Behavior, and Income Distribution*, by Jane Gravelle.

Comprehensive Tobacco Bills

Several comprehensive tobacco bills have been introduced, including S. 1415 (McCain); S. 1530 (Hatch); S. 1638 (Conrad); S. 1889 (Harkin), H.R. 3474 (Fazio), and H.R. 3868 (Hansen).[4] Table 1a provides a section-by-section comparison of the provisions of S. 1415, S. 1889, and S. 1530. Table 1b compares the provisions of the other three bills. The grey shaded areas in the tables indicate that a bill does not contain any provisions on a particular topic. For ease of comparison, the two tables are organized and formatted in the same way.

S. 1415 (McCain). The McCain bill, as introduced, mirrored the proposed settlement and, according to its sponsor, was intended to serve as a basis for discussion and amendment. To date, it is the only tobacco bill to see legislative activity. On April 1, the Senate Commerce Committee approved a substitute bill by a vote of 19–1. On May 14, the committee substitute bill was further amended and reported out of the Finance Committee by a vote of 13–6. The bill was further modified when it came to the Senate floor to reflect provisions agreed to in negotiations between the Commerce Committee and the White House. The Senate debated S. 1415 for 4 weeks, passing 7 amendments, before the bill was ordered to be recommitted to the Commerce Committee on June 17 on a procedural vote. Details of the floor votes may be found in the chronology page in the Tobacco Electronic Briefing Book on the CRS home page.

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[3] According to the Tobacco Institute, the average price of a pack of cigarettes, including generic brands, as of November 1, 1997, was $1.95. A recent study of tobacco product price elasticity estimates that for every 15% increase in price, the number of underage smokers decreases by about 10%.

[4] The National Tobacco Policy and Youth Smoking Reduction Act (S. 1415) was introduced by Senator McCain on November 7. The Placing Restraints on Tobacco's Endangerment of Children and Teens, or PROTECT Act (S. 1530) was introduced by Senator Hatch on November 13. The Healthy Kids Act (S. 1638) was introduced by Senator Conrad on February 12, 1998. The Kids Deserve Freedom from Tobacco Act (S. 1889) was introduced by Senator Harkin on March 31, 1998. The Healthy Kids Act (H.R. 3474) was introduced by Representative Fazio on March 17, 1998. The Bipartisan NO Tobacco for Kids Act (H.R. 3868) was introduced by Representative Hansen on May 14, 1998.

The modified committee substitute bill that came before the Senate mandates annual industry payments that would raise cigarette prices over the next 5 years by about $1.10 per pack and generate net revenues of about $65 billion during that period. It grants FDA new legal authority to regulate tobacco products and would fines the industry up to $4 billion a year if youth smoking does not decline by 60% in 10 years. The bill gives states the option of settling their lawsuits against the industry, settles the Castano class actions, and prohibits future addiction-based claims. The industry's legal liability is capped at $8 billion a year. Finally, the bill includes two competing titles—one favored by Senators Ford and Robb, the other favored by Senators Lugar and McConnell—that provide financial assistance to tobacco farmers and their communities (see discussion below).

The Senate passed 7 amendments to S. 1415, which are summarized in Table 1a in italics, including using tobacco revenues to offset the cost of a tax cut for middle and lower income families and pay for federal anti-drug programs. Other amendments would limit attorneys' fees, disallow the tax deduction for tobacco advertising, promotion, and marketing, provide funds to pay for veterans' tobacco-related health care, and mandate stiff company-specific penalties.

S. 1530 (Hatch). The Hatch bill is closely based on the proposed settlement and grants the industry broad protection from civil liability. It mandates annual industry payments totaling $398.3 billion over 25 years, compared to a 25-year total of $368.5 billion in the settlement. Unlike the settlement, S. 1530 authorizes and allocates funding for asbestos-related litigation and Native American health programs. It also establishes a new chapter in the FFDCA for regulating tobacco products, includes stiffer industry penalties if nationwide underage smoking reduction targets are not met, mandates greater restrictions on smoking in public indoor facilities, addresses attorneys' fees, and includes a limited anti-trust exemption for the industry.

S. 1889 (Harkin). A bipartisan bill introduced by Senators Harkin, Chafee, and Graham mandates industry payments of $25 billion a year, which would raise the price of a pack of cigarettes by about $1.50 over 2 years. S. 1889 grants the FDA broad authority to regulate tobacco products as restricted devices, and fines the industry up to $10 billion for failure to meet the youth reduction targets. It also gives states the option of settling their lawsuits, settles the class-action lawsuits based on addiction, and caps the industry's civil liability at $8 billion a year. The bill provides $13.5 billion for tobacco farmers and their communities.

S. 1638 (Conrad). The other bills provide the tobacco companies with little or no legal protection. The Conrad bill requires manufacturers to pay a health fee of $1.50 per pack, phased in over 3 years, and uses the net revenue, estimated to total $500 billion over 25 years, to fund tobacco control programs, biomedical research, and other health, welfare, and education programs. S. 1638 gives FDA unrestricted authority to regulate tobacco products as drugs and devices, and imposes both industry-wide and company-specific penalties on manufacturers that do not meet the reduction targets for underage tobacco use. The bill does not grant the industry any special protection from civil litigation, but it would settle the state and local government medical-cost reimbursement lawsuits.

H.R. 3474 (Fazio). The Fazio bill is largely based on the Conrad bill, except that it mandates annual industry payments over 25 years rather than assessing a per-pack fee on tobacco products. However, the projected net revenues in H.R. 3474 are the same as S. 1638. H.R. 3474 also establishes a $20 billion asbestos trust fund to pay asbestos injury claims of smokers.

H.R. 3868 (Hansen). The Hansen bill also assesses a $1.50 per pack fee on cigarettes and allocates the revenues for states, federal tobacco control programs, and reducing the national debt. It grants FDA unrestricted authority to regulate tobacco products as restricted devices and requires manufacturers to pay up to $2 per pack if youth smoking does not decline by 80% in 10 years. H.R. 3868 gives states the option of settling their lawsuits in return for funding.

A bill introduced by Senator Kennedy (S.1492) increases the federal tobacco excise tax by $1.50 per pack over 3 years and allocates the revenues to biomedical research, child health and development research, national and state counter-advertising and smoking cessation programs, and existing children's health, nutrition, and welfare programs. The tax increase, which is set out in a short companion bill, S. 1491, would generate as much as $500 billion over the first 25 years. In addition to authorizing spending on research and public health and welfare programs, S. 1492 grants FDA unrestricted authority to regulate tobacco products as drugs and drug-delivery devices. S. 1492 and S. 1491 were introduced in the House as H.R. 3028 and H.R. 3027 (DeLauro), respectively.

Tobacco Farmers

The proposed settlement does not include any provisions concerning tobacco farmers or the federal tobacco price support program, which was established in the 1930s as a way of limiting production in order to guarantee a higher and more stable price for the tobacco crop. Tobacco farmers, who are concentrated in six major tobacco-producing states, are concerned about the financial impact of the settlement on their farms and communities. There appears to be some agreement among lawmakers that comprehensive tobacco legislation should include financial assistance to address these concerns.

Title X of the modified McCain bill incorporates, with modification, the Long-Term Economic Assistance for Farmers Act, or LEAF Act (S. 1310; Ford), and the Tobacco Market Transition Act (S. 1582; Robb). It establishes a $28.5 billion fund to provide financial assistance for tobacco farmers, industry workers, and tobacco-dependent communities while maintaining the current tobacco price support program for burley tobacco growers. Flue-cured quotas would be replaced with nontransferable permits. Title XV of S. 1415 incorporates, with modification, the Tobacco Transition Act (S. 1313; Lugar), which terminates the federal tobacco price support program. It establishes an $18 billion fund to buy out quote owners and compensate tenants.

The Harkin, Conrad, and Fazio bills all set aside funding for tobacco farmers and their communities and require Congress to enact legislation authorizing the use of these funds. For more information about the agricultural provisions in the tobacco settlement bills, see CRS Report 97-1042, *Summary and Comparison of the Major*

Agricultural Provisions of the Tobacco Settlement Policy Proposals, and CRS Report 98-133, *Compensating Tobacco Farmers for the Tobacco Settlement*, both authored by Jasper Womach. Additional information may be found in the Tobacco Electronic Briefing Book on the CRS home page.

Other Tobacco Bills

In addition to the very broad tobacco settlement bills described above and summarized in Tables 1a and 1b, numerous other tobacco-related bills, more limited in scope, have been introduced during the 105th Congress. Many of these bills are summarized by topic below.

Advertising

H.R. 410 (Gordon) prohibits FDA regulation of tobacco sponsorship of professional motor sports.

H.R. 762 (Hansen) restricts the advertising and promotion of tobacco products.

American Indians

S. 1797 (Campbell) applies much of the tobacco settlement to federally recognized Indian tribes, allowing regulation enforcement and retailer licensing by qualified tribes and authorizing public health grants to tribes (subtracted from state grants) and trust fund payments to the Indian Health Service; subjects tribal tobacco-product manufacturers to tobacco trust fund payments; exempts Native American religious and traditional tobacco uses from requirements of the tobacco settlement act; and forbids state imposition of tobacco settlement act requirements on tribes. Reported (amended) by Indian Affairs Committee on April 1, 1998.

S. 2300 (Gorton) requires Indian tribes to collect and remit state excise tax from sales of tobacco products to nontribal members.

Attorneys' Fees

H.R. 2740 (McInnis) limits attorneys' fees paid in connection with the settlement of state litigation against the tobacco industry to $150 per hour plus out-of-pocket expenses approved by the court.

H.R. 3907 (Bryant) amends the Internal Revenue Code to tax attorneys' fees at a marginal rate of 95%.

S. 1570 (Faircloth) limits the plaintiff's attorneys' fees paid in connection with the settlement of state litigation against the tobacco industry to $125 per hour plus out-of-pocket expenses approved by the court.

Excise Taxes

H.R. 1263 (Pallone) amends the Internal Revenue Code to increase the federal tobacco excise tax to cover the cost of extending health care insurance coverage to children.

H.R. 1364 (Johnson) amends the Internal Revenue Code to increase the federal tobacco excise tax to fund state grants to provide uninsured children with health care insurance.

H.R. 2897 (Lewis) amends the Internal Revenue Code to impose an excise tax of $500 annually on tobacco product vending machines.

S. 1343 (Lautenberg)/H.R. 2764 (Hansen) increases federal tobacco excise tax by $1.50 per pack over 3 years, and establishes a trust fund for the new revenues; requires 75% of the trust funds to be allocated to states for tobacco control programs and existing child and maternal welfare programs; requires the remaining 25% to be used for federal tobacco control programs, financial assistance for tobacco farmers, and for NIH and CDC.

Farmers

H.R. 1826 (Furse) increases the deficit-reduction marketing assessments for participants in the federal tobacco price support program.

H.R. 3264 (Baesler) requires cigarette manufacturers to pay the costs of the USDA's tobacco programs. Establishes a voluntary tobacco quota retirement system for quota holders and provides market transition assistance for tobacco farmers and their communities.

H.R. 3664 (Lewis, R.) requires tobacco importers and tobacco product manufacturers to pay the USDA's tobacco program costs.

