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CRS Report for Congress

Tobacco Settlement Legislation: Summary and Comparison of S. 1415, S. 1492, S. 1530, S. 1638, S. 1889, and H.R. 3474

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ABSTRACT

This report provides a side-by-side comparison of two sets of legislative proposals introduced to implement the June 20, 1997, tobacco settlement or otherwise comprehensively limit tobacco use and marketing. Six bills are included: S. 1415, S. 1492, S. 1530, S. 1638, S. 1889, and H.R. 3474. The report also summarizes other tobacco-related bills introduced in the 105th Congress, and includes an overview of the provisions in 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.

Tobacco Settlement Legislation: Summary and Comparison of S. 1415, S. 1492, S. 1530, S. 1638, S. 1889, and H.R. 3474

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 or amend the settlement's provisions. Several comprehensive tobacco bills have been introduced, including S. 1415 (McCain); S. 1492 (Kennedy); S. 1530 (Hatch); S. 1638 (Conrad); S. 1889 (Harkin); and H.R. 3474 (Fazio).

With the exception of the Hatch bill, which is based on the proposed settlement and grants the industry broad immunity from civil liability, the bills provide the manufacturers with little or no legal protection. The original McCain bill (S. 1415), which was almost identical to the proposed settlement, was substituted with a substantially amended version that was approved by the Senate Commerce Committee on April 1 by a vote of 19-1. S. 1415, as amended, mandates annual industry payments of up to \$23.6 billion, which would raise cigarette prices by an estimated \$1.10 a pack over 5 years. It grants FDA new legal authority to regulate tobacco products and fines manufacturers up to \$3.5 billion a year if youth smoking rates do not decline by 60% in 10 years. The bill gives states the option of settling their lawsuits in return for a portion of the annual payments, and caps the industry's legal liability at \$6.5 billion a year. The McCain bill also provides \$28.5 billion over 25 years in financial assistance to tobacco farmers and their communities, as well as \$21 billion to pay the asbestos claims of smokers, and compensation for tobacco vending machine owners and operators.

The Harkin bill mandates annual payments of \$25 billion, which 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. The Kennedy and Conrad bills both directly raise the price of cigarettes by \$1.50 per pack and allocate the revenues for research, tobacco control activities, and existing children's health, nutrition, and welfare programs. They grant FDA unrestricted authority to regulate tobacco products as devices.

The Fazio bill is largely based on the Conrad bill, except that it mandates annual industry payments rather than a per-pack fee and establishes a \$20 billion asbestos - worker compensation fund. Unlike the proposed settlement, which did not include any provisions on tobacco farmers, the bills all include financial assistance for growers and tobacco-dependent communities. Numerous other tobacco-related bills, more limited in scope, have been introduced in the 105th Congress.

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Tobacco Settlement Legislation: Summary and Comparison of S. 1415, S. 1492, S. 1530, S. 1638, S. 1889, and H.R. 3474

Overview

In the past four years, 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. A detailed outline of the settlement appears in Table 2. 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. There appear to be four key issues affecting possible legislation.

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

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.

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.

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.

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 The case is currently before the U.S. Court of Appeals for the Fourth Circuit, which is scheduled to hear oral arguments from both sides on June 9.

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 non-compliance fee of up to \$1.50 per pack of cigarettes, and assessing the penalties on a company-specific basis, instead of 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 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 would reduce the number of underage cigarettes by as much as 20%.³

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.

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%.

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.

Tobacco Settlement Bills

Several comprehensive tobacco bills have been introduced, including S. 1415 (McCain); S. 1492 (Kennedy); S. 1530 (Hatch); S. 1638 (Conrad); S. 1889 (Harkin), and H.R. 3474 (Fazio).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.

With the exception of the Hatch bill, which is based on the proposed settlement and grants the industry broad immunity from civil liability, the other bills are much tougher on the industry and provide the manufacturers with little or no legal protection. The Hatch bill includes many of the provisions that appear in the settlement, though there are a number of important differences. For example, S. 1530 mandates slightly higher industry payments over 25 years. These payments would total \$398.3 billion, compared to a 25-year total of \$368.5 billion in the settlement. The bill also authorizes and allocates funding for asbestos-related litigation and Native American health programs. It 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.

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. On April 1, the Senate Commerce Committee substituted the original bill with a new and expanded version of S. 1415, which the committee approved by a vote of 19-1. The bill mandates annual industry payments beginning at \$14.4 billion and increasing to \$23.6 billion by the fifth year, which would raise cigarette prices by about \$1.10 per pack over 5 years. It grants FDA broad authority to regulate tobacco products and

⁴ The Universal Tobacco Settlement Act (S. 1414) was introduced by Senator McCain on November 7. The Healthy and Smoke Free Children Act (S. 1492) was introduced by Senator Kennedy on November 8. 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.

finest the industry up to \$3.5 billion a year if youth smoking does not decline by 60% in 10 years. S. 1415 gives states the option of settling their lawsuits against the industry. It also settles the Castano class actions and prohibits future addiction claims. The industry's legal liability is capped at \$6.5 billion a year. Finally, the bill provides \$28.5 billion for tobacco farmers and their communities, and \$21 billion over 15 years to pay the asbestos claims of smokers.

A bipartisan bill (S. 1889) 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.

The Kennedy bill (S. 1492) takes a different approach and is not modeled on the immunity-based settlement. It does not mandate annual industry payments, nor does it grant the industry any civil liability protection. Instead, it increases the federal tobacco excise tax by \$1.50 per pack 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. The tax would be implemented over 3 years (i.e., a 50 cents per pack increase each year), and indexed for inflation.

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 through notice-and-comment rulemaking. It also requires greater reductions in underage tobacco use, and stiffer penalties if those targets are not met, than does either S. 1415 or S. 1530.

S. 1492 and its companion bill, S. 1491, have also been introduced in the House as H.R. 3028 and H.R. 3027 (DeLauro), respectively. Only S. 1492 is included in Table 1a.

The Conrad bill (S. 1638) is similar to the Kennedy bill. It too would raise the cost of a pack of cigarettes by \$1.50 over three years and use the 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.

The Fazio bill (H.R. 3474) is largely based on the Conrad bill, except that it mandates annual industry payments over 25 years rather than assessing a per-unit 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.

A bill introduced by Senator Jeffords (S. 1648) is narrower in scope than the bills discussed above; it is described as intended to be part of more comprehensive tobacco legislation. It establishes a new chapter in the FFDCA for the regulation of tobacco products, and allocates money for biomedical research and federal, state, and local tobacco control programs.

Tobacco Farmers

The proposed settlement does not include any provisions for 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 any settlement legislation should include financial assistance to address these concerns.

Title X of the 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 provides 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 VIII of the Hatch bill phases out the price support program while compensating farmers for the loss in value. These provisions are almost identical to the Tobacco Transition Act (S. 1313; Lugar). The Hatch bill also includes financial assistance, similar to S. 1415, but at reduced levels of funding.

Title IV of the Kennedy bill includes provisions to assist farmers who agree to stop growing tobacco. The current price support program would remain in place for farmers who want to continue growing tobacco. 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.

Veterans' Compensation for Smoking-Related Diseases

The Department of Veterans' Affairs (VA) has concluded that nicotine addiction is a disease, and that illnesses linked to tobacco use that began during military service are service-connected disabilities. Under current law, a disability traceable to a period of military service is service-connected, even if the cause is unrelated to the service itself. To be compensable, a disability may not be the result of alcohol or drug abuse, or willful misconduct. The VA argues that tobacco use is not drug abuse, nor is it

willful misconduct. Thus, when nicotine addiction has its origins in military service, subsequent tobacco-related diseases are considered to be service-connected.

The President's FY1999 budget would prohibit the VA from paying tobacco-related disability compensation to veterans, at a savings the Congressional Budget Office projects to reach \$10.5 billion over 5 years. The Senate incorporated the proposal in its FY1999 Budget Resolution, earmarking the savings in part to offset additional discretionary spending under the reauthorized Intermodal Surface Transportation Efficiency Act (ISTEA). The House has yet to consider its Budget Resolution for FY1999. So far, no legislation to block tobacco-related compensation has been introduced.

At issue is the federal government's responsibility to its military personnel who made unwise health choices, which were facilitated, if not encouraged, by government actions. As recently as the Vietnam era, U.S. soldiers in combat zones were given free cigarettes as part of their rations, a practice that goes back at least to World War II. For further discussion of this issue, see CRS Report 98-373, *Veterans' and Smoking-Related Illnesses: Congress Considers Limits to Compensation*, by Dennis Snook.

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.

Excise Taxes

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.

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.

Tobacco Industry Tax Deductions

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.

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

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.]

Federal Medicaid Reimbursement

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.

Attorneys' Fees

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.

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.

Tobacco 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.

Environmental Tobacco Smoke

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.]

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

Youth Access

S. 1238 (Smith) 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.]

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.]

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.

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

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

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

Tobacco Product Labeling, Advertising, and Promotion

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

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

International Tobacco Control

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.

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.

Federal Tobacco Farming Programs

S. 1582 (Robb) 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.

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

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

Native Americans

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.

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 will require 60 votes to permit floor consideration of any tobacco legislation that provides funding for programs other than Medicare. The Senate Budget Resolution would also prohibit the VA from paying disability compensation for smoking-related diseases (see earlier discussion).

Laws Enacted by the 105th Congress

Two bills were signed into law last year that included provisions relating to tobacco products. The Balanced Budget Act of 1997 (P.L. 105-33) included a cigarette excise tax increase of 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 last month sent out a directive to all U.S. embassies and commercial offices abroad instructing them not to promote U.S. tobacco products. Also, 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.

