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TABLE 1a: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Regulation of Tobacco Industry, Tobacco Products, and Product Use			
	Title I	Titles II & IV	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. 101] Restricts use of non-tobacco trade or brand names for tobacco products; limits advertising to FDA-specified media; restricts glamorization of tobacco. [Sec. 102] Restricts advertising in non-adult facilities and publications to black-on-white format. [Sec. 103] Requires statement of intended use on advertisements. [Sec. 104] Prohibits non-tobacco merchandise and brand-name sponsorship. [Sec. 105]	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	Requires new, explicit warning labels in bold type. [Sec. 111-112] Preempts labeling by state and local governments. [Sec. 115] Exempts tobacco product exports from labeling requirements. [Sec. 117] Repeals existing federal tobacco product labeling laws. [Sec. 118]	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]	Requires new, explicit warning labels in bold type. 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; bans self-service sales except in adult-only facilities; allows mail-order sales subject to FDA review. [Sec. 121-122]	Similar provisions to S. 1414, except that vending machines are permitted in adult-only facilities. [Sec. 401]	

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Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Licensing of Retailers	Mandates state licensing of tobacco retailers and stipulates penalties, including license suspension and revocation, for non-compliance. [Sec. 131-134]	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 as follows: Defines tobacco products as drugs and Class II devices. Establishes strict regulatory requirements for reducing or eliminating nicotine and other tobacco product constituents, which include formal rule-making with judicial review, and demonstrating that the modified product reduces health risks and does not create a black market. Requires testing, reporting, and disclosure of tobacco smoke constituents. Establishes DHHS 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. [Sec. 142-143]	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]	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]
Corporate Culture and Compliance, Lobbyists, and Whistleblowers	Mandates industry plan to comply with all new laws on the manufacture and distribution of tobacco. Protects industry whistleblowers. Requires lobbyists to comply with the Act and agree not to support or oppose any federal or state legislation without consent of manufacturers. Disbands the Tobacco Institute and the Council for Tobacco Research. [Sec. 151-156]	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]	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]

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Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Reduction in Underage Tobacco Use			
	Title II	Title III	Title I
Underage Tobacco Use Targets	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. 202-204]	Same provisions as S. 1414. [Sec. 4, 312-314]	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	Fines manufacturers up to \$2 billion per year if reduction in underage tobacco use does not meet targets. Allows manufacturers to recover up to 75% 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. [Sec. 205-206]	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]	Requires manufacturers to pay a non-compliance fee of up to \$1.00 for each unit of tobacco product sold if reduction in underage tobacco use does not meet targets. No comparable provisions to recover non-compliance fees. [Sec. 101]

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Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Environmental Tobacco Smoke			
	Title III	Title VI	Title III
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) to enclosed, separately ventilated, designated smoking areas. Specifies that employees may not be required to enter smoking areas. Exempts restaurants (other than fast food), bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco outlets, and prisons. Allows state and local governments to enact stricter laws. [Sec. 301-306]	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]	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 IV	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 for 25 years: 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, and remaining at \$15 billion a year thereafter. Total payments = \$368.5 billion. Annual payments subject to inflation adjustment. Authorizes manufacturers to raise prices to cover cost of payments. [Sec. 402]	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]	

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Topic	S. 1414 (McCain)	S. 1530 (Haich)	S. 1492 (Kennedy)
Authorization of Trust Fund Expenditures	Authorizes expenditures from Trust Fund to award block grants to states and support national tobacco control programs (see Title V). [Sec. 401]	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			
	Title V	Title V	Title I
State Reimbursement (Medicaid)	Establishes a separate Public Health Trust Fund within the Settlement Trust Fund (see Title IV) to award block grants to states based on an allocation formula (to be determined). [Sec. 501-503] Block grant funds may be used for Medicaid reimbursement and to provide health insurance to uninsured minors. [Sec. 504] Allows DHHS Secretary to withhold block grant funds if states do not use them in accordance with section 504, [Sec. 505]	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]	Allocates 43% (i.e., 65 cents) of the annual revenues from the \$1.50 per pack excise tax, or approx. \$15 billion a year, as follows: reimburses state Medicaid accounts and allows each state to retain its federal matching share provided the funds are used for existing child health and welfare programs (similar to S. 1530); provides approx. \$2.3 billion a year for national and state counter-advertising and smoking cessation programs; establishes tobacco victims compensation fund (approx. \$5 billion a year). [Sec. 101]
Federal/State/Local Programs and Research	Establishes and authorizes funding for (i) the National Smoking Cessation Program, (ii) the National Reduction in Tobacco Usage Program, (iii) the National Tobacco-Free Public Education Program, (iv) the National Event Sponsorship Program, (v) the National Community Action Program, and (vi) the National Cessation Research Program. [Sec. 511-517]	Allocates a total of \$8 billion annually. \$4 billion goes to fund biomedical research at the National Institutes of Health, and the remaining \$4 billion is used 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]	Allocates 57% (i.e., 85 cents) of the annual revenues from the \$1.50 per pack excise tax, or over \$15 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]