H.R. 3867 (Baesler) provides financial assistance for tobacco farmers, industry workers, and tobacco-dependent communities. Maintains the federal tobacco price support program for burley tobacco growers and replaces the flue-cured quotas with nontransferable permits. [A combination of S. 1310 and S. 1582. Similar to Title X of S. 1415.]

S. 643 (Durbin)/H.R. 1438 (DeGette) prohibits the federal government from providing insurance or uninsured-crop disaster assistance for tobacco.

S. 1310 (Ford) provides financial assistance to tobacco farmers, displaced industry workers, and tobacco-dependent communities in response to any adverse impacts caused by the tobacco settlement; retains the federal tobacco price support program. [Incorporated in S. 1415 (McCain)].

S. 1313 (Lugar) terminates the federal tobacco price support program and compensates farmers for the loss in value; provides block grants for agricultural diversification and rural economic development. [Incorporated in S. 1530 (Hatch)].

S. 1582 (Robb)/H.R. 3437 (Goode) transfers the administration of the tobacco price support program from the USDA to a private corporation, and provides market transition assistance for quota holders, tobacco producers, and tobacco-growing counties.

Federal Medicaid

S. 1471 (Graham)/H.R. 2938 (Bilirakis) prohibits the federal government from claiming its share of the Medicaid funds recovered as part of state litigation with the tobacco companies.

Federal Medicare

H.R. 3172 (Peterson, J.) mandates that all unallocated tobacco settlement revenues be used for Part A of Medicare.

Industry Documents

H.R. 1881 (Waxman) establishes the Tobacco Accountability Board, to which each company must submit all documents relating to the health effects of tobacco use, control of nicotine in tobacco products, and the sale and marketing of tobacco products to children; requires the Board to make the documents available to the public.

Industry Tax Deductions

H.R. 1323 (McHale) amends the Internal Revenue Code to disallow deductions for advertising for tobacco products.

H.R. 3908 (Bryant) amends the Internal Revenue Code to exclude from gross income the dividends paid by tobacco companies which meet youth smoking reduction targets.

H.R. 4473 (Kaptur) amends the Internal Revenue Code to disallow deductions for tobacco-product advertising and expenses incurred influencing federal tobacco policy.

S. 1411 (Mack)/H.R. 3030 (Gekas) amends the Internal Revenue Code to prohibit a tax deduction for industry payments pursuant to any tobacco settlement, and establishes a National Institutes of Health research trust fund for the net increase in revenues received as a result of the tax code amendment.

S. 1755 (Reed) amends the Internal Revenue Code to disallow deductions for advertising tobacco products if manufacturers do not comply with certain advertising, marketing, and promotion restrictions. [These restrictions are identical to those in S. 1638.]

International

H.R. 2135 (Doggett) prohibits U.S. agencies from promoting the marketing and export of tobacco products; prohibits U.S. agencies from seeking the removal or reduction by any foreign country of any restrictions on the marketing of tobacco products; mandates that tobacco product exports be subject to the current labeling and advertising requirements for tobacco products in the United States.

H.R. 3738 (Doggett) incorporates the provisions in H.R. 2135. In addition, establishes the American Center on Global Health and Tobacco and provides grants for international tobacco control. Mandates serial numbers and export labels on packages and requires manufacturers and distributors to post a bond for all tobacco exports. [Similar to international tobacco control and anti-smuggling provisions in Title XI of S. 1415.]

S. 1060 (Lautenberg) prohibits U.S. agencies from promoting the marketing and export of tobacco products; prohibits U.S. agencies from seeking the removal or reduction by any foreign country of any nondiscriminatory law that restricts the marketing of tobacco products; mandates that tobacco product exports be subject to the labeling and advertising requirements that are applicable to tobacco products in the United States.

Minorities

H.R. 4189 (Thompson) amends the Public Health Service Act to require the Office of Minority Health to fund and coordinate federal efforts to address tobacco use among minorities; provides grants to minority medical schools for tobacco-related research and provides funding for community, migrant, and homeless health centers for tobacco-related health care.

Smoking Restrictions

H.R. 552 (Oberstar) bans smoking on all airline flights that touch down in the United States.

H.R. 1351 (Lewis) prohibits smoking in any federally funded transportation facility.

H.R. 2118 (Traficant) prohibits smoking in any building owned or leased by the federal government.

S. 826 (Lautenberg)/H.R. 1771 (Waxman) restricts smoking in public facilities, defined as any building entered by 10 or more individuals at least one day a week, to enclosed, separately ventilated areas; prohibits smoking on all airline flights within the United States, and on all international flights into and out of the United States. [The same definition of a public facility appears in the environmental tobacco smoke provisions in the proposed settlement and the comprehensive settlement bills.]

S. 938 (Bond) provides medical surveillance, research, and services aimed at the prevention and cessation of prenatal and postnatal smoking.

S. 2066 (Chafee) establishes a state grant program for education and outreach on the health impact of environmental tobacco smoke. Bans smoking on any international

flight that touches down in the United States. Restricts smoking in all federal buildings to separately ventilated smoking rooms.

Veterans

H.R. 3948 (Klink) entitles veterans to disability compensation for tobacco-related diseases.

H.R. 4070 (Frank) and **H.R. 4220 (Smith, L.)** repeal a provision in the Transportation Equity Act for the 21st Century (TEA-21; P.L. 105-178), which prohibits veterans from claiming tobacco-related disability compensation.

H.R. 4188 (Stearns) establishes a Veterans Tobacco Trust Fund and provides $3 billion for veterans' tobacco-related health care.

H.R. 4374 Kennedy, P.) entitles veterans to medical care for tobacco-related illnesses.

Youth Tobacco Use

H.R. 768 (LaHood) prohibits FDA from fining retailers for face-to-face tobacco sales that are in accordance with state law.

H.R. 2034 (Bishop) amends Section 1926 of the Public Health Service Act (i.e., Synar Amendment) to require states to enact a detailed law regarding the sale and distribution of tobacco products to minors or risk losing federal substance abuse block grant funds. [This bill incorporates all of S. 1238, plus it requires lockout devices on vending machines except in adult-only facilities, and a ban on the sale and distribution of tobacco products to minors via the Internet.]

H.R. 2519 (DeGette) increases the legal age of smoking from 18 to 21.

H.R. 2594 (Fox) restricts youth access to tobacco products by limiting vending machines to adult-only facilities, prohibiting sales to persons under age 18, requiring photo ID in face-to-face sales, requiring cigarettes be sold only in packs of 20, and requiring retailers to display prominently signs indicating the requirements for purchase of tobacco products.

H.R. 3298 (Rothman) prohibits tobacco product vending machines except in adult-only facilities.

H.R. 3457 (Luther) prohibits movies in which a tobacco company has paid to have its product featured.

H.R. 3655 (Green) provides incentives for states to enact laws that penalize minors for tobacco possession and retailers who sell tobacco products to minors.

H. R. 3889 (Upton) amends the Food, Drug, and Cosmetic Act to require ingredient labeling and explicit health warnings. Bans vending machines except in adult-only

facilities. Prohibits sales to individuals under age 18. Mandates 80% reduction in youth smoking over 10 years.

H.R. 4159 (Blunt) waives the Synar Amendment sanctions against states if they penalize minors caught purchasing or in possession of tobacco products by suspending their driver's license.

S. 527 (Lautenberg)/H.R. 1244 (Meehan) mandates explicit warning labels for packages and advertising, and requires ingredient disclosure and labeling.

S. 828 (Durbin)/H.R. 1772 (Waxman) sets reduction targets for underage tobacco use (by 90% in 6 years) and fines manufacturers $1 per unit of product sold if the targets are not met; fines escalate with repeated noncompliance.

S. 1238 (Smith, G.) amends Section 1926 of the Public Health Service Act (i.e., Synar Amendment) to require states to enact a detailed law regarding the sale and distribution of tobacco products to minors or risk losing federal substance abuse block grant funds. [Sec. 302 of the Hatch bill (S. 1530) is S. 1238, but with stiffer penalties. This bill, first introduced in 1997, was reintroduced in 1998 as S. 1713.]

Senate FY1999 Budget Resolution (S.Con.Res. 86)

On April 2, the Senate voted 57–41 to approve the FY1999 Budget Resolution, which reserves all tobacco settlement revenues for the Medicare Trust Fund. An amendment by Senator Conrad (S.Amdt. 2174) to provide tobacco funds for youth tobacco control and smoking cessation programs and to assist tobacco farmers was defeated by a vote of 46–54. Under the approved Budget Resolution, it would require 60 votes to permit floor consideration of any tobacco legislation that provides funding for programs other than Medicare. The Senate Budget Resolution also prohibits the VA from paying disability compensation for smoking-related diseases (see below).

Laws Enacted by the 105th Congress

The President has signed three bills that include provisions relating to smoking and tobacco products. Section 9302 of the Balanced Budget Act of 1997 (P.L. 105-33) increases cigarette excise tax by 15 cents per pack. The current federal excise tax of 24 cents per pack will increase by 10 cents in 2000, and an additional 5 cents in 2002.

Section 618 of the Commerce, Justice, and State appropriations bill for FY1998 (P.L. 105-119) prohibits funds from being used to promote the sale or export of tobacco or tobacco products, or to seek the removal or reduction by any foreign country of any nondiscriminatory law that restricts the advertising, manufacture, sale, labeling or distribution of tobacco products. This provision is associated with the efforts of Representative Doggett (see H.R. 2135 above), and is referred to as the Doggett Amendment. As required by the new law, the State Department in April sent out a directive to all U.S. embassies and commercial offices abroad instructing them not to promote U.S. tobacco products. In addition, the embassies and offices

are not to oppose policies that restrict the use of tobacco products unless those policies favor local tobacco products over those made in the United States.

The Transportation Equity Act for the 21st Century (TEA-21; P.L. 105-178) includes a provision (section 8202) that prohibits veterans from claiming tobacco-related disability compensation. That will result in an estimated savings of $16.9 billion over 5 years, of which $15.4 billion is to be used to offset the costs of TEA-21. The remaining $1.5 billion is for specific improvements to various veterans benefits. Three bills (H.R. 3948, H.R. 4070, and H.R. 4220) have been introduced to restore the veterans' entitlement to disability compensation for tobacco-related diseases. For more information, see CRS Report 98-373, *Veterans' and Smoking-Related Illnesses: Congress Considers Limits to Compensation,* by Dennis Snook.

Executive Actions

On August 9, 1997, President Clinton signed Executive Order 13058 that restricts smoking in all federal Executive Branch facilities to enclosed, separately ventilated areas. The order also prohibits smoking in front of building air intake ducts and directs agency heads to evaluate the need to limit smoking in doorways and courtyards. Agencies are also encouraged to offer smoking cessation assistance to their workforce.

On June 22, 1998, the President announced that the National Household Survey on Drug Abuse (NHSDA) would be expanded to include information on the cigarette brands teenagers smoke. The NHSDA is administered by the Substance Abuse and Mental Health Services Administration and has been conducted annually since 1990 using in-home interviews. In the future it will include 70,000 households and will utilize computer-assisted technology to improve disclosure of sensitive information. Households with teenagers under age 18 will be oversampled in order to obtain more accurate information on smoking prevalence and brand preference.

On July 17, 1998, the President directed the Secretary of Health and Human Services to report back within 90 days with a plan to make the millions of tobacco industry documents released during the Minnesota trial more accessible to the public.