Executive Order 13058

On August 9, 1997, President Clinton signed an executive order that restricts smoking in all federal Executive Branch facilities to enclosed, separately ventilated areas. The executive 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.

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)

Topic	S. 1415 (McCain et al.)	S. 1889 (Harkin/Chafee/Graham)	S.1530 (Hatch)
Regulation of Tobacco Industry, Tobacco Products, and Product Use			
	Titles I, III, VIII & XI	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. 101, 121-123]	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 requires new, explicit warning labels in bold type. Preempts labeling by state and local governments. Requires substantially equivalent labeling of tobacco product exports. [Sec. 301-304, 1102]	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 machine; bans self-service sales except in adult-only facilities; allows mail-order sales subject to FDA review. [Sec. 110, 1191]	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]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)

Topic	S. 1415 (McCain et al.)	S. 1889 (Harkin/Chafee/Graham)	S.1530 (Hatch)
Retailer Licensing or Registration	Sets minimum federal standards for state retail licensing programs. Provides block grants to states that implement and enforce such programs. Requires states to penalize both retailers that sell to minors, and underage youths who possess or purchase tobacco products. Establishes federal licensing of manufacturers and distributors. [Sec. 224, 1121]	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).
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. Establishes DHHS tobacco scientific advisory committee. 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]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)

Topic	S. 1415 (McCain et al.)	S. 1889 (Harkin/Chafee/Graham)	S.1530 (Hatch)
Corporate Culture and Compliance, Lobbyists, and Whistleblowers	Requires FDA to establish a Tobacco Agreement Accountability Panel to review the manufacturers' 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]
Reduction in Underage Tobacco Use			
	Title II	Title I	Title III
Underage Tobacco Use Targets	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. 201-202]	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	Fines manufacturers up to \$3.5 billion per year if reduction in underage tobacco use does not meet targets. Penalties are not tax-deductible. Authorizes DHHS to remove the liability limitations (see Title VII) for manufacturers that substantially fail to attain the youth reduction target. Provides a de-minimis exemption for payment of penalties for companies with less than 1% market share. [Sec. 202-204]	Mandates industry-wide and company-specific penalties (not tax-deductible) if youth reduction targets are not met. Company specific penalty = 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 et al.)	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. Delays implementation until state legislatures have had an opportunity to consider opting out. 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 Settlement 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. Total payments = \$574.5 billion. Annual payments subject to inflation adjustment and, beginning in the sixth year, subject to a volume-of-sales adjustment. Requires manufacturers to raise prices—by an estimated \$1.10 per pack over 5 years—to cover cost of payments. [Sec. 402]	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 et al.)	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. [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 I & III	Title V
State Reimbursement (Medicaid)	Establishes a separate State Litigation Settlement Fund within the Trust Fund to provide unrestricted funds to states based on an allocation formula to be determined by the states. Provides states a total of \$196.5 billion over the first 25 years, and 50% of the annual payment each year thereafter. Allows each state to keep its federal (Medicaid) matching share. [Sec. 402]	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 et al.)	S. 1889 (Harkin/Chafee/Graham)	S. 1530 (Hatch)
Federal/State/Local Programs and Research	Establishes a National Tobacco Task Force to oversee a coordinated federal research program. Mandates an IOM study of research priorities. Allocates \$4.195 billion over 10 years to CDC. Allocates \$25 billion over 10 years to NIH (tobacco-related) research (at least 33% on nicotine addiction). Establishes an Office of Tobacco-Related Research at NIH. [Sec. 1106] Mandates research on smoking among women and minorities to be conducted, where possible, at minority education institutions. Mandates counter-advertising programs aimed at minorities and women. Allocates \$3 billion over 10 years to Community and Migrant Health Centers to pay for tobacco-related health costs. [Sec. 1171-1173] Allocates \$300 for FDA regulation. Authorizes funds from the Trust Fund to be used to expand the Child Care Development Block Grant. [Sec. 411-412] Authorizes a national smoking cessation program, a national counter-advertising program, and a program for awarding grants for local community and school-based efforts. [Sec. 221-223] Note: Section 1181 (Sense of the Senate) recommends that funds be used to reimburse public health care financing programs, support tobacco control programs and tobacco-related research, assist tobacco farmers, fund clinical trials, establish a Tobacco Asbestos Trust, and fund the federal black lung program and veterans' benefit programs.	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 to tobacco 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]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)

Topic	S. 1415 (McCain et al.)	S. 1889 (Harkin/Chafee/Graham)	S.1530 (Hatch)
Consent Decrees, National Protocol, Non-Participating Manufacturers, Attorneys' Fees, and State Enforcement of Youth Access Laws			
	Titles II, VI & VII	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 (no details provided).	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 companies that violate any of 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 that also include 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 the Governor of each state. The Protocol embodies the advertising, promotion, and lobbying restrictions (described earlier in table). [Sec. 201]
Non-Participating Manufacturers	Requires that non-participating manufacturers make annual payments, and pay fees into a reserve fund to settle liability claims. Civil liability provisions of the Act to not apply to nonparticipants. [Sec. 708]	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, not by Trust Fund. [Sec. 707]	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]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)

Topic	S. 1415 (McCain et al.)	S. 1889 (Harkin/Chafee/Graham)	S.1530 (Hatch)
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 (at least 250 per 1 million state residents). States must meet compliance targets (75% compliance by year 5, 85% by year 7, and 90% compliance by year 10) or risk losing block grant funds. Repeals Synar Amendment. ^a [Sec. 211-213]	Codifies FDA's tobacco regulation into law, including restrictions on youth access that states are enforcing. [Sec. 201-242]	Expands on Synar Amendment ^a 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 VII	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. Establishes a Tort Trust Fund to pay damages. Caps total annual liability at \$6.5 billion. Modifies rule of evidence to establish a rebuttable presumption that nicotine is addictive and certain diseases are caused by tobacco use. [Sec. 701-706, 710]	Allows states to settle their lawsuits in return for funding from the Trust Fund, or continue with their lawsuits and forgo payments from the Trust Fund. Settles Castano class-action lawsuits. 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 (cap applies only to claims based on industry's past conduct). Places any unobligated funds from the Compensation Fund into an interest-bearing 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 et al.)	S. 1889 (Harkin/Chafee/Graham)	S.1530 (Hatch)
Industry Document Disclosure			
	Title IX	Title IV	Title VII
National Tobacco Document Depository	Establishes a public depository to which companies must submit all documents specified in the Act. Requires manufacturers to submit a detailed, itemized log of documents for which they assert attorney-client privilege or trade secrecy. Establishes a five-member National Tobacco Documents Review Board to settle disputes over making such privileged documents public. Establishes financial penalties for companies that do not comply. [Sec. 901-911]	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			
	Title X	Title V	Title VIII
Funding	Establishes Tobacco Community Revitalization Trust Fund to receive annual payments from the National Tobacco Settlement Trust Fund 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]
Farmer compensation	Provides payments to tobacco farm quota owners (up to \$8/lb) and tenants for production losses from baseline levels (totaling at most about \$16.5 billion). Maintains burley quotas. Replaces flue-cured quotas with nontransferable permits. [Sec. 1024]		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]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)

Topic	S. 1415 (McCain et al.)	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 (totaling about \$2.5 billion). [Sec. 1022]		
Community & Worker Economic Assistance	Provides annual community economic development grants of \$375-450 million for 25 years (up to \$11.1 billion). [Sec. 1023] Provides assistance for displaced industry workers (up to \$625 million). [Sec. 1031] Provides higher education grants for tobacco farm families (up to \$1.44 billion). [Sec. 1032]		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]
Immunity Provisions	Provides immunity to penalties for agriculture sector for lack of manufacturer compliance with national settlement legislation. [Sec. 1041]		
Native Americans, State and Local Preemption, International Tobacco Control, Antitrust Exemption, and Smuggling			
	Titles VI, X, & 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. Mandates tribes to collect all excise and state taxes from sales to non-tribal members. [Sec. 601-604]	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]

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)

Topic	S. 1415 (McCain et al.)	S. 1889 (Harkin/Chafee/Graham)	S.1530 (Hatch)
Preemption	Allows state and local governments to impose any additional tobacco product control measures that are not inconsistent with the provisions of this Act. [Sec. 1003]	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]
International Tobacco Control	Licenses any domestic concern that manufactures or distributes tobacco products. Licensing fee = \$1 per 1,000 cigarettes. [Sec. 1121] Establishes the American Center on Global Health and Tobacco (ACT) to fund anti-tobacco organizations abroad. Provides \$150 million/yr for ACT. Also establishes an International Tobacco Control Trust Fund using licensing fees to fund ACT and other international tobacco control efforts. Prohibits use of federal funds to promote U.S. tobacco exports or to seek removal of nondiscriminatory restrictions on tobacco by foreign countries. [Sec. 1131-1133]	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. 1161]		Provides participating manufacturers with limited exemption from federal and state antitrust laws. [Sec. 903]
Smuggling	Mandates serial numbers and export labels on packages. Requires manufacturers and distributors to post a bond for all tobacco product exports. Requires permits for all persons handling tobacco products in interstate and foreign commerce. Sets minimum prices for sales on military installations. Bans sales in duty-free shops. Amends Contraband Cigarette Trafficking Act to include all tobacco products. [Sec. 1141-1150]	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]	