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Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Consent Decrees, National Protocol, Non-Participating Manufacturers, Attorneys' Fees, and State Enforcement of Youth Access Laws			
	Title VI	Title II & III	
Consent Decrees and National Protocol	Requires manufacturers and states to enter into consent decrees that include many of the provisions of this Act, and that also include a waiver of constitutional claims. Within 6 months of enactment, requires manufacturers to enter into a legally binding and enforceable contract (the National Tobacco Control Protocol) developed by DHHS Secretary, which embodies the terms of this Act. [Sec. 611-612]	Requires manufacturers and states to enter into consent decrees that include many of the provisions of this 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 each state's Governor, which embodies the restrictions on advertising, promotion, and lobbying (described earlier in table). [Sec. 201]	
Non-Participating Manufacturers	Denies non-participating manufacturers liability protection (see Title VII), and imposes user fees on them, as well as annual payments into a reserve fund to settle liability claims. [Sec. 613]	Same provisions as S. 1414. [Sec. 243, 259]	
Attorneys' Fees		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]	

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Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
State Enforcement of Youth Access Laws	Requires states to enforce laws prohibiting the sale or distribution of tobacco products to minors, and 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. [Sec. 621-623]	Expands on Synar Amendment ² 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 IIC	
Legal Immunity	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. Limits the total damages paid by the industry each year to 33% of the annual payment to the Trust Fund. [Sec. 701-703]	Same provisions as S. 1414. [Sec. 255-258] In addition, requires each state to adopt these civil liability provisions as state law in order to receive Title V funds (see Sec. 501). [Sec. 261]	

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Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Industry Document Disclosure			
	Title VIII	Title VII	Title I
National Tobacco Document Depository	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. 802]	Similar provisions to S.1414. [Sec. 701-703]	Similar provisions. [Sec. 101]
Agriculture and Rural Community Adjustment			
	Title IX (S. 1310, Ford)	Title VIII	Title IV
Funding	Tobacco Community Revitalization Trust Fund of \$28.5 billion. [Sec. 911-912]	Tobacco Transition Account of \$16 billion. [Sec. 101, 811, 841-842]	Trust Fund (from higher excise taxes) expected to spend \$13 billion on this Title. [Sec. 101, subsection 2815]
Farmer compensation	Payments to tobacco farm quota owners (up to \$8/lb) and tenants for production losses from baseline levels (totaling about \$15.8 billion). Quota and no-net-cost price support loan programs maintained. [Sec. 921]	Quota owner buyout (\$8/lb) and tenant compensation (\$1.20/lb) (totaling about \$14.7 billion with 100% participation). Mandatory end to quota program and 3-year phase out of price support loan program. [Sec. 812-814]	Quota buyout offer to owners (\$4/lb) and tenant compensation offer (\$4/lb) (\$9.2 billion exposure with 100% participation). Quota and price support loan programs continue. [Sec. 411-414]
Other USDA tobacco activities	All costs for extension services, crop insurance, loan program administration, leaf grading and inspection, and other activities associated with tobacco production will be paid from Trust Fund (totaling about \$2.5 billion). [Sec. 922]		

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Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Community & Worker Economic Assistance	Annual community economic development grants for 25 years (totaling \$8.3 billion). [Sec. 923] Assistance for displaced industry workers (not more than \$500 million). [Sec. 931] Education grants for tobacco farm families (about \$1.4 billion). [Sec. 932]	Annual community economic development grants for 3 years (totaling \$300 million). [Sec. 821] Assistance for displaced industry workers (not more than \$500 million). [Sec. 816] Education grants for farm families (about \$1.4 billion). [Sec. 817]	Annual community economic development grants for 6 years (totaling \$3.8 billion). [Sec. 431]
Immunity Provisions	Agriculture sector immune to penalties for lack of manufacturer compliance with national settlement legislation. [Sec. 941]		
Native Americans, State and Local Preemption, International Tobacco Control, Antitrust Exemption, and Asbestos			
	Title X	Title IX	Title I
Native Americans	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 eligibility for public health funding (see Title V). [Sec. 1002]	Provides that the requirements of this Act relating to the manufacture, distribution, and sale of tobacco products apply on tribal lands. Considers tribes as states for the purposes of this Act. Provides IHS with \$200 million a year from Trust Fund for Indian health programs (see Title I). [Sec. 901]	
Preemption	Allows state and local governments to 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 do not conflict with the regulatory provisions in this Act. [Sec. 401]	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]
International Tobacco Control			
Antitrust Exemption		Provides participating manufacturers with limited exemption from federal and state antitrust laws. [Sec. 903]	