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Regulation of Tobacco Industry, Tobacco Products, and Product Use			
	Titles I, II, III, VIII, XI & XIV	Titles II & IV	Titles II & IV
Marketing and Advertising Restrictions	Prohibits outdoor tobacco product advertising; prohibits use of human or cartoon images in advertising; prohibits Internet advertising; restricts point-of-sale advertising. Restricts use of non-tobacco trade or brand names for tobacco products; limits advertising to FDA-specified media; restricts glamorization of tobacco. Restricts advertising in non-adult facilities and publications to black-on-white format. Requires statement of intended use on advertisements. Prohibits non-tobacco merchandise and brand-name sponsorship. [Sec. 1403-1405]	Prohibits outdoor tobacco product advertising; prohibits the use of human or cartoon images in advertising; prohibits Internet advertising; restricts point-of-sale advertising. Prohibits use of non-tobacco trade or brand names for tobacco products; limits advertising to FDA-specified media; prohibits glamorization of tobacco. Restricts advertising in non-adult facilities and publications to black-on-white format. Requires statement of intended use on advertisements. Prohibits non-tobacco merchandise and brand-name sponsorship. [Sec. 201, 411]	Prohibits outdoor tobacco product advertising; prohibits use of human or cartoon images in advertising; prohibits Internet advertising; restricts point-of-sale advertising. [Sec. 212] Restricts use of non-tobacco trade or brand names for tobacco products; limits advertising to FDA-specified media; restricts glamorization of tobacco. [Sec. 213] Restricts advertising in non-adult facilities and publications to black-on-white format. [Sec. 214] Prohibits non-tobacco merchandise and brand-name sponsorship. [Sec. 215]
Warnings, Labeling and Packaging	Amends existing federal labeling laws to require new, explicit warning labels in bold type. Authorizes DHHS to revise warning labels as necessary. Requires labeling of tobacco product exports. [Sec. 301-304, 1106]	Requires new, explicit warning labels in bold type, subject to regular review and updating by DHHS. Preempts labeling by state and local governments. Repeals existing federal tobacco product labeling laws. [Sec. 212]	Requires new, explicit warning labels in bold type. Exempts tobacco product exports from labeling requirements. [Sec. 401] Repeals existing federal tobacco product labeling laws. [Sec. 402]
Youth Access Restrictions	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machines; bans self-service sales except in adult-only facilities; allows mail-order sales subject to FDA review. [Sec. 231, 1162]	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machine and self-service sales except in adult-only facilities; allows mail-order sales subject to FDA review. [Sec. 212]	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machine and self-service sales except in adult-only facilities; allows mail-order sales subject to FDA review. [Sec. 401]
Retailer Licensing or Registration	Requires states to license tobacco retailers. Establishes penalties for noncompliance, including license suspension and revocation. [Sec. 231]	Establishes minimum federal licensing standards for tobacco manufacturers, importers, exporters, and distributors, and the registration of tobacco retail outlets. Stipulates penalties for noncompliance, including license and registration revocation. [Sec. 221-232]	Mandates state licensing under model state law (see section 301-102).