Table 1a: Comparison of Tobacco Settlement Bills (S. 1415, S. 1889, and S. 1530)			
Topic	S. 1415 (McCain et al.)	S. 1889 (Harkin/Chafee/Graham)	S.1530 (Hatch)
Veterans, Vending Machine Owners/Operators, and Asbestos Workers			
	Titles X, XI, & XII		
Veterans	Permits the Dept. Veterans' Affairs to sue the industry to recover the costs of smoking-related disability compensation. [Sec. 1301]		
Vending Machine Owners/Operators	Transfers funds from Trust Fund to Tobacco Vending Reimbursement Corporation to compensate tobacco vending machine owners/operators. [Sec. 1191]		
Asbestos Worker Compensation	Allocates \$21 billion over 15 years to pay asbestos claims of smokers. [Sec. 1201-1206]		Allocates \$200 million per year to pay asbestos claims of smokers. [Sec. 101]

^a 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 S. 1492)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
Regulation of Tobacco Industry, Tobacco Products, and Product Use			
	Titles II, VII and VIII	Titles II, VII and VIII	Titles I & II
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]	
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. Includes limited preemption of warning labels by state and local governments. Exempts tobacco product exports from labeling requirements. Does not repeal existing federal tobacco product labeling laws. [Sec. 204]
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]	

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and S. 1492)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
Licensing of Retailers	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]	
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 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 the Federal Food, Drug, and Cosmetic Act as follows: Defines nicotine in tobacco products as a drug, and tobacco products as Class II devices. Requires FDA to issue regulations, through notice-and-comment rulemaking, for manufacturing, marketing, advertising, and distributing tobacco products. Authorizes FDA to require product modification, including nicotine content and yield, based on public health findings. Requires testing, reporting, and disclosure of tobacco smoke constituents. Requires disclosure of amounts of all non-tobacco ingredients for each brand. Subjects manufacturers to good manufacturing practice standards. Mandates new warning labels (described earlier in table). Provides incentives for development of reduced-risk tobacco products. Establishes DHHS scientific advisory committee. [Sec. 204]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and S. 1492)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
Corporate Culture and Compliance, Lobbyists, and Whistleblowers	Protects industry whistleblowers. [Sec. 802]	Same provisions as S. 1638. [Sec. 802]	Protects industry whistleblowers. Establishes a Tobacco Oversight and Compliance Board, with subpoena power, to monitor industry compliance with all provisions of this Act. [Sec. 101]
Reduction in Underage Tobacco Use			
	Title III	Title III	Title I
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 survey to determine the percentage of individuals under age 18 who used each manufacturer's products within the past 30 days. Sets reduction targets for underage use of cigarettes (by 50% in 5 years, 65% in 7 years, and 80% in 10 years). Sets same reduction targets for underage use of smokeless tobacco products. [Sec. 101]
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]	Requires manufacturers to pay a non-compliance fee of up to \$1.50 for each unit of tobacco product sold if reduction in underage tobacco use does not meet targets. Penalties increase with repeated non-compliance. A manufacturer may have its penalty reduced if it can demonstrate that an arbitrary and capricious survey overestimated youth tobacco use. [Sec. 101]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and S. 1492)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
Environmental Tobacco Smoke (ETS)			
	Title V	Title V	Title III
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]	Amends the Occupational Safety and Health Act to restrict 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, hotel guest rooms, tobacco outlets, and prisons. Prohibits smoking and use of smokeless tobacco products in schools and other facilities serving children. Prohibits smoking on public transportation. Allows state and local governments to enact stricter laws. [Sec. 301]
Tobacco Trust Fund			
	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.* Companies may not use insurance coverage to make payments. [Sec. 101- 102]	

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and S. 1492)			
Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
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]	
Distribution/Allocation of Trust Funds or Excise Tax Revenues			
	Title I	Title I	Title I
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 43% (i.e., 65 cents) of the annual revenues from the \$1.50 per pack excise tax, or approx. \$11 billion a year, as follows: to reimburse state Medicaid accounts and allow each state to retain its federal matching share provided the funds are used for existing child health and welfare programs (similar to S. 1530); to provide approx. \$2.3 billion a year for national and state counter-advertising and smoking cessation programs; to establish tobacco victims compensation fund (approx. \$4 billion a year). [Sec. 101]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and S. 1492)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
Federal/State/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 57% (i.e., 85 cents) of the annual revenues from the \$1.50 per pack excise tax, or approx. \$14 billion a year, as follows: one-half to be awarded as grants for biomedical and basic research; and one-half to be allocated for child health and development research and national programs (e.g., Head Start). [Sec. 101]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and S. 1492)			
Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
Consent Decrees, National Protocol, Non-Participating Manufacturers, Attorneys' Fees, and State Enforcement of Youth Access Laws			
	Title VII	Title VII	
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]	
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]	

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and S. 1492)			
Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
Civil Liability			
	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]	
Industry Document Disclosure			
	Title II	Title II	Title I
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]	Similar provisions to S. 1414. [Sec. 101]
Agriculture and Rural Community Adjustment			
	Title IV	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]	Establishes trust fund from higher excise taxes of an estimated \$13 billion. [Sec. 101, subsection 2815]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and S. 1492)			
Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
Farmer compensation			Provides quota buyout offer to owners (\$4/lb) and tenant compensation offer (\$4/lb) (\$9.2 billion exposure with 100% participation). Maintains quota and price support loan programs. [Sec. 411-414]
Other USDA tobacco activities			
Community & Worker Economic Assistance			Provides annual community economic development grants for 6 years (totaling \$3.8 billion). [Sec. 431]
Immunity Provisions			
Native Americans, State and Local Preemption, International Tobacco Control, Antitrust Exemption, and Smuggling			
	Titles VIII and IX	Titles VIII & IX	Title I
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]	
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]	Allows state and local governments to impose any additional tobacco product control measures that are not inconsistent with the provisions of this Act. [Sec. 101, 204]

Table 1b: Comparison of Tobacco Settlement Bills (S. 1638, H.R. 3474, and S. 1492)			
Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S.1492 (Kennedy)
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]	
Antitrust Exemption			
Smuggling			
Veterans, Vending Machine Owners/Operators, and Asbestos Workers			
		Title X	
Veterans			
Vending Machine Owners/Operators			
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 Proposed Tobacco Settlement (June 20, 1997)

Title	Provisions
I. Tobacco Industry Reformation Marketing and Advertising Warnings, Labeling and Packaging Restrictions on Access to Tobacco Products	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). Amends the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 <i>et seq.</i>) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 <i>et seq.</i>) 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. 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.

Table 2: Summary of Proposed Tobacco Settlement (June 20, 1997)

Title	Provisions
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.
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.

Table 2: Summary of Proposed Tobacco Settlement (June 20, 1997)

Title	Provisions
Non-Tobacco Ingredients Corporate Culture and Compliance	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. 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).
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.

Table 2: Summary of Proposed Tobacco Settlement (June 20, 1997)

Title	Provisions
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).
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. If 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.

Table 2: Summary of Proposed Tobacco Settlement (June 20, 1997)

Title	Provisions
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 labels on drugs and medical devices to bear adequate directions for use. ^a <i>21 CFR §801.126</i>	
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. <i>21 CFR §803.19(f)(g)</i>	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. <i>21 CFR §804.25(c)</i>	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. <i>21 CFR §807.65(j)</i>	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. <i>21 CFR §820.1(e)(f)</i>	Implementation delayed ^c
Youth Access, Labels, and Advertising (Sec. 897) General responsibilities of manufacturers, distributors, and retailers Additional responsibilities of manufacturers Prohibition of sale and distribution to persons younger than age 18	Manufacturers, distributors, and retailers are responsible for complying with all applicable requirements of this regulation. <i>21 CFR §897.10</i> 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. <i>21 CFR §897.12</i> (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. <i>21 CFR §897.14(a)(b)</i>	Implementation delayed ^c Implementation delayed ^c Effective February 28, 1997

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

Section	Provisions	Status
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. <i>21 CFR §897.14(c)(d)(e)</i>	Implementation delayed ^c
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. <i>21 CFR §897.16(a)(b)(c)(d)(e)</i>	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." <i>21 CFR §897.24, 21 CFR §897.25</i>	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. <i>21 CFR §897.30(a)(b)</i>	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." <i>21 CFR §897.32(a)(b)(c)</i>	Implementation delayed ^c

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

Section	Provisions	Status
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. <i>21 CFR §897.34(a)(b)</i>	Implementation delayed ^c
Sponsorship of events	Bans brand-name sponsorship of sporting and other cultural and social events. Only corporate-name sponsorship permitted. <i>21 CFR §897.34(c)</i>	Due to take effect on August 28, 1998

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, pending further instructions from the court (see page 3).

Comparison of Major Elements of Tobacco Proposals

Issue	HEALTHY Kids	Kennedy	Hatch	Proposed Settlement
Payments	Payments of 50 cents/pack in 1999, \$1.00 in 2000, and \$1.50 in 2001. Subsequent payments indexed to medical inflation. Other tobacco products assessed equivalent amounts. Payments do not reduce other tax liability. Total revenue: about \$560 B?	Increase the excise tax by same amounts as HEALTHY Kids payments. These payments are not tax deductible; this effectively makes them 50% higher because manufacturers pay income tax on the payments. Total revenue: \$550 B to Trust Fund plus \$275 B in income tax = \$825 B	Payments of about 67 cents/pack when fully phased in. Total revenue (after adjusting for volume decline): about \$320 B.	Payments of about 62 cents/pack when fully phased in. Total revenue (after adjusting for volume decline): about \$300 B.
Lookback	Industry wide penalties of 10 cents/pack; company specific penalties of up to 40 cents/pack. Penalties double for repeated non-compliance.	Company specific penalties of up to \$1.00/pack. Penalties double for repeated non-compliance. Tougher targets.	Industry-wide penalties of up to 20 cents/pack in first five years; 40 cents/pack thereafter. Rebates for companies that try to reduce teen smoking.	Industry wide penalties of up to 8 cents/pack. Rebates for companies that try to reduce teen smoking.
FDA Authority	Full authority	Full authority	Some restrictions	Many restrictions
Youth Access/Retailers	Requires State licensing and enforces youth access restrictions.	No provision (jurisdictional concern -- Labor vs. Commerce Cmte)	Requires State licensing and enforces youth access restrictions.	Requires State licensing and enforces youth access restrictions.