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Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Asbestos		Allocates \$200 million per year to pay asbestos claims of smokers. [Sec. 101]	

* 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. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
Regulation of Tobacco Industry, Tobacco Products, and Product Use			
	Titles II, VII and VIII	Titles II, VII and VIII	Titles I and 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]	Prohibits outdoor tobacco product advertising; prohibits use of human or cartoon images in advertising; prohibits Internet advertising; restricts point-of-sale advertising. Restricts use of non-tobacco trade or brand names for tobacco products; limits advertising to FDA-specified media; restricts glamorization of tobacco. Restricts advertising in non-adult facilities and publications to black-on-white format. Prohibits non-tobacco merchandise and brand-name sponsorship. [Sec. 101]
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. Exempts tobacco product exports from labeling requirements. [Sec. 101] Supercedes/repeals existing federal tobacco product labeling laws. [Sec. 102]
Youth Access Restrictions	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machine and self-service sales except in adult-only facilities; permits mail-order sales subject to FDA review. [Sec. 202]	Same provisions as S. 1638. [Sec. 202]	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machine and self-service sales except in adult-only facilities; permits mail-order sales subject to FDA review. [Sec. 202]

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Pazio)	S. 1648 (Jeffords)
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]	Mandates state licensing of tobacco retailers and stipulates penalties, including license suspension and revocation, for non-compliance. [Sec. 202]
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 access to, and the advertising and promotion of, 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-comments rulemaking that may include the reduction or elimination of nicotine or other harmful constituents. Requires testing, reporting, and disclosure of tobacco smoke constituents. Requires disclosure of amounts of all non-tobacco ingredients in each brand. Requires ingredients to be included on the product label. Establishes DHHS scientific advisory committee. [Sec. 201-205]	Same provisions as S. 1638. [Sec. 201-205]	Amends Federal Food, Drug, and Cosmetic Act as follows: Creates new FDA authority to regulate tobacco products. Permits FDA to issue regulations through notice-and-comments rulemaking to reduce or eliminate nicotine or other harmful constituents, subject to congressional review/approval. Encourages tobacco companies to develop and market reduced risk tobacco products. 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. Authorizes assessment and collection of \$100 million annually in fees to fund FDA regulation. [Sec. 101]
Corporate Culture and Compliance, Lobbyists, and Whistleblowers	Protects industry whistleblowers. [Sec. 802]	Same provisions as S. 1638. [Sec. 802]	

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
Reduction in Underage Tobacco Use			
	Title III	Title III	Title II
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]	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. 202]
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]	Fines manufacturers up to \$500 million per percentage point short of the target for underage use of cigarettes targets. Allows manufacturers to recover 75% 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 to exceed reduction targets. [Sec. 202]

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
Environmental Tobacco Smoke			
	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 require OSHA to issue within 12 months a final indoor air quality regulation, which includes smoking restrictions in industrial and nonindustrial worksites. [Sec. 301]
Tobacco Trust Fund			
	Title I	Title I	Title II
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/pack in first year, \$1.00/pack in second year, and \$1.50/pack in third year 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 increasing 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]	The Act assumes the establishment of a Tobacco Settlement Trust Fund under separate legislation.

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Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
Authorization of Trust Fund Expenditures	Authorizes annual expenditures from Trust Fund (see below). [Sec. 101]	Authorizes annual expenditures from Trust Fund (see below). [Sec. 101]	Authorizes annual expenditures for 10 years from Tobacco Settlement Trust Fund (see below). [Sec. 202]
Distribution/Allocation of Trust Funds or Excise Tax Revenues			
	Title I	Title I	Title II
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]	

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
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) to 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) to 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]	Requires CDC to allocate annually to states up to \$440 million to promote state and community tobacco control programs. Allocates annually to states up to \$1.5 billion for tobacco cessation programs, including efforts to encourage health plans and insurers to provide coverage for cessation treatment. Mandates an Institute of Medicine report to provide recommendations for tobacco-related research. Creates interagency National Tobacco Task Force to address tobacco-related research priorities. Allocates up to \$345 million annually to CDC for tobacco-related surveillance, epidemiology, and prevention. Allocates \$2.5 billion annually to NIH for tobacco-related research. Allocates \$500 million annually for counter advertising. [Sec. 202]

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)			
Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
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]	