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Amendment of Federal Food, Drug, and Cosmetic Act: Regulation of Tobacco Product Development and Manufacturing	Amends Federal Food, Drug, and Cosmetic Act by adding a new chapter (incorporating much of the existing device authority) for regulating tobacco products under a public health standard. Authorizes FDA to regulate the sale, distribution, access to, advertising, and promotion of tobacco products. Establishes regulatory requirements for reducing nicotine and other tobacco product constituents. Requires congressional review of any proposal to eliminate nicotine or ban tobacco products. Requires testing, reporting, and disclosure of tobacco smoke constituents. Requires FDA approval of all health claims for reduced-risk tobacco products. Subjects manufacturers to good manufacturing practice standards. Requires disclosure of amounts of all non-tobacco ingredients for each brand. Requires submission of all health research information, and notification of any modification of existing products or release of new products. [Sec. 101, 305, 311]	Amends Federal Food, Drug, and Cosmetic Act as follows: Defines nicotine as a drug and tobacco products as restricted devices. Authorizes FDA to use a public health standard for regulating tobacco products. Prohibits FDA from banning the sale of tobacco products to adults. Requires full disclosure of amounts of all nontobacco ingredients for each brand. Requires testing, reporting, and disclosure of tobacco smoke constituents. Requires FDA approval of all health claims for reduced-risk tobacco products. Subjects manufacturers to good manufacturing practice standards. Requires companies to disclose to FDA research information, including data on reduced-risk products. Requires new labeling (described earlier in table). [Sec. 201-205, 211-214]	Amends Federal Food, Drug, and Cosmetic Act as follows: Defines tobacco products as drugs. Directs DHHS Secretary to issue regulations, through notice-and-comment rulemaking and in consultation with experts, for reducing or eliminating nicotine and other tobacco product constituents. Requires Secretary to consider various factors in any such action, including reducing health risks and the creation of a black market. Requires disclosure of amounts of all non-tobacco ingredients for each brand. Subjects manufacturers to good manufacturing practice standards. Mandates new warning labels and youth access restrictions (described earlier in table). Provides incentives for development of reduced-risk tobacco products. Establishes DHHS scientific advisory committee. [Sec. 401]
Corporate Culture and Compliance, Lobbyists, and Whistleblowers	Requires each manufacturer to submit annually to DHHS a report reviewing their compliance with the Act and efforts to reduce youth smoking. Provides for suspending the annual cap on legal liability if a manufacturer's actions or inactions impede progress in reducing youth smoking. Protects industry whistleblowers. Prohibits any domestic tobacco concern from contributing, in any way, to youth sales overseas. [Sec. 801-802, 1102]	Requires industry to comply with all the provisions of the Act and not lobby against any provisions of the Act. Disbands the Tobacco Institute. (Note: These and other provisions are embodied in consent decrees, described below.) Protects industry whistleblowers. [Sec. 411, 701]	Protects industry whistleblowers. [Sec. 902] Requires lobbyists to comply with the Act and agree not to support or oppose any federal or state legislation without consent of manufacturers. [Sec. 221] Disbands the Tobacco Institute and the Council for Tobacco Research. [Sec. 222]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Reducing Underage Tobacco Use, Lookback Penalties			
	Title II	Title I	Title III
Underage Tobacco-Use Targets	*S.Amdt. 2438 (Durbin) 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 5 years and 67% in 10 years) and smokeless tobacco products (by 25% in 5 years and 45% in 10 years). [Sec. 201-204]*	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 reductions targets for underage use of tobacco products (by 30% in 5 years, 50% in 7 years, and 65% in 10 years). [Sec. 131-133]	Mandates an annual survey to determine the percentage of individuals under age 18 that use tobacco products daily. Sets reduction targets for underage use of cigarettes (by 30% in 5 years, 50% in 7 years, and 60% in 10 years) and smokeless tobacco products (by 25% in 5 years, 35% in 7 years, and 45% in 10 years). [Sec. 4, 312-314]
Industry Penalties	*S.Admt. 2438 (Durbin) mandates industry-wide and manufacturer-specific penalties (not tax-deductible) if targets are not met. Industry-wide penalties capped at $2 billion a year; manufacturer-specific penalties capped at $5 billion a year. Provides a de-minimus exemption for companies with less than 1% market share. [Sec. 205-206]*	Mandates industry-wide and company-specific penalties (not tax-deductible) if youth reduction targets are not met. Company specific penality = up to 6 cents per unit sold by a manufacturer whose products fail to meet the targets. Similar industry-wide penalties. Caps annual penalties at $10 billion (indexed to inflation). Does not provide any abatement or rebate relief to companies. [Sec. 134-135]	Fines manufacturers up to $5 billion per year in the first 5 years after enactment and $10 billion per year thereafter if reduction in underage tobacco use does not meet targets. Allows manufacturers to recover all of the fine if they pursued all reasonably available measures to reduce underage tobacco use and did nothing to undermine any provisions of the Act. Provides industry with incentives (i.e., reduced annual payments) to exceed reduction targets. [Sec. 311-317]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Environmental Tobacco Smoke (ETS)			
	Title V	Title VI	Title VI
Smoking Restrictions in Public Facilities	Restricts smoking in public facilities (i.e., those entered by 10 or more individuals at least 1 day a week), including federally owned or leased buildings, to enclosed, separately ventilated, designated smoking areas. Specifies 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. Establishes penalties for violators. 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. [Sec. 501-507]	Provides $100 million annually to states for education and outreach activities to reduce ETS exposure. Provides $100 million annually to states to establish programs to reduce ETS exposure. Requires Congress to comply with no-smoking policies in effect in the Executive Branch (i.e., Executive Order 13058). [Sec. 601-603]	Restricts smoking in public facilities (i.e., those entered by 10 or more individuals at least 1 day a week) to enclosed, separately ventilated, designated smoking areas. Specifies that employees may not be required to enter smoking areas. Exempts bars, private clubs, hotel guest rooms, casinos, bingo parlors, and tobacco outlets. No exemption for prisons or restaurants with a seating capacity over 50. Restricts smoking and use of smokeless tobacco products in schools and other facilities serving children to enclosed, separately ventilated, designated smoking areas. Allows state and local governments to enact stricter laws. [Sec. 601-605]
Tobacco Trust Fund			
	Title IV	Title I	Title I
Establishment of Tobacco Trust Fund and Annual Industry Payments	Establishes National Tobacco Trust Fund. Mandates tax-deductible industry payments into Trust Fund: an up-front sum of $10 billion, and annual payments beginning at $14.4 billion in the first year, increasing to $23.6 billion in the fifth year, and remaining at $23.6 billion a year thereafter. **Estimated total net revenue over first 25 years = $516 billion.** Annual payments subject to inflation adjustment beginning in the sixth year, and subject to a volume-of-sales adjustment beginning in 2002. Requires manufacturers to raise prices to cover cost of payments. [Sec. 401-406]	Establishes National Tobacco Trust Fund. Mandates industry payments (75% of which are tax-deductible) into Trust Fund: an up-front sum of $10 billion, and annual payments of $20 billion in the first year, and $25 billion thereafter. **Total payments over first 25 years = $630 billion.** Annual payments subject to inflation adjustment. Requires companies to raise prices by at least $1 per pack in the first year, and an additional 50 cents per pack in the second year to cover cost of payments. [Sec. 101-102]	Establishes National Tobacco Settlement Trust Fund. Mandates industry payments into Trust Fund for 25 years: an up-front sum of $10 billion, and annual payments beginning at $9.8 billion in the first year, increasing to $16.5 billion in the sixth year, and remaining at approx. $16.5 billion a year thereafter. **Total payments = $398.3 billion.** Annual payments subject to inflation adjustment, and subject to a volume-of-sales adjustment. [Sec. 101-102] Allows manufacturers to raise prices to cover cost of payments. [Sec. 904]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Authorization of Trust Fund Expenditures	Authorizes expenditures from Trust Fund to reimburse states for smoking-related medical costs and provide funds for tobacco control programs, health research, and to assist tobacco farmers and their communities. [Sec. 401]	Authorizes expenditures from Trust Fund to provide payments to states and to fund national anti-tobacco and public health programs. [Sec. 101]	Authorizes and allocates expenditures from Trust Fund: $8 billion a year to states and $8 billion a year for federal research and public health programs (see Title V); $200 million a year for asbestos-related compensation; $200 million a year for Native Americans (see Title IX); and a total of $16 billion over 25 years for the agriculture program (see Title VIII). [Sec. 101]
Distribution/Allocation of Trust Funds or Excise Tax Revenues			
	Titles II, IV & XI	Titles 1 & III	Title V
State Reimbursement (Medicaid)	Allocates 40% of the amount in the Trust Fund to a separate State Litigation Settlement Account for distribution to states based on an allocation formula to be determined by the states. Use of funds by states as follows: 50% unrestricted, and 50% restricted, i.e., to be used for existing child health, welfare, and education programs. Does not require states to reimburse federal Medicaid expenditures. [Sec. 451-452] *S.Amdt. 2689 (Kerry) requires states to use at least 50% of the restricted funds for child care.*	Allocates a total of $8 billion annually to states (allocation percentages detailed in Act) as follows: $4 billion in unrestricted funds, and $4 billion in the form of a Health, Human Services and Education block grant to be used to meet each state's particular needs in these areas. Provides an additional $500 million annually to states that exceed youth tobacco reduction targets. [Sec. 101, 111-112]	Allocates a total of $8 billion annually to states based on state-by-state percentages detailed in Act. Allows each state to use its state matching share (according to Medicaid matching percentage rates) for purposes it deems appropriate. Allows each state to retain its federal matching share provided the funds are used for existing programs including child nutrition programs, maternal and child health, Head Start, school lunch, Indian Health Service, Community and Migrant Health Centers, and social services block grants. [Sec. 501-502]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Federal, State, and Local Programs, and Research	Allocates 22% of the amount in the Trust Fund (plus all net revenue from lookback penalties) for a separate Public Health Account to fund smoking cessation programs, community-based tobacco control programs, counter-advertising, Indian health, international tobacco control, FDA regulation, and anti-smuggling activities. Allocates 22% of the amount in the Trust Fund for a separate Health and Health-Related Research Account to fund NIH, CDC, AHCPR, and NSF research and to extend Medicare coverage of clinical cancer trials. Allocates 16% of the amount in the Trust Fund over the first 10 years for a separate Farmers Assistance Account to provide financial assistance to tobacco farmers. Beginning in year 11, 12% of the funds in this account are credited to the Medicare Trust Fund. Authorizes funds from the Trust Fund to expand the Child Care and Development Block Grant.	Allocates $1.5 billion/yr for cessation programs, $500 million/yr for counter-advertising, $1.25 billion/yr for community and school-based prevention programs, $100 million/yr for 10 years to sponsor social and cultural events, and $175 million/yr for surveillance and epidemiology. Allocates $3.225 billion/yr for NIH (tobacco-related) research, $600 million/yr for CDC prevention research, and $300 million/yr for FDA regulation. Provides $13.5 billion over 15 years in financial assistance t obacco farmers and their communities. Allocates $4 billion/yr for settling legal claims against companies (see Title IV), $200 million/yr for ETS (see Title VI), $200 million/yr for Native Americans, $100 million/yr for anti-smuggling activities (see Title II), and $100 million/yr for international tobacco control (see Title III). [Sec. 101, 301-302, 311, 321-322, 335-337, 344]	Allocates a total of $8 billion annually as follows: $4 billion to fund biomedical research at the National Institutes of Health, and the remaining $4 billion to fund national anti-tobacco campaigns (including counter-advertising) and cessation programs. Note: At least one half of the non-NIH funds must be made available to states as block grants. [Sec. 521-522]
Consent Decrees, National Protocol, Non-Participating Manufacturers, Attorneys' Fees, and State Enforcement of Youth Access Laws			
	Titles II & XIV	Titles II & IV	Title II & III
Consent Decrees and National Protocol	Requires manufacturers, states, and the federal government to enter into voluntary, but legally binding consent decrees that include 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 any company that violates the provisions of the Act. [Sec. 1402-1405]	Requires manufacturers, states, and the federal government to enter into voluntary, but legally binding consent decrees that include many of the provisions of the Act (e.g., FDA regulatory authority, document disclosure, advertising restrictions, lobbying restrictions). Excludes from annual liability cap any company that violates the terms of the consent decree. [Sec. 411]	Requires manufacturers and states to enter into consent decrees that include many of the provisions of the Act and a waiver of constitutional claims. [Sec. 241-242] Within 90 days of enactment, requires each manufacturer to enter into a legally binding and enforceable contract (the National Tobacco Control Protocol) with the U.S. Attorney General and each state. The Protocol embodies the Act's advertising, promotion, and lobbying restrictions. [Sec. 201]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Non-Participating Manufacturers	Civil liability provisions of the Act do not apply to nonparticipants. [Sec. 1406]	Requires all manufacturers with at least a 0.5% share of the underage market to make payments. Failure to comply results in fines, loss of liability limitation, and license revocation. [Sec. 102-103, 223, 401]	Denies non-participating manufacturers liability protection, and imposes user fees, as well as annual payments into a reserve fund to settle liability claims. [Sec. 243, 259]
Attorneys' Fees	Establishes a 3-person arbitration panel to determine and award attorneys' fees and expenses. Awards to be paid by participating manufacturers. [Sec. 1413] *S.Amdt. 2705 (Gorton) limits plaintiff attorneys' fees to $4,000/hr for lawsuits filed prior to 1995, and limits fees in future lawsuits to $500/hr.*	Establishes a 6-person arbitration panel to determine and award attorneys' fees and expenses. Awards to be paid by participating manufacturers, not by Trust Fund. Mandates public disclosure of attorneys fees. [Sec. 403]	Establishes a 6-person arbitration panel to determine and award attorneys' fees and expenses, subject to an annual cap equal to 5% of Trust Fund receipts for the applicable year. Awards to be paid by participating manufacturers, not by Trust Fund. [Sec. 227]
State Enforcement of Youth Access Laws	Requires states to enforce laws prohibiting the sale or distribution of tobacco products to minors, and to conduct monthly unannounced inspections. States must meet compliance targets (80% compliance by year 4 and 90% by year 7) or risk losing block grant funds (totaling $200 million a year). Repeals Synar Amendment.[b] [Sec. 231-233]	Codifies FDA's tobacco regulation into law, including restrictions on youth access that states are enforcing. [Sec. 201-242]	Expands on Synar Amendment[b] by requiring states to enact a law consistent with the provisions of a model state law described in the Act, or risk losing Title V funds (see Sec. 501). Model state law includes retailer licensing, state inspections and enforcement, fines for minors and adults supplying minors, and no direct access to tobacco products. [Sec. 301-302]
Civil Liability			
	Title XIV	Title IV	Title IIC
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 Castano class-action lawsuits and prohibits addiction claims. Caps total annual liability at $8 billion. Modifies rule of evidence to establish a evidentiary presumption that nicotine is addictive and certain diseases are caused by tobacco use. [Sec. 1406-1412]	Allows states to settle their lawsuits in return for funding from the Trust Fund, or continue with their lawsuits and forgo the funding. Settles Castano class-actions. Allocates $4 billion/yr from the Trust Fund to a National Victims' Compensation Fund to pay for damages. If damages in any given year exceed $4 billion, the industry pays the excess amount. Caps total annual liability at $8 billion (applies only to claims based on industry's past conduct). Places any unobligated funds from the Compensation Fund into a Contingency Reserve Account to be used in the event that damages exceed $8 billion in any given year. [Sec. 400-401]	Terminates all pending class-action lawsuits, civil actions by state attorneys general, and nicotine addiction and dependence claims, and provides manufacturers with immunity from such lawsuits in the future. Preserves the right of individuals to bring personal injury claims. Prohibits awarding punitive damages in civil actions arising from past industry conduct. Requires states to adopt these civil liability protections as state law in order to receive Title V funds. Limits the total damages paid by the industry each year to 33% of the annual payment to the Trust Fund. [Sec. 255-258, 261]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Industry Document Disclosure			
	Titles IX & XIV	Title IV	Title VII
National Tobacco Document Depository	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 3-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. Establishes financial penalties for companies that do not comply. [Sec. 901-909, 1403]	Establishes a public depository to which companies must submit all research and marketing documents. Requires manufacturers to submit a detailed, itemized log of documents for which they assert attorney-client privilege or trade secrecy. Establishes a five-member arbitration panel to settle disputes over making such privileged documents public. Penalties for noncompliance include manufacturer license revocation and a waiver of the annual liability cap. [Sec. 404]	Establishes a public depository of industry health research documents. Requires manufacturers to deposit all documents provided to plaintiffs in recent specified lawsuits. Allows manufacturers to determine and withhold documents protected by attorney-client privilege. Requires manufacturers to deposit a detailed, itemized log of privileged documents. Establishes a three-judge federal arbitration panel to settle disputes over making privileged documents public. [Sec. 701-703]
Tobacco Farmers and Rural Communities			
	Titles X (top) & XV (bottom)	Title V	Title VIII
Funding	Authorizes funding over 25 years totaling $28.5 billion. [Sec. 1011-1012]	Establishes Trust Fund for Tobacco Farming Families and Communities to receive annual payments from the National Tobacco Trust Fund over 15 years totaling $13.5 billion. Requires Congress to enact legislation by Jan. 1, 2000, authorizing use of funds for assisting tobacco farmers and their communities. [Sec. 501]	Establishes Tobacco Transition Account of $16 billion. [Sec. 101, 811, 841-842]
	Establishes a 5-year Tobacco Community Revitalization Trust Fund. Estimated funding $18 billion. [Sec. 1511]		
Farmer compensation	Provides payments to quota owners (up to $8/lb) and tenants (up to $4/lb) for production losses from baseline levels (10-year estimated cost = $16.5 billion). Maintains burley quotas. Replaces flue-cured quotas with nontransferable permits.		Provides quota owner buyout ($8/lb) and tenant compensation ($1.20/lb) (totaling about $14.7 billion with 100% participation). Mandates end to quota program and 3-year phase out of price support loan program. [Sec. 812-814]
	Terminates quota program and phases out price support loan program over 3 years. Buys out quota owners ($8/lb) and compensates tenants ($4/lb). Estimated 3-year cost = $17 billion.		