DISCUSSION DRAFT

Issue	HEALTHY Kids	Kennedy	Hatch	Proposed Settlement
Liability Protections <i>opt out provision</i>	Gives industry immunity from Federal, State and local suits for past misconduct. Settles Castano suits. No special privilege for future misconduct. No special privileges for claims by individuals.	No provision.	Settles all current suits. Broad immunity against all lawsuits: no aggregation or punitives for past misconduct; no aggregation for future misconduct.	Settles all current suits. Broad immunity against all lawsuits: no aggregation or punitives for past misconduct; no aggregation for future misconduct.
Attorney Fees	No payments from settlement funds. Arbitration panel decides payments based on ABA ethical guidelines.	No provision.	Similar to HEALTHY Kids.	No provision.
Farmers	Based on LEAF Act. Preserves tobacco farm program; reimburses farmers for lost quota; rural development, worker retraining, scholarships.	Ends tobacco program. Buys out quota.	Ends tobacco program. Buys out quota.	No provision. (But McCain includes LEAF Act.)
Documents	Turns over relevant documents to FDA. Allows FDA to make documents public. Trade secrets and attorney client privilege protected unless disclosure serves public health interest.	Turns over documents to Board. Attorney client privilege protected unless three judge panel rules that it has been improperly invoked. Regular discovery preserved.	Turns over documents to document depository. Attorney client privilege protected unless three judge panel rules that it has been improperly invoked. No regular discovery.	Turns over documents to document depository. Attorney client privilege protected unless three judge panel rules that it has been improperly invoked. No regular discovery.

DISCUSSION DRAFT

Issue	HEALTHY Kids	Kennedy	Hatch	Proposed Settlement
ETS	Restricts smoking in public places. Exempts Bars, hotel guest rooms, tobaccoists, prisons, casinos and private clubs.	Similar. Exempts bars, hotel guest rooms, tobaccoists, and prisons.	Similar. Exempts bars, hotel guest rooms, tobaccoists, casinos, bingo parlors, and restaurants with fewer than 50 seats. No smoking in prisons.	Similar. Exempts bars, hotel guest rooms, tobaccoists, prisons, casinos, bingo parlors, private clubs, and restaurants other than fast food.
Liggett	Allows Liggett to have its deal with States; exempts it from that portion of payments.	No provision.	No provision.	No provision.
Spending	First makes LEAF payments of \$2.1 B, \$300 M to FDA, and \$200 M to Native Americans. Splits remainder as follows: 25% to Federal Health (NIH research and Medicare); 25% to States (to reimburse Medicaid; Federal share directed to kids' health); 25% to anti-tobacco programs; 25% to Children (early childhood development, education, and/or debt reduction).	43% goes to States and anti-tobacco programs. 57% gets split between health research and early childhood programs. (Note: distribution is not clear.)	Sets aside \$200 M for asbestos, \$200 M for Native Americans, and \$16 B over 25 years for agriculture. Splits remainder: 50% to States, 25% each to anti-tobacco programs and research. No-state portion subject to reduction if victims win suits against industry.	Gives 52% to States. Remainder funds anti-tobacco and trust fund for victims. (Note: allocation is very unclear.)

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	Purpose/ opening statement of bill	Top of 1st page	1	The current statement of purpose is inaccurate. The legislation, particularly the FDA sections, does more than implement the settlement, and many provisions significantly differ from it.	After "Purpose: To" strike out "facilitate implementation of the settlement reached between the Attorneys General of the several States and manufacturers of tobacco products," ; and insert "reduce youth tobacco use and otherwise protect and improve the public health,".	FDA
Technical	Findings	2(18)	8		In finding no. 18, insert "each year" after "60,000 deaths"	DOJ
Technical	Findings	2(25)	10		In finding no. 25, strike "sales to" and replace with "use by"	DOJ
Technical	Findings	2(30)	11		In finding no. 30, strike "will accomplish" and replace with "can accomplish:	DOJ
Technical	Purpose	3(8)	13	FDA already has authority to regulate tar.	In line 10, strike "provide," and insert "confirm". In line 10-11, strike "Administration with the" and insert "Administration's".	FDA

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	Purpose	3(9)	13	Bill allows privilege assertions, so it does not require disclosure of all research	In purpose no. 9, strike both uses of the word "all"	DOJ
Technical	Non-Preemption	5(b)	18	FDCA section 521 and section 751, et seq, apply, respectively, to devices and over-the-counter drugs and cosmetics. This sentence is unnecessary (but is probably not detrimental to the agency).	In lines 12-19, strike sentence beginning with "Section 521 . . . tobacco products."	FDA

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	Definitions	6	18-23	General issue: this section defines terms that are used throughout the document. It would be advisable to check each usage of the defined terms to ensure that the definition here is appropriate for each usage.	Review of entire document is suggested.	FDA
Technical	Definitions	6	18-23	A number of the definitions, (4) distributor, (8) manufacturer, (10) package, (11) point of sale, (12) retailer, are limited to cigarettes and smokeless tobacco. This may not be appropriate for all uses of the terms in the document.	If appropriate for entire bill, delete "cigarettes and smokeless tobacco" and insert "tobacco products".	FDA

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	Definitions	6	18-23	With respect to FDA, some of this definitions are inconsistent with FDA usage, either in its regulations or as generally understood under the FDCA.	Page 18, line 21, after "In", insert "I titles I.B. - XI of". (This change would exclude title I.A., the FDCA section)	FDA
Technical	Definitions issues	6(2)	19	Definition of "cigarette tobacco" is inconsistent with definition of "cigarette".	Line 14, strike "contains or delivers nicotine and".	FDA
Technical	Definitions	6(1)	19	Definition of brand may not be sufficiently broad to carry out the intention of the bill	Page 19 line 1, strike "or packaging," and replace with "packaging, logo, registered trademark or brand name, identifiable pattern of colors,"	CDC
Technical/ Policy	Definitions	6(1)	19	Definition of cigarette leaves out related products that could be used by manufacturers as a vehicle for advertising	Page 19 line 11, strike, "cigarette." and replace with "cigarette, and includes cigarette tubes and cigarette sticks."	CDC

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	Definitions	6(12)	21	Retailer definition refers to protocol unnecessarily	Lines 15-17: strike text after "permitted under" and insert "pursuant to the Federal, Food, Drug, and Cosmetic Act, as amended by this Act."	FDA
Technical/ Policy	Definitions	6(10)	21	Definition of package leaves out products with health effects to which packaging and labeling provisions should apply	Page 21 strike lines 4 to 5 and replace with "pack, box, carton, container of any kind or, if no other container, any wrapping including cellophane, in which tobacco products are offered for sale,"	CDC
Technical	Definitions	6(13)	21	Definition of roll-your-own is inconsistent with that of cigarette tobacco; doesn't explicitly state that it is subject to requirements for cigarettes	Page 21 line 23 add "Unless otherwise stated, the requirements for cigarettes shall also apply to roll-your-own tobacco."	CDC

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(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical/ Legal	Definitions	6(17)	22	Definition of "tobacco product" is not consistent with FDCA definition.	Lines 17-19, strike "cigarettes . . . fine cut products." and insert "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."	FDA
Technical	I.A., FDA	101 FDCA 902 (a)(1)	27	4/1 Committee amendment should have added a clause (agreed upon with Frist staffer).	Line 10, before the semicolon, insert "or is otherwise contaminated".	FDA
Technical	I.A., FDA	101 FDCA 902 (a)(5)	27	technical	Line 23, insert after "910", "(a)"	FDA
Technical	I.A., FDA	101 FDCA 902 (a)(7)	28	technical	Line 19, strike "90--(xx) [investigational]" and insert "906(f)".	FDA

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	I.A., FDA	101 FDCA 903 (a)(10)	33	Need misbranding provision that includes violations of section 904.	Line 3, after "section" insert "904 or"	FDA
Technical	I.A., FDA	101 FDCA 903 (a)(10)	33	Need misbranding provision that includes violations of section 904.	Line 3, after "section" insert "904 or"	FDA
Technical	I.A., FDA	101 FDCA 904 (a)(2)	33	Wording	Line 21, as amended, strike "nicotine", and after "content, delivery, and form of" insert "nicotine of".	FDA
Technical	I.A., FDA	101 FDCA 905(j)	42	4/1 Committee amendment contained error. The changes were agreed upon with Frist staffer.	Line 7, after "marketed" insert "(other than for test marketing)". Line 8, strike "the date of enactment of the Tobacco Product Control Act of 1998" and insert "August 11, 1995,".	FDA

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	I.A., FDA		47	Conforming amendment re: information that applicants for exemptions must include in applications	Line 20, after "required" insert "for the protection of the public health and"	FDA
Technical/ policy	I.A., FDA	101 FDCA 906 (e)(2)(C)	48	In device law, this provision includes consideration of whether the GMP requirement is necessary for a reasonable assurance of safety and efficacy. The public health should be considered in the context of exemptions for tobacco products.	Line 24, after "required" insert "for the protection of the public health and".	FDA

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	I.A., FDA	101 FDCA 913 (a)(3)	80	As written, designation by the Secretary as being a reduced risk product is not required to market it as a reduced risk product.	Lines 21-24, as amended, renumber (A) and (B) as (B) and (C). Insert before line 21: “(A) has been designated as a Reduced Risk Tobacco Product by the Secretary under paragraph (2);”.	FDA
Technical	I.A., FDA	101 FDCA 914 (a)(3)(B)	85	The intent of this provision was to include advertising restrictions. The wording should parallel the express reference to advertising in the 906(d).	Line 21, insert at the end before the period “, including the requirements related to the access to, and the advertising and promotion of a tobacco product”.	FDA
Technical	I.A., FDA	102(b)	91	Need a prohibited act provision that includes violations of section 904.	Line 3, after “section” insert “904 or”	FDA
Technical	I.A., FDA	102(j)(2)	93	technical	Line 13, strike “(I)” and insert “(j)”; Line 14, strike “90—” and insert “905”.	FDA

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	I.A., FDA	102(l)	95	Conforming changes to one paragraph of the FDCA export provision were not included in original draft.	Lines 3-11, renumber paragraphs (4) - (6) as (5) - (7). Line 2, insert a new (3) as follows— (3) In the paragraph that follows the new (3)(B), insert "or tobacco product" after "device" each time it appears; insert "or Section 801(e)(4)" after "801(e)(2)"; insert "or 910" after "515"; and insert "device, or tobacco product" after "drug" in the last sentence of the paragraph.	FDA
Technical	I:B Advertising	122 (a)(1)(E)	97	Bill does not, as drafted, require manufacturers to comply with FDA regulations	At the end of subsection (E), add "and implementing regulations."	DOJ
Technical	II A	202(a)	104	Does not use correct term to describe underage tobacco use in sentence that requires Secretary to determine percent "incidence" of underage tobacco use.	Substitute "prevalence" for "incidence." Incidence only includes new tobacco users while prevalence includes all users.	ASPE/ HHS

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	II	202	104-105	Requires use of University of Michigan "Monitoring the Future" survey (or survey with same methodology) to measure underage tobacco use.	Strike 202(a) and insert: "Determination of Underage Use. – The Secretary shall conduct an annual performance survey of underage tobacco use; such survey shall comply with the following requirements: ▶ be based on a nationally representative sample of at least 20,000 completed interviews of young individuals to assure sufficient survey precision. ▶ be a household-based, in person survey. ▶ measure use of each type of tobacco product within the past 30 days. ▶ identify usual brand of each type of tobacco product used within the past 30 days. ▶ permit the calculation of the actual percentage reductions in underage use of a type of tobacco product (or, in the case of the manufacturer-specific surcharge, the use of a type of tobacco product of a manufacturer) based on the point estimates of the percentage of young individuals reporting use of a type of tobacco product (or, in the case of the manufacturer-specific surcharge, the use of a type of tobacco product of a manufacturer) from the annual	ASPE/ HHS

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical (continued)	II	202	104-105	Requires use of University of Michigan "Monitoring the Future" survey (or survey with same methodology) to measure underage tobacco use.	[continued from above] type of tobacco product of a manufacturer) is such that the 95% confidence interval around such point estimates is no more than + or - 1%. A survey using the foregoing methodology shall be deemed conclusively proper, correct, and accurate for purposes of this Act. Further, the Secretary by notice and comment rulemaking may subsequently adopt a different survey methodology so long as the different methodology is as statistically accurate as the methodology described above and prescribed by this Act."	ASPE/ HHS
Technical	II	202	104-105	No language that protects confidentiality of data and respondents.	Page 105, before line 12 (b), insert: " If the information collected in the course of conducting the annual performance survey results in the young individual supplying the information or described in it to be identifiable, such information may not be used for any purpose other than the purpose for which it was supplied unless such young individual (or such individual's guardian) has consented to its use for such other purpose. Such information may not be published or released in other form if the person supplying the information or described in it is identifiable unless such young individual (or such individual's guardian) has consented to its publication or release in other form."	ASPE/ HHS

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	IIA	202(b)(2)	106	Incorrect amount in table on non-attainment penalty for smokeless tobacco: if non-attainment percentage is not more than 5%, the penalty is "\$8,000,000, multiplied ..."	Table between lines 6 and 7, strike "\$8,000,000" and insert "\$80,000,000."	ASPE
Technical	IIA	202(b)(2)	106	Incorrect amount in table on non-attainment penalty for smokeless tobacco: if non-attainment percentage is more than 5% but not more than 10%, the penalty is "\$40,000,000 plus \$16,000,000..."	Table between lines 6 and 7, strike "\$40,000,000" and insert "\$400,000,000"; strike "\$16,000,000" and insert "\$160,000,000."	ASPE
Technical	IIA	202(b)(2)	106	Incorrect amount in table on non-attainment penalty for smokeless tobacco: if non-attainment percentage is more than 10% but not more than 20%, the penalty is "\$120,000,000 plus \$24,000,000..."	Table between lines 6 and 7, strike "\$120,000,000" and insert "\$1,200,000,000"; strike "\$24,000,000" and insert "\$240,000,000."	ASPE

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	IIA	202(b)(2)	106	Incorrect amount in table on non-attainment penalty for smokeless tobacco: if non-attainment percentage is more than 20%, the penalty is "\$350,000,000."	Table between lines 6 and 7, strike "\$350,000,000" and insert "\$3,500,000,000."	ASPE
Technical	II	202(b)	105-106	Two sections	Page 106 line 1 delete "(2)" and substitute "(3)" line 7 delete "(3)" and substitute "(4)".	
Technical	IIA: Reduction in Underage Tobacco Use	202	106	Inflation adjustment to lookback assessment	Lookback penalties must be inflated to stay constant in real terms. So add: (5) INFLATION ADJUSTMENT - The amounts referred to in sections (2), (3), and (4) shall be increased by the greater of 3 percent or an increase in the Consumer Price Index for all urban consumers for the prior year, from year 1 onwards.	TR
Technical	II: Reduction in Underage Tobacco Use	202(d)	107	Late Payment Charges	The late payment charge seems unduly onerous for failure to satisfy a financial obligation. If that is what Congress intends it should prescribe a specific penalty rather than leave it to regulations prescribed by the Secretary.	TR
Technical	II: Reduction in Underage Tobacco Use	202(c)(4)	107	Exemption for Small Manufacturers	Clarify that an exempt manufacturer's share is excluded in applying the allocation formula to other manufacturers by adding the following sentence at the end of (c)(4): Such manufacturer's products shall be disregarded in applying paragraph (3).	TR

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(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	II	202(g)	109	Two Sections 202(f)	Line 4 delete "(f)" and insert "(g)"	
Technical	II: Reduction in Underage Tobacco Use	202 and 203	110	Consequence of nonattainment in excess of 20 percent	Loss of liability protection should be determined on a manufacturer-by-manufacturer rather than a brand-by-brand basis. In addition, it is impossible to determine whether a given company caused the industry to miss its target by more than 20%. Thus, should replace 203(a)(1) with: "If the Secretary determines that the non-attainment percentage for cigarettes is greater than 20 percentage points for any cigarette manufacturer, measured as the average percentage prevalence of use of all brands manufactured by that manufacturer, the Secretary may commence an action under this section against that tobacco product manufacturer..." [meke same change for smokeless].	TR
Technical	II.A. reductions in underage use	203(d)	112	technical	Lines 5-10, strike "-- (1)" and move up text flush with rest of paragraph. Line 10, strike "; and" and insert a period at the end.	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical/Policy	II	204	117	The term "cigarette manufacturers" does not include potential new manufacturers entering the marketplace.	Strike paragraph 4 (lines 4-6). Insert: "The term 'cigarette manufacturer' means any person who manufactures or imports a tobacco product. (1) "EXISTING MANUFACTURER.-- The term 'existing manufacturer' means a manufacturer which manufactured or imported a tobacco product on or before the date of the enactment of this title. (2) "NEW MANUFACTURER.--The term 'new manufacturer' means a manufacturer which begins to manufacture or import a tobacco product after the date of the enactment of this title."	
Technical	II	204	119	The term "total underage population" does not include persons age 12. The age of onset of tobacco use is often younger than 13.	Line 13: strike "aged 13" and substitute "aged 12."	