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Other USDA tobacco activities	Mandates payments from Trust Fund for extension services, crop insurance, loan program administration, leaf grading and inspection, and other activities associated with tobacco production (cost = about $2.5 billion).		
Community & Worker Economic Assistance	Provides annual community economic development grants of $375-450 million for 25 years (up to $11.1 billion). Provides assistance for displaced industry workers (up to $625 million). Provides higher education grants for tobacco farm families (up to $1.44 billion).		Provides annual community economic development grants for 3 years (totaling $300 million). [Sec. 821] Provides assistance for displaced industry workers (not more than $500 million). [Sec. 816] Provides education grants for farm families (about $1.4 billion). [Sec. 817]
	Provides community economic development grants for 5 years (totaling $1 billion)		
Immunity Provisions	Provides immunity to penalties for agriculture sector for lack of manufacturer compliance with Act.		
Native Americans, State and Local Preemption, International Tobacco Control, Antitrust Exemption, and Smuggling			
	Titles VI & XI	Titles II, III &VII	Titles I, IV & IX
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. [Sec. 601-603]	Provides that the requirements of this Act relating to the manufacture, distribution, and sale of tobacco products apply on tribal lands. Allows tribes to compete for grants to fund anti-smoking activities. Provides IHS with $200 million a year from Trust Fund for Indian health programs. [Sec. 703]	Provides that the requirements of this Act relating to the manufacture, distribution, and sale of tobacco products apply on tribal lands. Considers tribes as states for the purposes of this Act. Provides IHS with $200 million a year from Trust Fund for Indian health programs (see Title I). [Sec. 901]
Preemption	Allows state and local governments to adopt and enforce any additional tobacco product control measures. [Sec. 5]	Allows state and local governments to impose any additional tobacco product control measures that are not inconsistent with the provisions of this Act. [Sec. 704]	Allows state and local governments to impose any additional tobacco product control measures that do not conflict with the regulatory provisions in this Act. [Sec. 401]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
International Tobacco Control	Provides funding for international tobacco control efforts ($350 million/yr over first 5 years). Prohibits use of federal funds to promote U.S. tobacco exports or to seek removal of nondiscriminatory restrictions on tobacco by foreign countries. [Sec. 1101-1107]	Prohibits use of federal funds to promote U.S. tobacco exports or to seek removal of nondiscriminatory restrictions on tobacco by foreign countries. Provides $100 million/yr for global tobacco control efforts. [Sec. 344, 703]	
Antitrust Exemption			Provides participating manufacturers with limited exemption from federal and state antitrust laws. [Sec. 903]
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. [Sec. 1131-1140]	Licenses tobacco manufacturers, exporters, importers, and distributors, and registers tobacco retailers. Allocates $100 million/yr for anti-smuggling program. Establishes new criminal penalties for smuggling. [Sec. 223-232]	
Veterans, Vending Machines, and Asbestos Workers			
	Titles XI, XII & XIII		
Veterans	*S.Amdt. 2446 provides $600 million/yr for 5 years from the Trust Fund for tobacco-related veterans' health care. [Sec. 1301]*		
Vending Machines	Bans tobacco vending machines. Authorizes funds to compensate tobacco vending machine owners/operators. [Sec. 1162]		
Asbestos Worker Compensation	Authorizes appropriations from Trust Fund if Congress establishes a program to pay asbestos claims. [Sec. 1201]		Allocates $200 million per year to pay asbestos claims of smokers. [Sec. 101]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	**S. 1415 (McCain)[a]**	**S. 1889 (Harkin/Chafee/Graham)**	**S.1530 (Hatch)**
Income Tax Provisions, Anti-Drug Activities, Advertising/Promotion Tax Deduction			
Income Tax Cuts	*S.Amdt. 2686 (Gramm) mandates up to 33% of Trust Funds be used to reduce the marriage penalty for families with incomes of less than $50,000/yr and allow self-employed workers a full deduction for health insurance expenses. Estimated 5-year cost = $21 billion.*		
Anti-Drug Programs	*S.Amdt. 2451 (Coverdell) authorizes about $3 billion/yr for 5 years from theTrust Fund to boost funding for existing federal drug interdiction efforts. Also authorizes funding to help communities devise anti-drug strategies. (Note: includes authorization to fund school vouchers, and bans federal funding of needle exchange programs.)*		
Advertising/ Promotion Tax Deduction	*S.Amdt. 2702 (Reed) disallows the tax deduction for advertising, promotion, and marketing expenses unless the manufacturers comply with the FDA tobacco regulation.*		

[a] The table summarizes the modified committee substitute bill that was debated on the Senate floor (May 18 - June 17). The amendments that passed are in italics.
[b] 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 annual 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 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and H.R. 3868)			
Topic	**S. 1638 (Conrad)**	**H.R. 3474 (Fazio)**	**H.R. 3868 (Hansen/Meehan/Waxman)**
Regulation of Tobacco Industry, Tobacco Products, and Product Use			
	Titles II, VII & VIII	Titles II, VII & VIII	Titles II & VII
Marketing and Advertising Restrictions	Prohibits outdoor tobacco product advertising; prohibits use of human or cartoon images in advertising; prohibits Internet advertising; restricts point-of-sale advertising. [Sec. 726] Restricts use of non-tobacco trade or brand names for tobacco products; limits advertising to FDA-specified media; restricts glamorization of tobacco. [Sec. 727] Restricts advertising in non-adult facilities and publications to black-on-white format. [Sec. 728] Prohibits non-tobacco merchandise and brand-name sponsorship. [Sec. 729]	Same provisions as S. 1638. [Sec. 726-729]	Prohibits outdoor tobacco product advertising; prohibits use of human or cartoon images in advertising; prohibits Internet advertising; restricts point-of-sale advertising. Restricts use of non-tobacco trade or brand names for tobacco products; limits advertising to FDA-specified media; restricts glamorization of tobacco. Restricts advertising in non-adult facilities and publications to black-on-white format. Prohibits non-tobacco merchandise and brand-name sponsorship. [Sec. 204-205]
Warnings, Labeling and Packaging	Requires new, explicit warning labels in bold type. Preempts labeling by state and local governments. [Sec. 205] Repeals existing federal tobacco product labeling laws. [Sec. 206]	Same provisions as S. 1638. [Sec. 205-206]	Requires new, explicit warning labels in bold type. Preempts labeling by state and local governments. Repeals existing federal tobacco product labeling laws. [Sec. 205, 207]
Youth Access Restrictions	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machine and self-service sales except in adult-only facilities; permits mail-order sales subject to FDA review. [Sec. 202]	Same provisions as S. 1638. [Sec. 202]	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machine and self-service sales except in adult-only facilities; permits mail-order sales subject to FDA review. [Sec. 205]
Retailer Licensing or Registration	Mandates state licensing of tobacco retailers and stipulates penalties, including license suspension and revocation, for non-compliance. [Sec. 205]	Same provisions as S. 1638. Also allows states to provide technologies to aid retailers in verifying the age of purchasers. [Sec. 205]	Mandates state licensing of tobacco retailers and stipulates penalties, including license suspension and revocation, for non-compliance. [Sec. 205]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and H.R. 3868)			
Topic	**S. 1638 (Conrad)**	**H.R. 3474 (Fazio)**	**H.R. 3868 (Hansen/Meehan/Waxman)**
Amendment of Federal Food, Drug, and Cosmetic Act: Regulation of Tobacco Product Development and Manufacturing	Amends Federal Food, Drug, and Cosmetic Act as follows: Defines nicotine as a drug, and tobacco products as devices, and gives FDA authority to regulate tobacco products as a drug, a device, or both. Gives FDA authority to regulate advertising, promotion, and access to tobacco products. Exempts tobacco product regulation from the general safety and efficacy standard if it is achieves the best public health result. Permits FDA to issue regulations through notice-and-comment rulemaking that may include the reduction or elimination of nicotine or other harmful constituents. Requires testing, reporting, and disclosure of tobacco smoke constituents. Requires disclosure of amounts of all non-tobacco ingredients in each brand. Requires ingredients to be included on the product label. Establishes DHHS scientific advisory committee. [Sec. 201-205]	Same provisions as S. 1638. [Sec. 201-205]	Amends Federal Food, Drug, and Cosmetic Act as follows: Defines nicotine as a drug, and tobacco products as devices, and gives FDA authority to regulate tobacco products under a public health standard. Considers all the provisions of the FDA tobacco regulation (21 CFR 897) to be promulgated and directs the agency to revise its regulations to incorporate the additional provisions in the June 20, 1997, settlement (to the extent permitted by the First Amendment). [Sec. 201-205]
Corporate Culture and Compliance, Lobbyists, and Whistleblowers	Protects industry whistleblowers. [Sec. 802]	Same provisions as S. 1638. [Sec. 802]	Establishes a Tobacco Accountability Board within DHHS to report to Congress on the tobacco industry's future conduct. Grants the Board responsibility for managing the document depository (see below). Protects industry whistleblowers. [Sec. 701, 703-707]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and H.R. 3868)			
Topic	**S. 1638 (Conrad)**	**H.R. 3474 (Fazio)**	**H.R. 3868 (Hansen/Meehan/Waxman)**
Reducing Underage Tobacco Use, Lookback Penalties			
	Title III	Title III	Title III
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. [Sec. 302] Sets reduction targets for underage use of cigarettes (by 40% in 5 years, 55% in 7 years, and 67% in 10 years) and smokeless tobacco products (by 25% in 5 years, 35% in 7 years, and 45% in 10 years). [Sec. 303]	Extends the survey requirements in S. 1638 to include the percentage of each ethnic group of individuals under age 18 who used each brand in the past 30 days. [Sec. 302] Sets the same reduction targets for underage use of cigarettes and smokeless tobacco products (by 40% in 5 years, 55% in 7 years, and 67% in 10 years). [Sec. 303]	Mandates an annual household-based survey to determine the percentage of each ethnic group of individuals under age 18 that use each tobacco-product brand. Sets reduction targets for underage use of tobacco products: 50% in 5 years, 67% in 7 years, and 80% in 10 years. [Sec. 301-302, 306-307]
Industry Penalties	Mandates industry-wide and manufacturer-specific penalties (not tax-deductible) if targets are not met. Industry-wide penalty = $0.10 per unit sold. Manufacturer-specific penalty = up to $0.40 per unit sold by a manufacturer whose products fail to meet the targets. Penalties increase with repeated non-compliance. [Sec. 304] A manufacturer may have its penalty reduced if it can demonstrate that an arbitrary and capricious survey overestimated youth tobacco use. [Sec. 306]	Mandates only manufacturer-specific penalties (not tax-deductible) if targets are not met. For each manufacturer whose products fail to meet the targets, the penalty = $0.02 per percentage point short of the target per unit sold. Penalties increase with repeated non-compliance. [Sec. 304] A manufacturer may have its penalty reduced if it can demonstrate that an arbitrary and capricious survey overestimated youth tobacco use. [Sec. 306]	Mandates manufacturers to increase prices by up to $0.06 a pack if targets are not met (inflation-adjusted). Requires additional point-of-sale and packaging restrictions for repeated noncompliance. Caps price increase at $2.00 a pack. Requires manufacturers to pay the U.S. Treasury an amount equal to the per-pack price increase multiplied by the total number of packs. Authorizes these funds to be used for tobacco control programs. [Sec. 303-304]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and H.R. 3868)			
Topic	**S. 1638 (Conrad)**	**H.R. 3474 (Fazio)**	**H.R. 3868 (Hansen/Meehan/Waxman)**
Environmental Tobacco Smoke (ETS)			
	Title V	Title V	Title IV
Smoking Restrictions in Public Facilities	Amends the Occupational Safety and Health Act to restrict smoking in public facilities (i.e., those entered by 10 or more persons at least 1 day a week) to enclosed, separately ventilated, designated smoking areas. Specifies that employees may not be required to enter smoking areas. Exempts small restaurants (other than fast food), bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco outlets, and prisons. Prohibits smoking in schools and other facilities serving children, and on public transportation. Allows state and local governments to enact stricter laws. [Sec. 501]	Same provisions as S. 1638 except that there is no exemption for small restaurants. [Sec. 501]	Requires the EPA to issue regulations to restrict smoking in public facilities (i.e., any building in which activities substantially affecting interstate commerce occur) to enclosed, separately ventilated, designated smoking areas. Specifies that employees may not be required to enter smoking areas. Includes all federal, state, and local government buildings. Exempts bars, private clubs, prisons, and tobacco outlets. Establishes penalties for violators. Allows state and local governments to enact stricter laws. [Sec. 401-406]
Tobacco Trust Fund			
	Title I	Title I	Title I
Establishment of Tobacco Trust Fund and Annual Industry Payments	Establishes the Health Enhancement and Lowered Tobacco Hazards for Young Kids (HEALTHY Kids) Trust Fund. Mandates initial industry payment of $15 billion (not tax-deductible). Mandates annual assessments of each manufacturer as follows: $0.50 a pack in year 1, $1.00 a pack in year 2, and $1.50 a pack in year 3 and thereafter. Beginning in fourth year, payments subject to inflation adjustments. **Five-year projected total = $82 billion.** Companies may not use insurance coverage to make payments. [Sec. 101- 102]	Establishes the Health Enhancement and Lowered Tobacco Hazards for Young Kids (HEALTHY Kids) Trust Fund. Mandates initial industry payment of $16 billion (not tax-deductible). Thereafter, mandates annual, tax-deductible payments into Trust Fund for 25 years, beginning at $24.33 billion and rising to more than $29 billion by year 10. Annual payments subject to inflation adjustment. **Five-year projected net total = $82 billion.**[a] Companies may not use insurance coverage to make payments. [Sec. 101- 102]	Mandates initial industry payment of $10 billion (not tax deductible). Mandates annual assessment of each manufacturer as follows: $0.50 a pack in year 1, $1.00 a pack in year 2, and $1.50 a pack in year 3 and thereafter (adjusted for inflation). [Sec. 102]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and H.R. 3868)			
Topic	**S. 1638 (Conrad)**	**H.R. 3474 (Fazio)**	**H.R. 3868 (Hansen/Meehan/Waxman)**
Authorization of Trust Fund Expenditures	Authorizes annual expenditures from Trust Fund (see below). [Sec. 101]	Authorizes annual expenditures from Trust Fund (see below). [Sec. 101]	Authorizes annual expenditures to reduce the public debt, fund tobacco control programs, and reimburse states (see below). [Sec. 101]
Distribution/Allocation of Trust Funds or Excise Tax Revenues			
	Title I	Title I	Titles V & VIII
State Reimbursement (Medicaid)	Allocates 14.5% annually ($12 billion over first 5 years) for reimbursement of state and local Medicaid programs, based on each state's share of total federal Medicaid payments. [Sec. 111] Allocates 17% annually ($14 billion over first 5 years) to states for child care programs. [Sec. 131] Allocates 6% annually ($5 billion over first 5 years) to states for elementary school teachers. [Sec. 132] Allocates 4% annually ($3 billion over first 5 years) to states to expand children's health care coverage. [Sec. 133]	Allocates 14.5% annually ($12 billion over first 5 years) for reimbursement of state and local Medicaid programs, based on each state's share of total federal Medicaid payments. [Sec. 111] Allocates 20% annually for the first 5 years (for a total of $16.5 billion) and 17% annually thereafter to states for child care programs. [Sec. 131] Allocates 9% annually for the first 5 years (for a total of $7.5 billion) and 6% annually thereafter to states for elementary school teachers. [Sec. 132] Allocates 4% annually ($3 billion over first 5 years) to states to expand children's health care coverage. [Sec. 133]	Allocates $8 billion/yr (same as June 20, 1997 settlement) to states in unrestricted funds. Requires states to reimburse local governemnts that incurred tobacco-related health costs. [Sec. 801-803] Awards grants to states as follows: $200 million/yr for child-oriented tobacco control efforts; $400 million/yr for community-based tobacco control programs. [Sec. 811]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and H.R. 3868)			
Topic	**S. 1638 (Conrad)**	**H.R. 3474 (Fazio)**	**H.R. 3868 (Hansen/Meehan/Waxman)**
Federal, State, and Local Programs, and Research	Allocates 15.5% annually ($13 billion over first 5 years) for tobacco control activities including: $300 million/yr for FDA; $200 million/yr for Indian Health Service; $200 million/yr for behavioral research; $100 million/yr for surveillance; $300 million/yr for school- and community-based programs; $500 million/yr for counter advertising; $700 million/yr for cessation programs; and $60 million/yr for smokers' medical costs. (Funding amounts are estimates over first 5 years.) [Sec. 602, 603, 611, 621-626] Allocates 21% annually ($17 billion over first 5 years) for NIH research. [Sec. 121, 601] Allocates 12% annually ($10 billion over first 5 years) to tobacco farmers and communities (see Title IV). Allocates 4% annually ($3 billion over first 5 years) to Medicare, and 6% annually ($5 billion over first 5 years) to Social Security; allocations grow to 10% and 12%, respectively, after 10 years. [Sec. 101]	Allocates 15.5% annually ($13 billion over first 5 years) for tobacco control activities including: $300 million/yr for FDA; $200 million/yr for Indian Health Service; $200 million/yr for behavioral research; $100 million/yr for surveillance; $300 million/yr for school- and community-based programs; $500 million/yr for counter advertising; $700 million/yr for cessation programs; and $60 million/yr for smokers' medical costs. (Funding amounts are estimates over first 5 years.) [Sec. 602, 603, 611, 621-626] Allocates 21% annually ($17 billion over first 5 years) for NIH research. Requires that research be conducted at minority institutions. [Sec. 121, 601] Allocates 12% annually ($10 billion over first 5 years) to tobacco farmers and communities (see Title IV). Allocates 4% annually ($3 billion over first 5 years) to Medicare, and, beginning in year 6, 6% annually ($5 billion over first 5 years) to Social Security; allocations grow to 10% and 12%, respectively. [Sec. 101]	Allocates funds for federal programs as follows: $300 million/yr for FDA, $200 million/yr for cessation programs, $500 million/yr for counter-advertising, and $1 billion/yr for research, epidemiology, and surveillance (inflation-adjusted). [Sec. 501-506]
Consent Decrees, National Protocol, Non-Participating Manufacturers, Attorneys' Fees, and State Enforcement of Youth Access Laws			
	Title VII	Title VII	Title II
Consent Decrees and National Protocol	Requires manufacturers and states to enter into consent decrees that include many of the provisions of this Act. [Sec. 711] Within 90 days of enactment, requires each manufacturer to enter into a legally binding and enforceable contract (the National Tobacco Control Protocol) with the U.S. Attorney General and the Attorney General of each state. The Protocol embodies the advertising and promotion restrictions in the June 20, 1997, proposed settlement (described earlier in table). [Sec. 721, 725-729]	Same provisions as S. 1638. [Sec. 721, 725-729]	