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	II.C. reductions in underage use	221	128	Need to make it clear that approval of cessation products is only for purposes of payments, and to include cessation products that are not devices.	Subsection (c)(1), line 4, strike "product"; Subsection (c)(2), line 8-9, strike "product"; Line 10, strike "product" insert "use" and strike "device" and insert "product"; Line 15, strike "device" insert "product"; Subsection (d), line 19, insert after "approval" "for purposes of subsection (c)"; Line 20, strike "devices" insert "products"; Line 22, strike "safe" insert "appropriate"; Line 23, strike "devices" insert "products".	FDA
Technical /Policy	2 II.C	235	134	State retail licensing program	Clarify that this block grant is within the "State share" by amending 235(a)(1) to read "ESTABLISHMENT OF PROGRAM.—The Secretary shall provide a block grant under this Act, <u>from the funds available under Title IV in the State Litigation Settlement Account</u> , to each State that has in effect....	HHS/ASMB
Technical	2	221, 222, 223	p 136-134	Public health programs	Revise language to be new sections in the Public Health Service Act.	HHS/ASMB
Technical	II.C. reductions in underage use	235©	137	As worded, could be construed to suggest Congressional intent to limit federal enforcement of the FDA Tobacco Rule.	Page 137, lines 7-8, subsection (c): replace "Federal program of license requirements, enforcement measures, and penalties" with "Federal retail licensing program."	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	III, Tobacco product warning and smoke constituent disclosures	303-304 CSTHE Act	147-151	The text of the bill is ambiguous as to whether the portions of CSTHEA section 3 that are not amended by section 303 or 304 remain in effect. Section 3(f) is the media ad ban. Subsections (c), (d), and (e) are not expressly repealed and are inconsistent with (a) and (b) as amended.	Page 151, line 5, after "further amended" strike "by adding at the end the following" and insert "by deleting subsections (c), (d), and (e), renumbering subsection "(f)" as "(d)", and by adding after (b) the following:" Page 151, line 7, replace "(d)" with "(c)".	FDA
Technical	III, Tobacco product warning and smoke constituent disclosures	303 CSTHE Act § 3 (a)(2)(B)	148	technical	Line 7, after "subsection" insert "(b)(3)".	FDA
Technical	III, Tobacco product warning and smoke constituent disclosures	305	153	Subparagraph © could be read to limit FDA authority.	Line 7, after "except" insert "unless otherwise required under the Federal Food, Drug, and Cosmetics Act.".	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	III.B. Tobacco product warning and smoke constituent disclosures	311	153	12 months is not adequate time to promulgate regulations for testing, reporting, and disclosure or smoke constituents.	Line 20, strike "12" and insert "24".	FDA
Technical	IV: National Tobacco Settlement Trust Fund	401(a)(2)	155	Bill appoints Commissioner of FDA as trustee of trust fund along with the Secretary of HHS, and AG	On page 155, line 12, strike "Commissioner, the Secretary, and the Attorney General." and insert "the Secretary and the Attorney General."	HHS/ ASMB
Technical	Title IV: National Tobacco Settlement Trust Fund	401 (a) (1)	P. 155, as amended by technical package.	The bill states that " <u>None</u> of the funds in the account [State Litigation Settlement Account] shall <u>not</u> be available to the Secretary as reimbursement of Medicaid expenditures."	Delete "not" to fix double-negative statement.	OMB

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	Title IV: National Tobacco Settlement Trust Fund	401 (a) (1), as amended by technical package	P.155	The bill creates a \$196.5 billion "State Litigation Settlement Account," but does not give a year-by-year funding stream or specifically indicate how these funds would be allocated to the States. Sec. 401 (c) (1) states that these funds "shall be as provided in the Master Settlement Agreement," but it is not clear if this document would address formulas or year-by-year allocations.	The Administration has already stated its views on the appropriate funding level for unrestricted grants to States and State funding formulas. Even if the Committee does not address the Administration's views, however, the bill should at least indicate a year-by-year funding stream and provide a basis for state-by-state allocation. This could be accomplished by specifying a % of each year's funds that would be available.	OMB
Technical	IV. National Tobacco Settlement Trust Fund	401 (b) (1)	P. 155	Section 205 referenced in Section 401 (b) (1) is missing.	Need to see the content of Section 205 in order to understand what the sections on transfers to the Settlement Trust Fund means.	OMB

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(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	IV: National Tobacco Settlement Trust Fund	401 and 408	155 and 172	Transfers between Trust Fund and General Fund	The Trust Fund should be required to transfer to the General Fund amounts equal to the revenue loss attributable to offsetting reductions in excise and income taxes. Also, Treasury's administrative costs should be reimbursed. Add at the beginning of (d)(2) "Except as provided in paragraph (3)," and add a new paragraph (3) providing: Each month the Tobacco Settlement Trust Fund shall transfer to the general fund of the Treasury an amount, as determined by the Secretary of the Treasury, equal to the reduction in tax revenues attributable to payments to the Trust Fund in the preceding month. Add a second sentence to section 409, identical to the first sentence except that the appropriate dollar amount is substituted for \$300,000,000 and the Secretary of the Treasury is substituted for the Commissioner of the Food and Drug Administration.	TR
Technical	IV: National Tobacco Settlement Trust Fund	402	158	Trustees' Responsibility	Why are trustees acknowledging and agreeing in a statutory provision? Isn't it enough to state the rule that nobody else has any responsibility? The reference to the trustees acknowledgment and agreement should be deleted.	TR
Technical	IV. National Tobacco Settlement Trust Fund	402 (c)	P. 158	The trust language needs to be clarified.	It is unclear in Sec. 402 (c) who the trustees are holding this fund "in trust" for. Federal trust funds are not generally considered to be the same as the private sector usage of the term. If something more is intended than to have the term "trust" be a label, it needs to be made clear.	OMB

TECHNICAL COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/14/98

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	IV. National Tobacco Settlement Trust Fund	402 (b)	P. 158	The timing of annual payments by tobacco manufacturers to the Tobacco Trust Fund is unclear.	Language needs to be revised to clarify when Year 1 begins. Is it the first one-year period that begins right after the date of enactment i.e., if the bill is enacted on 9/1/98, does the first year run from 9/1/99 to 8/31/2000? Year 1 needs to be FY 1999.	OMB
Technical	IV: National Tobacco Settlement Trust Fund	402	159	Apportionment of Annual Payment	The formula doesn't work. If each manufacturer is paying one-third of its annual share on each payment date, then the share can't be redetermined for each payment date. Revise (3) to read as follows: "Each annual payment due under subsection (b) shall be payable in three equal installments due on March 1, June 1, and September 1. Each participating manufacturer shall be liable for its share of each installment in proportion to its relative market share of tobacco products sold in the domestic market for the most recent available calendar quarter, as determined by the Administrator not more than two months or less than one month before the payment is due [retain last sentence]."	TR

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	IV: National Tobacco Settlement Trust Fund	402 and 403	158 and 161	Indexing	We believe that the intention of this section is to fund a stream of payments that achieves a year by year price increase of \$.65/\$.70/\$.80/\$1.00/\$1.10 and then fixes the fifth year revenue number of \$23.6 billion in real terms into the future. To do so, three changes are needed: 1) The \$21.0 billion in year 4 in the bill should be changed to \$21.4 billion. The \$21.4 billion figure is the correct number based on the bill's price-per-pack stream. 2) The payment for year 5 should be \$23.6 billion; strike 402(b)(6) which sets a payment of \$21 billion for year 6. 3) For subsequent years, the payment should be the payment for the preceding year increased by the greater of 3 percent or the CPI increase for the preceding year. Page 161 of the chairman's mark, line 20-22 should therefore read: "... The annual base amount payment for year 6 <u>and beyond</u> shall be increased pursuant to this paragraph."	TR HHS/ ASMB OMB

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(Comments on text "TABAC.1"--3/29/98 8:46 pm; "LIABILITY.1" and "S1415.TEX.1")

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	IV: National Tobacco Settlement Trust Fund	402	159	Term "units of tobacco products" on line 6 has not been defined.	Clarify how "units" are to be defined in this section as follows. Market share should be determined by quantities sold rather than gross receipts. Treat one pack of cigarettes as the basic unit and prescribe a weight equivalent to a pack of cigarettes for other tobacco products. Appropriate weights are: 20 small cigarettes = 1 base consumption unit 20 large cigarettes = 2.1 base consumption units 20 small cigars = 1 base consumption unit 1 large cigar = 1.3 base consumption units per ounce 1.2 ounces of snuff = 1.6 base consumption units 3 ounces of chewing tobacco = 4 base consumption units 1.5 ounces of pipe tobacco = 2 base consumption units 1.5 ounces of roll-your-own tobacco = 2 base consumption units	TR/ OMB
Technical	IV. National Tobacco Settlement Trust Fund	403 (a) (2)	P. 162	The term "base volume" in line 2 is not defined adequately.	A definition of "base volume" is needed in order to know how "volume adjustments" section would work.	OMB

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	IV: National Tobacco Settlement Trust Fund	408(a)	166	Establishes that the Trust Fund shall be held by the Attorney General	On page 166, line 24, strike "Attorney General as a Trustee" and insert "Secretary and Attorney General as Trustees"	HHS/A SMB
Technical	IV. National Tobacco Settlement Trust Fund	408 (d) (2)	P. 172	No transfers would be permitted to or from the Tobacco Trust Fund with Treasury's General Fund.	Strike 408 (d) (2), since retaining it would mean that the Tobacco trust fund could not earn interest on its holding of Treasury securities. It also would mean that the Trust Fund could not fund programs outlaid from another account in the budget.	OMB
Technical	IV, trust fund	409	172	technical	Line 12, strike "the Food and Drug Administration" and insert "Food and Drugs". Line 13, before "Administration" insert "Food and Drug".	FDA
Technical	V: Involuntary Exposure to tobacco smoke	501 (1) 503 (a) & (e) 505	174-179	Need to use the correct term for the director of OSHA.	Replace term "Administrator" throughout the document with "Assistant Secretary." Amend definition to read as follows: " The term Assistant Secretary means the Assistant Secretary of the Occupational Safety and Health Administration, U.S. Department of Labor. "	

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	V: ETS	501 (2)(a) (A)-(B)	174	The definition of "public facility" will raise a concern regarding Congress' power under United States v. Lopez unless a jurisdictional limitation on intrastate commerce is included	Line is "any building" the phrase "that is used for purposes that affect interstate or foreign commerce and that is." Also, to clarify the exclusion for residential buildings, strike the phrase " "other than . . . residential purposes" from subsection (A) and insert the phrase "used for residential purposes or into subsection (B) immediately following "which is."	DOJ
Technical	V	501(2)(C)	175	A non-controversial definition of "fast food" and "family-style" restaurants is easily inserted in this bill rather than deferring to a potentially lengthy rulemaking process. The definition needs clarification to ensure that restaurants frequented by children are not excluded from the Title's requirements.	Amend to read as follows: "(C) Fast food and family-style restaurants. The terms "fast food restaurant" and " family-style restaurant "refer to any cafeteria , restaurant or chain of restaurants that primarily distribute food through a customer pick up (either at a counter or drive-through window), or establishments where at least 40% of the patrons are less than 18 years of age, or the average length of the meal is an hour and a quarter or less. "	

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	V	502 (C)(1)	176	The definition of Direct Exhaust Ventilation is easily included in the bill rather than deferring to a potentially lengthy rulemaking process.	Insert: "Direct exhaust ventilation is a dedicated system that exhausts contaminated air from a designated smoking room in such a way that it is transported to the outside of the building, through exhaust ducts under negative pressure to avoid duct leakage into nonsmoking areas that the duct passes through."	DOL
Technical	V	502 (c)(2)	177	A non-controversial definition of Negative Pressure is easily included in the bill rather than deferring to a potentially lengthy rulemaking process.	Insert: "Negative pressure is achieved by exhausting more air from the space than is supplied to the space in quantities sufficient to induce air flow into the room. Transfer air must enter the designated smoking room to make up the volumetric flow rate differential between supply and exhaust air. It may be necessary to provide a tight architectural enclosure so as to achieve negative pressure and containment. Containment may be checked by using smoke trails or continuous monitoring devices to verify direction of air flow."	DOL
Technical	V	503(f)	174-179	Need to renumber section for consistency.	Change 503(f) to 503(e).	DOL

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	V	506	179	Need to change this section to make it consistent with the deletion of section 507.	Amend to read as follows: "The provisions of this title shall take effect one year from the date of enactment. "	DOL
Technical	VI: Application to Indian Tribes	603(a)	180	Provision states that the Act's provisions will apply to tobacco manufacturing, distribution and sales within boundaries of Indian reservations or lands.	Provision was amended to clarify that "Indian reservation boundaries or lands" would have the same meaning as contained in 18 USC 1151 , i.e. " <i>Except as otherwise provided in sections 1154 and 1156 of this title, the term "Indian country", as used in this chapter, means (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state, and © all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.</i> " 18 USC 1151 definition is more precise in determining those conditions identifying lands over which tribes have civil authority, and would specifically include dependent Indian communities such as those in the State of Oklahoma	IHS / HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	VI, Indian tribes	603	181	technical	Line 21, strike "chapter IX" and insert "the provisions"; Line 22, before the period, insert "for tobacco products."	FDA
Technical	VII, civil liability	701(16)	VII: 4	Is not consistent with FDCA provisions on reduced risk products.	Strike lines 13-14, and insert "a product so designated by the Secretary pursuant to section 916(a)(2) of the Federal Food, Drug, and Cosmetic Act, and in compliance with section 916."	FDA
Technical	VII, civil liability	702(b)(7)(A)	VII: 10	Prohibited acts for tobacco products in FDCA are not in chapter IX.	Lines 15-16, strike "of chapter IX".	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	VII, civil liability	705 (d)(1)	VII: 13	The provision for future reduced risk products is ambiguously worded and could be used to provide greater protection than intended. It would be preferable to allow state common law to be applied.	Strike lines 16-22; Line 14, strike "requirements" and insert "requirement"; Line 15, strike "apply" and insert "applies"; Line 23, strike "(2)".	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	VIII compliance	801	191-193	The responsibilities of this section (establishing an accountability panel) are more appropriately vested in the HHS Secretary than the FDA Commissioner.	Page 191, line 12, strike "Commissioner of the Food and Drug Administration" and insert "Secretary"; Page 191, line 21, strike "Commissioner" and insert "Secretary"; Page 191, line 24, strike "Commissioner" and insert "Secretary"; Page 192, line 1, strike "Commissioner" and insert "Secretary"; Page 192, line 6, strike "Commissioner" and insert "Secretary"; Page 192, line 23, strike "Commissioner" and insert "Secretary"; Page 193, lines 9-11, strike "Commissioner" and insert "Secretary" each time it appears.	FDA
Technical/ legal	VIII compliance	802 (a)(1)	194	Notification to the Attorney General should also be included within the scope of the provision.	Line 21, after "Drugs," insert "the Attorney General,".	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical/ legal	IX, document disclosure	903©	206	Provision regarding future documents raises workability issues (there are also legal issues as well). Paragraph (3) is too narrow	If retain: Strike lines 8-9, and insert "the depository in accordance with a schedule established by the Board the following documents:". Line 23, strike "and the use of tobacco products by".	FDA
Technical	IX, document disclosure	908(f)	215-16	technical	Page 215, Line 21, after 903(b) insert "or 903(c)"; Line 25, before "Administration" insert "Food and Drug"; Page 216, Line 7, before "Administration" insert "Food and Drug" ; Line 11, before "Administration" insert "Food and Drug"; Line 16, before "Administration" insert "Food and Drug".	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	IX, document disclosure	909(a)	216-17	Redundant of 908(f) and wording is problematic.	Strike line 23, page 216, - line 20, page 217.	FDA
Technical		1106 PHSA 2802	315	Study Considerations	Add: (F) economic research relating to the responsiveness of youth smoking to price and other economic factors.	TR
Technical Policy	XI -Misc.	1106(a) (2802 of the PHS Act)	317	<u>National Tobacco Task Force</u> : Bill provides for a National Tobacco Task Force to foster coordination regarding tobacco-related research activities. The task force is chaired by the Director of CDC. The Director of NIH sits on the Task Force.	Amend § 2802(c). Strike in line 6 "the Director of the Centers for Disease Control and Prevention" and replace with "the Secretary." As the lead Department in the Federal government engaged in health research related to tobacco, the Secretary is the most logical individual to chair the Task Force. Various OPDIVS are engaged in tobacco-related research (as indicated by the various members of the Task Force), and have different contributions and perspectives to bring to the work of the Task Force. Thus, we believe it appropriate for the Secretary to chair the Task Force and the head of each relevant agency to sit as a member.	HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical	XI -Misc.	1106(b) (1707(b) of the PHS Act)	324	<u>Research on Minority Smoking and Tobacco- Related Diseases.</u> -	Bill appears to replace the current varied duties of the Office of Minority Health with tobacco-related activities only. Should be redrafted so that tobacco-related activities are added duties.	HHS
Technical	XI: Misc.	1145	348	Prohibitions on manufacture without a permit	Clarify that prohibition does not apply to foreign manufacturers selling abroad.	TR
Technical	XXVIII. National Efforts to Reduce Youth Smoking; Subtitle F	1171-1174	P. 357- 362	The minority health provisions in sections 1171-1174 include funding items for grants to States, tobacco cessation, and counter advertising. The funding in terms of percentages of a currently unspecified section 101 (d) (5) (C).	The contents of the unspecified section 101 must be made available in order to understand what are the funding levels for these minority health programs.	OMB
Technical	Subtitle G: Sense of the Senate	1181	362	support for tobacco- related health research activities	line 23, insert "services" after health	HHS

DRAFT

MARCH 17, 1998

Provision	Harkin/Chafee (S ____)	Conrad (S 1638)	Hatch (S 1530)	McCain (S 1414)	Kennedy (S 1492)	Jeffords (S 1648) Revised
Goals/ Targets	-Yearly reductions in youth tobacco use up to 65% in year 10 -Industry and firm targets -incentives for states to meet targets	-Cigarette consumption reduction of 67% by 2008 -Smokeless consumption reduction of 45% by 2008 -Industry and firm targets	-Cigarette consumption reduction of 60% in year 10 -Smokeless consumption reduction of 45% in year 10 -Industry targets -Incentives for exceeding targets	-Cigarette consumption reduction of 60% in year 10 -Smokeless consumption reduction of 45% in year 10 -Industry targets	-Tobacco use reduction of 80% by year 10 -Firm targets	-Cigarette consumption reduction of 60% in year 10 -Smokeless consumption reduction of 45% in year 10 -Firm targets -Incentives for exceeding targets
Measures	-Survey based on past 30 day use	-New Survey based on brand use in past 30 days	-Uses MTF -Based on daily use	-Uses MTF -Based on daily use	-New survey based on brand use in the past 30 days	-Uses MTF -Based on past 30 day use
Surcharges	-Industry wide flat surcharge -Company specific flat surcharge -Non-tax deductible -No abatement	-Industry wide flat surcharge -Escalating company specific surcharge -Surcharge increases with consecutive years of noncompliance -No penalty adjustments -No caps on penalty -Judicial review allowed	-Industry wide escalating surcharge -Adjustments in penalty allowed -Caps on penalties -abatement rebates allowable	-Industry wide flat capped surcharge -Adjustments in penalty allowed -Caps on penalties -abatement allowable	-Company specific escalating surcharge -No penalty adjustments -Surcharge increases with consecutive years of noncompliance -No cap -Judicial review of penalties	-Company specific escalating surcharge -Adjustments in penalty allowed -No cap -Abatement allowable
Price Increases/ Revenue Sources	-\$1.50 per pack increase in two installments (\$1.00 the first year, \$.50 the second year) -Annual industry payments totaling \$20 billion in year one and \$25 billion annually thereafter -Initial payment of \$10 billion -Non-tax deductible	-Estimates based on a \$1.50 per pack increase in three installments and a \$15 billion up-front payment -Non-tax deductible	-Trust fund w/State and Federal accounts -\$408 billion over 25 years -Initial payment of \$10 billion -Tax deductible	-Creates a National Tobacco Settlement Trust Fund in the U.S. Treasury -Tax deductible	-\$1.50 per pack increase/ 3 year phase in -Includes net revenues of \$67 billion over 5 years -Non-tax deductible	-Tobacco Settlement Trust Fund -Payment amount not specified