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and H.R. 3868)			
Topic	**S. 1638 (Conrad)**	**H.R. 3474 (Fazio)**	**H.R. 3868 (Hansen/Meehan/Waxman)**
Non-Participating Manufacturers			
Attorneys' Fees	Establishes a 7-person arbitration panel to determine and award attorneys' fees and expenses, subject to the American Bar Association's ethical guidelines. [Sec. 702]	Same provisions as S. 1638. [Sec. 702]	
State Enforcement of Youth Access Laws	Requires states to restrict access of minors to tobacco products, through licensing, compliance checks, and enforcement. States must meet compliance target of 95% within 3 years. Establishes penalties for retailers, their employees, and minors for sales to minors. [Sec. 205]	Same provisions as S. 1638. [Sec. 205]	Requires states to enact a law consistent with the provisions of a model state law described in the Act, or risk losing Title VIII funds. Model state law must include retailer licensing, and state compliance inspections and enforcement. [Sec. 205]
Civil Liability			
	Title VII	Title VII	Title VII
Legal Immunity	Settles state lawsuits and prohibits state and local governments from future action against the industry based on its past conduct. States that elect not to receive any funds ever from the Trust Fund may continue with their lawsuits. Prohibits federal lawsuits for past actions by the industry. [Sec. 701]	Same provisions as S. 1638. [Sec. 701]	Gives states the option of settling their lawsuits against the tobacco industry in exchange for Title VIII funds. [Sec. 801]
Industry Document Disclosure			
	Title II	Title II	Title VII
National Tobacco Document Depository	Requires industry to submit to DHHS Secretary all health-related documents. Secretary will make them available to the public. Public health considerations override privileged documents. [Sec. 205]	Same provisions as S. 1638. [Sec. 205]	Requires manufacturers to submit to the Tobacco Accountability Board all health, sales, and marketing-related documents. Allows Board to determine whether trade secrets should remain protected. [Sec. 702]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and H.R. 3868)			
Topic	**S. 1638 (Conrad)**	**H.R. 3474 (Fazio)**	**H.R. 3868 (Hansen/Meehan/Waxman)**
Agriculture and Rural Community Adjustment			
	Title IV	Title IV	
Funding	Establishes Tobacco Transition Trust Fund to receive payments from HEALTHY Kids Trust Fund as follows: $10 billion over first 5 years, then gradually phased out over 25 years. Requires Congress to enact legislation by Jan. 1, 2000, authorizing use of funds for assisting tobacco farmers and their communities. [Sec. 101, 401]	Establishes Tobacco Transition Trust Fund to receive payments from HEALTHY Kids Trust Fund as follows: $21 billion over first 10 years, then gradually phased out over 25 years. Requires Congress to enact legislation by Jan. 1, 2000, authorizing use of funds for assisting tobacco farmers and their communities. [Sec. 101, 402] Requires that cigarette manufacturers purchase a certain amount of tobacco grown in the United States. [Sec. 401]	
Farmer compensation			
Other USDA tobacco activities			
Community & Worker Economic Assistance			
Immunity Provisions			
Native Americans, State and Local Preemption, International Tobacco Control, Antitrust Exemption, and Smuggling			
	Titles VIII and IX	Titles VIII & IX	Titles II & VI
Native Americans	Applies provisions of the Act to Indian lands (exempts religious or ceremonial use of tobacco). Tribes that manufacture tobacco products are subject to the same annual assessments as the tobacco companies. Provides the IHS with $200 million/yr for Indian health programs. [Sec. 901]	Same provisions as S. 1638. [Sec. 901]	Treats Indian tribes as states for the purposes of licensing and inspecting retailers operating on Indian lands. [Sec. 205]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and H.R. 3868)			
Topic	**S. 1638 (Conrad)**	**H.R. 3474 (Fazio)**	**H.R. 3868 (Hansen/Meehan/Waxman)**
Preemption	Allows state and local governments to impose and enforce additional measures to further the purposes of this Act. [Sec. 804]	Same provisions as S. 1638. [Sec. 804]	
International Tobacco Control	Creates a non-profit corporation and provides funds for international tobacco control programs. [Sec. 624] Prohibits use of federal funds to promote U.S. tobacco exports or to seek removal of nondiscriminatory restrictions on tobacco products by foreign countries. [Sec. 801] Prohibits U.S. employees of tobacco companies from marketing to children overseas. Requires tobacco product exports to carry warning labels.[Sec.803]	Same provisions as S. 1638. [Sec. 624, 801, 803]	Prohibits U.S. tobacco companies and their foreign affiliates from marketing to children in other countries. Prohibits use of federal funds to promote U.S. tobacco exports or to seek removal of nondiscriminatory restrictions on tobacco products by foreign countries. Imposes a $0.05 per unit fee on tobacco products manufactured and sold abroad to be paid into an International Tobacco Control Trust Fund. Allocates $150 million/yr for an American Center on Global Health and Tobacco. [Sec. 601-607]
Antitrust Exemption			
Smuggling			
Veterans, Vending Machines, and Asbestos Workers			
		Title X	
Veterans			
Vending Machines			
Asbestos Worker Compensation		Establishes the Tobacco Asbestos Trust Fund. Transfers up to $3 billion/yr of the annual industry payment to the Trust Fund. Total amount transferred over 15 years = $20 billion. Requires funds to be used to pay asbestos claims of smokers. [Sec. 1001-1005]	

[a] The projected 5-year total is based on Dept. Treasury estimates and excludes money transferred to the asbestos trust fund and money withheld in lieu of taxes. Note that the annual industry payments are tax-deductible.

Table 2: Summary of June 20, 1997 Tobacco Settlement	
Title	**Provisions**
I. Tobacco Industry Reformation	
Marketing and Advertising	Incorporates the following provisions of the FDA rule: (i) Prohibits use of non-tobacco brand names for tobacco products unless such names were in existence as of 1/1/95 (897.16(a)); (ii) Restricts tobacco product advertising to FDA-specified media (897.30(a)); (iii) Restricts permissible tobacco product advertising to black text on a white background except for advertising in adult-only facilities and adult publications (897.32 (a-b)); (iv) Requires advertisements to include FDA-mandated statement, "Nicotine-Delivery Device for Persons 18 and Older" (897.32(c)); (v) Bans sale and distribution of non-tobacco items, services, and gifts, and brand-name sponsorship of sporting and other cultural events (897.34(a-c)). Modifies and extends the FDA rule as follows: (i) Bans **all** outdoor tobacco product advertising and **all** brand-name advertising directed outside from a retail store (modifies 897.30(a-b)); (ii) Bans the use of human and cartoon images in tobacco advertising and packaging; (iii) Prohibits tobacco product advertising on the Internet unless designed to be inaccessible from the United States; (iv) Prohibits payments to glamorize tobacco use in media appealing to minors; (v) Prohibits payments for tobacco product placement in movies, TV programs, and video games; (vi) Establishes additional restrictions on point-of-sale advertising (e.g., regulates number of permissible advertisements).
Warnings, Labeling and Packaging	Amends the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 *et seq.*) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 *et seq.*) to require new warning labels on tobacco product packages and cartons, and on all tobacco advertisements. For cigarettes, the warnings would be in bold type and occupy 25% of the front of the package.[a] Requires packages to include FDA-mandated statement, "Nicotine-Delivery Device for Persons 18 and Older" (897.25). Transfers from the Federal Trade Commission (FTC) to FDA the authority to measure and report tar, nicotine, and carbon monoxide levels in tobacco smoke, and the authority to require disclosure of such information on labels and advertising.
Restrictions on Access to Tobacco Products	Incorporates the following provisions of the FDA rule: (i) Sets a minimum age of 18 to purchase tobacco products and requires retailers to check photo ID of anyone under age 27 (897.14(a-b)); (ii) Requires face-to-face transactions for all tobacco sales, bans sale of individual cigarettes, and requires retailers to remove all displays and advertising that do not comply with this regulation (897.14(c-e)); (iii) Establishes a minimum package size of 20 cigarettes and bans the sampling of tobacco products (897.16(b)(d)); (iv) Bans self-service displays except in adult-only facilities (897.16(c)). Modifies and extends the FDA rule as follows: (i) Bans **all** vending machine sales; (ii) Permits mail-order sales, subject to proof of age and FDA review (modifies 897.16(c)); (iii) Mandates that tobacco products be placed out of reach of the customers (i.e., behind counter or under lock and key), except in adult-only facilities.
Licensing of Retail Sales	Mandates minimum federal standards for licensing tobacco product retailers. Retailers would face fines for selling tobacco without a license of at least $1,000 per violation. Licensed retailers who sell to minors would face fines starting at $500 and rising to $25,000 for repeated violations. Retailers caught selling to minors 10 times within any two-year period could lose their license. Licensing fees would cover the administrative costs of issuing state licenses.

Table 2: Summary of June 20, 1997 Tobacco Settlement	
Title	**Provisions**
Tobacco Product Development and Manufacturing	Recognizes explicitly FDA's authority to regulate tobacco products. Classifies tobacco products as Class II devices[b] under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) and permits FDA to require the modification of tobacco products in accordance with Performance Standards: (i) For at least 12 years following enactment of the settlement, FDA would be permitted to adopt Performance Standards to reduce nicotine yields and eliminate other harmful tobacco product ingredients, provided that the modification significantly reduces health risks, is technologically feasible, and does not create a black market for unmodified products. FDA must show "substantial evidence" for any such modification in a formal rulemaking subject to the Administrative Procedure Act, with the right of judicial review.[c] Any such action would also be subject to congressional review under the Regulatory Reform Act of 1996.[d] (ii) After the initial 12-year period, FDA would be permitted to adopt Performance Standards to eliminate nicotine, provided that the modification meets the same criteria listed in item (i). FDA must base any such modification on a "preponderance of evidence" pursuant to a Part 12 hearing, or notice and comment rulemaking, with the right of judicial review.[e] Any such action would be phased in after a two-year period to allow for congressional review under the Regulatory Reform Act of 1996. (iii) Requires FDA approval of all health claims for tobacco products. Permits FDA to mandate the introduction of less hazardous tobacco products that are technologically feasible.[f] Any such action would require a formal rule- making subject to the Administrative Procedure Act, with the right of judicial review. Requires FDA to establish a scientific advisory committee to study issues related to the regulation of nicotine and other health and safety issues.
Good Manufacturing Practice	Subjects tobacco companies to good manufacturing practice standards comparable to those applicable to other FDA-regulated industries (see 820.1(e)(f)).
Industry Documents	Establishes a public depository of industry documents related to smoking and health, addiction or nicotine dependency, safer or less hazardous cigarettes, and underage tobacco use and marketing. The depository would not include documents that are determined by the industry to be "privileged against disclosure," but would instead include a detailed, descriptive log of such privileged documents. Establishes a three-judge federal arbitration panel to settle disputes over making privileged documents public.
Non-Tobacco Ingredients	Supersedes the current federal ingredient law by requiring manufacturers to disclose annually to FDA on a "strictly confidential" basis the amounts of all non-tobacco ingredients added to each brand.[g] Requires manufacturers to disclose ingredients information to the public in a manner comparable to current federal requirements for food products. Manufacturers must submit safety testing results for each non-tobacco ingredient within five years, and demonstrate that there is a reasonable certainty that the ingredient is not harmful under the intended conditions of use. FDA would have 90 days to review each safety assessment.
Corporate Culture and Compliance	Includes requirements to ensure that the industry complies with both the letter and spirit of the settlement, including the establishment of internal procedures to promote compliance with laws barring tobacco sales to minors. Provides "whistleblowers" in the tobacco industry with protection. Requires tobacco lobbyists to agree in writing to comply with all the provisions of the settlement, and not support or oppose any state or federal legislation without the manufacturer's authorization. Disbands the Tobacco Institute and the Council for Tobacco Research.[h] Grants tobacco companies immunity from federal and state antitrust laws thereby allowing them to confer and act in concert to meet the requirements of the settlement (e.g., raising prices to cover annual payments).

Table 2: Summary of June 20, 1997 Tobacco Settlement	
Title	**Provisions**
II. Look-Back Provisions, State Enforcement Incentives	Sets targets for reduction in underage cigarette use. The industry would face fines of up to $2 billion per year if underage cigarette use does not decline by 30% in five years, 50% in seven years, and 60% in 10 years, or underage use of smokeless tobacco products does not decline by 25% in five years, 35% in seven years, and 45% in 10 years. Allows the industry to petition FDA to recover 75% of the fine if it can establish that it pursued all "reasonably available measures" to reduce youth smoking and did nothing to undermine the settlement goals. Requires states to undertake significant enforcement steps to reduce the incidence of underage tobacco use, which go beyond the provisions of the Synar Amendment (42 U.S.C. 300x-26; 45 C.F.R. 96.130). States must maintain a specific level of enforcement activity or risk losing health care funds (see Title VII).[i]
III. Penalties, Consent Decrees, Non-Participating Tobacco Companies	Requires manufacturers and states to enter into legally enforceable consent decrees that include many of the provisions of the settlement. Violations of the proposed settlement's requirements would carry civil and criminal penalties based upon the penalty provisions of the Food, Drug and Cosmetic Act and the provisions of the United States criminal code. In addition, the industry would face civil penalties of up to $10 million for each violation of the requirements to disclose information about non-tobacco ingredients and the health effects of tobacco products. Non-participating tobacco companies would be subject to all the regulations outlined in Title I of the settlement, but would receive none of the civil liability protection outlined in Title VIII. Requires non-participating companies to make annual payments into an escrow fund earmarked for potential liability claims against the companies.
IV. Environmental Tobacco Smoke	Restricts smoking in public facilities (i.e., any building entered by 10 or more individuals at least one day a week) to separately ventilated locations. Ensures that no employee may be required involuntarily to enter a smoking area. Exempts restaurants (other than fast food restaurants) and bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco merchants and prisons.[j] Allows state and local governments to enact stricter laws.
V. Scope and Effect	The settlement includes all tobacco products sold in U.S. commerce, and also covers imports and U.S. duty free items. Preserves the legal authority of state and local governments to regulate further the sale and distribution of tobacco products. Retains the fiscal authority over tobacco products of the Bureau of Alcohol, Tobacco and Firearms, and the existing authority of the FTC, except for tar, nicotine and carbon monoxide testing (see Title I, sec. B).

Table 2: Summary of June 20, 1997 Tobacco Settlement	
Title	**Provisions**
VI. Programs and Funding	Mandates annual industry payments in perpetuity to reimburse states for Medicaid outlays for smoking-related illnesses,[k] pay damages to settle individual lawsuits (see Title VIII), provide funds for public health programs and research, and to cover the costs of implementing and enforcing the programs and regulations outlined in the settlement (see Title VII). The industry would pay an up-front sum of $10 billion, and annual payments beginning at $8.5 billion in the first year, increasing to $15 billion in the fifth year of the settlement. The annual payments would remain at $15 billion per year thereafter. The annual payments would be subject to adjustment for inflation, and would be deemed an ordinary and necessary business expense and, therefore, tax deductible. Companies would raise prices on tobacco products to cover the cost of the annual payments.[l] The annual payments would also be subject to a sales-volume adjustment. If adult consumption decreases, annual payments would be reduced proportionately. It total consumption increases, annual payment would be increased proportionately. **Total estimated payments over the first 25 years = $368.5 billion (in 1998 dollars)[m]**
VII. Distribution of Annual Payments	Recommends distribution of annual payments as follows: (i) Unrestricted funds to states totaling $8 billion/yr by the sixth year (allocated according to a formula) to reimburse their Medicaid programs; (ii) Funding for tobacco cessation programs (totaling $1.5 billion/yr by the sixth year); (iii) Funding for a public health trust to pay for biomedical and behavioral tobacco-related research (payments into trust total $25 billion over the first 8 years); (iv) Funding for tobacco control programs (totaling $1.5 billion/yr by the fourth year), which include counter advertising ($0.5 billion/yr), FDA regulation, local community programs, research on reducing tobacco use, and also compensation for sporting and cultural events that lose tobacco industry sponsorship. Provides up to $4 billion/yr to pay damages in individual lawsuits (see Title VIII). Unused funds would be allocated for other tobacco-related activities and programs by a presidential commission .
VIII. Civil Liability	Provides the participating companies with protection from civil liability by legislatively settling the state attorneys generals' and class-action lawsuits. Prohibits future class-action lawsuits. Preserves the rights of individuals to sue tobacco companies for past or future conduct. Individual lawsuits arising from past conduct could claim only compensatory damages, whereas individual lawsuits arising from future conduct could claim both compensatory and punitive damages. Defines permissible parties that can act as plaintiffs and defendants in such lawsuits. Limits the total damages paid by the industry in any one year to 33% of the annual industry base payment.[n] Allows industry to deduct 80% of its liability costs each year from the annual payment.
IX. Board Approval	The terms of the settlement are subject to approval by the Boards of Directors of the participating tobacco companies.