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Provision	Harkin/Chafee (S ____)	Conrad (S 1638)	Hatch (S 1530)	McCain (S 1414)	Kennedy (S 1492)	Jeffords (S 1648) Revised
NIH	-National Fund for Health Research -\$3.2 billion annually	-\$1.1 billion in 1999, increasing to \$4.5 billion in 2001 for NIH research activities	-NIH Trust Fund for Health Research -\$2.1 billion in the first year, \$4 billion in year 5 and thereafter, \$95 billion over first 25 years	No provision.	-\$1.57 billion in 1999, increasing to \$4.53 billion in 2001 for basic research	-\$2.5 billion annually for 10 years to NIH
State Funding	-\$193.5 billion over 25 years for States. -\$500 million annually for "Performance Bonus Pool" for states that meet or exceed the reduction targets	-Programs funded directly	-No less than 50% of public health funds available to states for anti-tobacco use and cessation.	-\$25 billion, to be paid over 8 years (\$17.5 billion over the first five years), then \$2.5 billion annually thereafter to reimburse states for tobacco related expenditures.	-\$1.1 billion increasing to \$1.8 billion by 2009	-Programs funded directly
Cessation	-\$1.5 billion when fully implemented	-Provides \$884 million in 1999; \$650 million in 2001	-No specific amount provided	-First 4 years, \$1 billion, thereafter, \$1.5 billion -Trust Fund used to assist individuals who want to quit	-Included in State block grants	\$1 billion increasing to 1.5 billion in 2008, terminating in 2009, for State and Community Cessation Programs
Counter-Advertising	-\$750 million annually for a nationwide campaign with national, state and local components.	-\$669 million in 1999; \$490 million in 2001, for media counter-advertising and non-media prevention and cessation campaign.	-No specific amount provided	-\$500 million to be spent annually	-\$500 million annually for Federal campaign	-\$500 million annually for 10 years
Funding for Regulation and Enforcement	?	-\$300 million for FDA tobacco outreach and enforcement activities	-No specific amount provided	-\$300 million annually for FDA enforcement	-\$300 million for FDA tobacco outreach and enforcement activities	-\$100 million for regulation and control of tobacco products

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Provision	Harkin/Chafee (S ____)	Conrad (S 1638)	Hatch (S 1530)	McCain (S 1414)	Kennedy (S 1492)	Jeffords (S 1648) Revised
International tobacco control	- \$100 million annually for global education efforts. - Terminates support for tobacco promotion overseas by the US Government. - \$300 million to strengthen federal anti-smuggling activities, domestically and internationally	- \$54 million in 1999 (\$40 million in 2001) for governmental programs - \$27 million in 1999 and \$20 million in 2001 for non-governmental programs.	No provision	No provision	No provision	No provision
Medicaid	- Not clear	- 4% of the overall settlement amount will go towards Medicaid outreach	No provision	No specified activity	No specified activity	No specified activity
Child Care and Development	- Not clear	- Expansion of CDCRG	No provision	No provision	- Expansion of CDCRG	No provision
Protection of Farmers	- \$15 billion for compensation, income support and traditional assistance to tobacco farming families, and for economic development and related assistance	- \$2.46 billion in 1999 (1.91 billion in 2001) for agricultural community revitalization	- \$3.1 billion in year one; \$6.2 billion in year three; and \$16 billion over 25 years - Terminates the federal tobacco programs while making compensation to quota owners and tobacco farmers	- \$2.1 billion annually from 1999 to 2008 and \$500 million annually from 2009 to 2023 for tobacco quota buyouts and assistance to tobacco communities	- \$3 billion annually for quota buyouts from 1999-2001 - \$500 million annually in 1999 and 2000 then \$800 million annually from 2001 to 2003, and \$400 million in 2004, for tobacco community transition assistance block grants	No provision
Event Sponsorship	- Not clear	- \$27 million in 1999 (\$20 million in 2001) to compensate events, teams, or entries in events, who lose sponsorship by tobacco industry	No provision	- \$75 million annually for 10 years to compensate events, teams, or entries in events	- Included in State tobacco block grants	No provision

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MARCH 17, 1998

Provision	Harkin/Chafee (S ____)	Conrad (S 1638)	Hatch (S 1530)	McCain (S 1414)	Kennedy (S 1492)	Jeffords (S 1648) Revised
Assistance to Sufferers	-\$4 billion annually for a National Victim's Compensation Fund	-\$80 million in 1999; \$60 million in 2001	-\$200 million to victims of asbestos related injuries		-\$780 million in 1999, increasing to \$2.26 billion in 2001, for victims assistance compensation fund	No specific provision
FDA Authority	-Authority to regulate manufacture and distribution of tobacco products -Regulate nicotine as drug and tobacco products as medical devices -Can't ban sale of tobacco to adults	-Regulate nicotine as drug and tobacco products as devices -May ban nicotine to achieve best public health result	-Limited authority to regulate nicotine as drug but cannot regulate tobacco products as devices -Congress must approve by joint resolution regulation to ban tobacco products	-Regulate nicotine as drug and tobacco products as devices -May not prohibit tobacco products solely because tobacco causes disease -Can ban nicotine after 12 years only by showing preponderance of evidence	-Regulate nicotine as drug and tobacco product as devices -Can ban nicotine immediately	-No provisions to allow authority to regulate nicotine as a drug or tobacco products as devices -Congress must approve by joint resolution decision to ban nicotine or tobacco products
Liability	-No ban on class action suits or punitive damages -Annual cap on civil liability payments for past behavior claims -Trust fund for awards and settlements funded by industry payments	-No limits on civil actions by individuals for past, present, or future misconduct -States must resolve civil actions for past behavior -Federal government: No civil actions for past behavior	Past Conduct -Terminates pending state suits and class actions -Grants immunity from future state suits and class actions -Limits civil liability: punitive damages prohibited and individual trials only -Cap on settlements and judgements Future Conduct -Punitive damages allowed: No class actions not based on subrogation	-Same as Hatch	No provisions	No provisions

FIRST**SECOND****THIRD**

PRODUCT REGULATION - FDA AUTHORITY	Admin. Proposal	Conrad (§201): drafted by FDA; reaffirms FDA authority that cigarettes are drug delivery devices	
ACCESS RESTRICTIONS	FDA: Conrad		
ADVERTISING	Admin. Proposal (currently being formulated)	Harkin/Chafee: statute contains only general consent decree requirements, but raises constit. concerns	Conrad or McCain: raises constitut. concerns
PRICE			
PENALTIES			
LICENSING	Administration proposal --2 tier system: ATF licensing for distrib and manuf; FDA regis. for retailers	McCain (§131): requires states to have licensing system and imposes federal penalties	Jeffords (§2822): requires states to have licensing system with state penalties (not federal) for violations
DOCUMENT DISCLOSURE	Administration proposal --review by indep. board with no abrogation of attorney/client priv.	McCain (§701): review by indep. board, which resolves trade secret, attorney work product, and privilege claims. Panel's decisions would be binding in other court proceedings	Conrad (Title II §578): captures a broad range of documents, but the Secretary's power to release privileged or protected documents raises constit. concerns (att.work product not addressed)
ENVIRON. TOBACCO SMOKE	Admin. Proposal: phase-in of restrictions to include hospitality industry	CDC: McCain (§301)--remove all exemptions of sites	CDC: Kennedy (§301): remove exceptions of bars. Add private right of action.

FIRST**SECOND****THIRD**

INTERNATIONAL PROVISIONS	Admin. Proposal: 1) super-Doggett with exceptions; plan for public health funding	CDC: Doggett (S.2135)	
MINORITIES	Admin. Proposal?	CDC: Conrad: cancer research in minority communities; minority outreach as part of state prevention programs; Native Americans	CDC: Jeffords (Title XXVIII, Subtitle C, §2835): programmatic efforts in minority communities in the areas of prevention and cessation
PREEMPTION	FDA: Conrad	FDA: Kennedy	
LEGAL FEES	Admin. Proposal -- cap on hourly rate; review by body appted by AG	Conrad (§702): arbitration panel applying multi-factored test; raises constit. concerns	McCain (§601): drawn directly from settlement: participating manufacturers are responsible for payment of all attny fees and costs
CONSENT DECREES	Admin. Proposal	Conrad (§711) or McCain (§511) -- manuf. must enter into consent decrees to be protected from liab; both Conrad and McCain contain provisions to preclude constit. challenges	Jeffords: no consent decrees included (if the Admin. ends up not supporting consent decrees)
FARMERS	Ford/Robb?		
PUBLIC HEALTH PROGRAMS (Structure)	Admin. Proposal	CDC: Jeffords (Title XXVIII, Subtitle C) - -modify funding formula to include base amt. plus per capita amounts	CDC: Conrad (Title VI, Subtitle B) -- modify funding formula to include base amt. plus per capita amounts

FIRST**SECOND****THIRD**

CESSATION	Admin. Prop -- funding for states, Medicare, Medicaid, IHS and HRSA	CDC: Conrad (Title VI, Subtitle C, § 622)--include specific mention of role of states in cessation --needs to include at-risk, uninsured	CDC: Jeffords (Title XXVIII, Subtitle D) - -needs to include provision for funding for at-risk, uninsured, etc.
RESEARCH	Admin. proposal	CDC: Jeffords (Title XXVIII, Subtitle E): explicitly addresses research in recommended categories including public health/ community and prevention research. Discusses dissemination and practical application of research findings to the state and community levels.	CDC: Hatch (Title V, Subtitle B, §521): explicitly addresses public health/ community research. Needs to include mention of other HHS agencies in addition to NIH.
SURVEILLANCE	Admin. Proposal	CDC: Conrad (Title VI, Subtitle A, § 603): recognizes the need for a stand-alone survey to assess the lookback provision	CDC: Kennedy: recognizes the need for a stand-alone survey to assess the lookback provision.