[a] The nine warnings on cigarettes packs include: "WARNING: Cigarettes are addictive" and "WARNING: Cigarettes cause cancer." The four warnings on smokeless tobacco products include: "WARNING: Smokeless tobacco is addictive" and "WARNING: This product can cause mouth cancer." The warnings would appear in Canadian format (i.e., alternating black text on a white background and white text on a black background). They would be introduced concurrently on all tobacco product packages and cartons, and rotated quarterly on all advertisements. The settlement preserves the preemptive language in both the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, which prevents state and local governments from requiring additional health warnings on tobacco products.

[b] Class II medical devices (e.g., syringes, hearing aids, and powered wheelchairs) are those for which FDA requires special controls to assure safety and effectiveness. These controls may include special labeling requirements, mandatory performance standards, and postmarket surveillance.

[c] Most regulations are issued informally under the notice-and-comment procedure established by the Administrative Procedure Act (APA; 5 U.S.C. 551 *et seq.*). The agency publishes a notice of proposed rulemaking in the Federal Register, permits interested persons to submit comments, and incorporates in the final rule a concise statement of the rule's basis and purpose. These regulations are reviewed under the "arbitrary, capricious, abuse of discretion" standard. Under this standard, a reviewing court would uphold an agency's action if it is rational, based on a consideration of the relevant factors, and within the scope of the authority designated to the agency by Congress. The settlement, however, would require FDA to undertake a formal rulemaking subject to the APA. This would involve trial-type hearings at which parties present evidence and conduct cross examinations. Furthermore, the "substantial evidence" standard required by the settlement may be more stringent than the "arbitrary, capricious, abuse of discretion" standard employed in informal rulemaking.
[d] This presumably refers to the Small Business Regulatory Fairness Enforcement Act of 1996 (P.L. 104-121), under which Congress has 60 session days to block a regulation by passing a joint resolution of disapproval. This procedure may be applied to any rule that results in an annual effect on the economy of at least $100 million.
[e] A Part 12 hearing refers to a formal evidentiary public hearing under FDA regulations (21 C.F.R. 12), involving presentation of evidence, cross examination, and other trial-type procedures. Requiring that an agency base its action on a "preponderance of evidence" is, according to some analysts, extremely unusual.
[f] The term "less hazardous tobacco products" refers to innovative products such as smokeless cigarettes, as opposed to chemically modified existing products.
[g] Under current law, the industry is required to provide annually to the Secretary of Health and Human Services a list of all the additives used in the manufacture of tobacco products. The Secretary is granted no authority to regulate additives that are suspected of being hazardous.
[h] The Tobacco Institute is the industry's Washington DC-based lobbying organization, and the Council for Tobacco Research provides industry funds for biomedical research.
[i] The Synar Amendment to the Public Health Service Act requires states to enforce their laws prohibiting the sale of tobacco products to individuals under age 18. States must conduct annual 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. Under the settlement, a state would lose up to 20% of its Medicaid reimbursement funds (see Title VI) if after 10 years its enforcement program failed to reach a 90% compliance rate.
[j] On March 25, 1994, the Occupational Safety and Health Organization (OSHA) proposed an indoor air quality regulation that would restrict smoking to separately ventilated, designated smoking rooms. The smoking restriction would apply to all industrial and non-industrial buildings under OSHA's jurisdiction, including restaurants and bars.
[k] The settlement negotiators intend that funding provided to the states would be sufficient to extend health insurance to uninsured children.
[l] Arithmetically, an increase of 62 cents per pack would raise $15 billion in additional revenue, based on (1996) cigarette sales of 24.165 billion packs. However, this estimate does not take into account any wholesale or retail price mark-up.
[m] This 25-year total includes $60 billion in lieu of punitive damages for the tobacco industry's past conduct.
[n] By the ninth year, the total annual damages paid by the industry is capped at $5 billion per year.

Table 3: FDA's Regulation of Cigarettes and Smokeless Tobacco Products		
Section	**Provisions**	**Status**
Labeling (Sec. 801)	Exempts cigarettes and smokeless tobacco from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which requires drug and device labels to bear adequate directions for use.[a] *21 CFR §801.126*	
Medical Device Reporting (Sec. 803)	Requires manufacturers of cigarettes and smokeless tobacco to submit reports only for serious adverse health events beyond those well-documented by the scientific community, including events related to product contamination, or a change in any ingredient or manufacturing process. *21 CFR §803.19(f)(g)*	Implementation delayed [c]
Medical Device Distributor Reporting (Sec. 804)	Requires distributors of cigarettes and smokeless tobacco to submit reports only for adverse health events related to contamination. *21 CFR §804.25(c)*	Implementation delayed [c]
Registration and Listing of Medical Devices (Sec. 807)	Requires manufacturers of cigarettes and smokeless tobacco to comply with establishment registration and device listing requirements for medical devices. *21 CFR §807.65(j)*	Implementation delayed [c]
Good Manufacturing Practice (GMP) for Medical Devices (Sec. 820)	Requires manufacturers of cigarettes and smokeless tobacco to comply with GMP regulations for medical devices. Distributors of tobacco products are exempted from this requirement. *21 CFR §820.1(e)(f)*	Implementation delayed [c]
Youth Access, Labels, and Advertising (Sec. 897)		
General responsibilities of manufacturers, distributors, and retailers	Manufacturers, distributors, and retailers are responsible for complying with all applicable requirements of this regulation. *21 CFR §897.10*	Implementation delayed [c]
Additional responsibilities of manufacturers	Manufacturers must remove from each point of sale all self-service displays, advertising, labeling, and other items owned by the manufacturers that do not comply with the requirements of this regulation. *21 CFR §897.12*	Implementation delayed [c]
Prohibition of sale and distribution to persons younger than age 18	(i) Retailers may not sell cigarettes or smokeless tobacco to persons younger than age 18. (ii) Persons under age 27 must verify age by means of photographic identification. 21 CFR §897.14(a)(b)	Effective February 28, 1997
Additional responsibilities of retailers	(i) Retailers must perform sale in a direct, face-to-face exchange without assistance of mechanical or electronic device (e.g., vending machine). (ii) Retailers may not sell or distribute individual cigarettes. (iii) Retailers must remove all self-service displays, advertising, labeling, and other items that do not comply with this regulation. *21 CFR §897.14(c)(d)(e)*	Implementation delayed [c]

Table 3: FDA's Regulation of Cigarettes and Smokeless Tobacco Products

Section	Provisions	Status
Conditions of manufacture, sale, and distribution	(i) Prohibits manufacturers from using a trade name or product name of a non-tobacco product for a cigarette or smokeless tobacco product unless such names were in use prior to 1/1/95. (ii) Prohibits distribution and sale of cigarette packages containing fewer than 20 cigarettes. (iii) Bans vending machines and self-service displays except in locations where the retailer ensures that no person under age 18 is permitted at any time. Permits mail-order sales. (iv) Bans distribution of free samples of cigarettes and smokeless tobacco. (v) Bans sale and distribution of cigarettes and smokeless tobacco with labels, labeling, or advertising not in compliance with this regulation. *21 CFR §897.16(a)(b)(c)(d)(e)*	Implementation delayed [c]
Package labels	Cigarette and smokeless tobacco packages must bear an appropriate, established name (e.g., "Cigarettes" or "Loose Leaf Chewing Tobacco") and include the following statement: "Nicotine-Delivery Device for Persons 18 or Older." *21 CFR §897.24, 21 CFR §897.25*	Implementation delayed [c]
Permissible forms of labeling and advertising [b]	(i) Permits labeling and advertising of cigarettes and smokeless tobacco products in newspapers, magazines, periodicals, billboards, posters, placards, in nonpoint-of-sale promotional materials (including direct mail), and in point-of-sale promotional materials (including audio and video formats). FDA must be notified of any intention to use any other medium not listed. (ii) Bans outdoor advertising of cigarettes and smokeless tobacco within 1000 feet of a public playground, elementary or secondary school. *21 CFR §897.30(a)(b)*	Implementation delayed [c]
Format and content requirements for labeling and advertising	(i) Cigarettes and smokeless tobacco labeling and advertising must use only black text on a white background. Publications read by fewer than 2 million persons under age 18, or whose youth readership is 15 percent or less of the total readership are exempt from this requirement. Point-of-sale advertising in adult-only facilities is also exempt, provided that the advertising is not visible from the outside. (ii) Labeling and advertising in an audio format is limited to words with no music or sound effects. Video format is limited to static black text on a white background. (iii) Labeling and advertising must include the product's established name, followed by the words: "A Nicotine-Delivery Device for Persons 18 or Older." *21 CFR §897.32(a)(b)(c)*	Implementation delayed [c]
Sale and distribution of non-tobacco items, services, and gifts	(i) Prohibits marketing, licensing, distribution or sale of all non-tobacco items and services that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic (e.g., promotional tee shirts and caps). (ii) Prohibits gifts of non-tobacco items as well as credits and coupons that are linked to the purchase of cigarettes and smokeless tobacco. *21 CFR §897.34(a)(b)*	Implementation delayed [c]
Sponsorship of events	Bans brand-name sponsorship of sporting and other cultural and social events. Only corporate-name sponsorship permitted. *21 CFR §897.34(c)*	Implementation delayed [c]

Source: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents. *Federal Register*, v. 61, no. 168, Aug. 28, 1996. pp. 44396-45318.

[a] The regulation does not exempt tobacco products from section 502(f)(2) of the FFDCA, which requires adequate warnings against use by children and others whose medical condition (e.g., pregnancy) makes use of the product dangerous to health. According to FDA, this requirement is satisfied by the rotating Surgeon General's warning labels. The regulation also requires package labeling for *intended use*. According to FDA, this requirement is satisfied by sections 897.24 and 897.25 of the regulation.

[b] The terms "labeling and advertising" are used in sections 897.30 and 897.32 to include all commercial uses of the brand name of a product, logo, symbol, motto, selling message, or any other indicia of product identification similar or identical to that used for any brand of cigarette or smokeless tobacco product.

[c] Implementation of these provisions was delayed by a North Carolina federal district court judge. FDA jurisdiction over tobacco products remains unclear pending the Administration's appeal of the August, 1998 federal appeals court ruling (see page 3).