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
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. Established penalties for retailers, their employees, and minors for sales to minors. [Sec. 205]	Same provisions as S. 1638. [Sec. 205]	Requires states to enact a law consistent with the provisions of a model state law described in the Act, or risk losing funding provided by this section. Grants CDC enforcement authority. States must meet compliance target of 90%. Model state law includes retailer licensing, state inspections and enforcement, fines for retailers, their employees, and minors for sales to minors. Allocates \$65 million annually to states from the Trust Fund. [Sec. 202]
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]	

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
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]	Requires industry to submit to DHHS all health-related research documents. Secretary will determine whether privileged information be exempt from disclosure. [Sec. 101]
Agriculture and Rural Community Adjustment			
	Title IV	Title IV	
Funding	Establishes Tobacco Transition Trust Fund to receive payments from HEALTHY Kids Trust Fund: \$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: \$21 billion over first 10 years, then gradually phased out over 25 years. Requires Congress to enact legislation by Jan. 1, 2000, authorizing use of funds for assisting tobacco farmers and their communities. [Sec. 101, 402] Requires that cigarette manufacturers purchase a certain amount of tobacco grown in the United States. [Sec. 401]	
Farmer compensation			
Other USDA tobacco activities			
Community & Worker Economic Assistance			
Immunity Provisions			

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
Native Americans, State and Local Preemption, International Tobacco Control, Antitrust Exemption, and Asbestos			
	Titles VIII and IX	Titles VIII, IX and X	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 and enforce additional measures to further the purposes of this Act. [Sec. 101]
International Tobacco Control	Creates 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 to remove 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			
Asbestos		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.

APPENDIX

SUMMARY OF PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
I. Tobacco Industry Reformation Marketing and Advertising Warnings, Labeling and Packaging	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.⁴ 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.

SUMMARY OF PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
Restrictions on Access to Tobacco Products	Incorporates the following provisions of the FDA rule: (i) Sets a minimum age of 18 to purchase tobacco products and requires retailers to check photo ID of anyone under age 27 (897.14(a-b)); (ii) Requires face-to-face transactions for all tobacco sales, bans sale of individual cigarettes, and requires retailers to remove all displays and advertising that do not comply with this regulation (897.14(c-e)); (iii) Establishes a minimum package size of 20 cigarettes and bans the sampling of tobacco products (897.16(b)(d)); (iv) Bans self-service displays except in adult-only facilities (897.16(c)). Modifies and extends the FDA rule as follows: (i) Bans all vending machine sales; (ii) Permits mail-order sales, subject to proof of age and FDA review (modifies 897.16(c)); (iii) Mandates that tobacco products be placed out of reach of the customers (i.e., behind counter or under lock and key), except in adult-only facilities.
Licensing of Retail Sales	Mandates minimum federal standards for licensing tobacco product retailers. Retailers would face fines for selling tobacco without a license of at least \$1,000 per violation. Licensed retailers who sell to minors would face fines starting at \$500 and rising to \$25,000 for repeated violations. Retailers caught selling to minors 10 times within any two-year period could lose their license. Licensing fees would cover the administrative costs of issuing state licenses.
Tobacco Product Development and Manufacturing	Recognizes explicitly FDA's authority to regulate tobacco products. Classifies tobacco products as Class II devices¹ 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.² Any such action would also be subject to congressional review under the Regulatory Reform Act of 1996.³ (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.⁴ 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.⁵ 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.

SUMMARY OF PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
Good Manufacturing Practice Industry Documents Non-Tobacco Ingredients Corporate Culture and Compliance	Subjects tobacco companies to good manufacturing practice standards comparable to those applicable to other FDA-regulated industries (see 820.1(e)(f)). 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. 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.^a 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.^b 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

SUMMARY OF PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
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. ¹ Allows state and local governments to enact stricter laws.
V. Scope and Effect	The settlement includes all tobacco products sold in U.S. commerce, and also covers imports and U.S. duty free items. Preserves the legal authority of state and local governments to regulate further the sale and distribution of tobacco products. Retains the fiscal authority over tobacco products of the Bureau of Alcohol, Tobacco and Firearms, and the existing authority of the FTC, except for tar, nicotine and carbon monoxide testing (see Title I, sec. B).
VI. Programs and Funding	Mandates annual industry payments in perpetuity to reimburse states for Medicaid outlays for smoking-related illnesses,² 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.³ 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)⁴

SUMMARY OF PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
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 includes 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' general's 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.^a Allows industry to deduct 80% of its liability costs each year from the annual payment.
IX. Board Approval	The terms of the settlement are subject to approval by the Boards of Directors of the participating tobacco companies.

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

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

^c Most regulations are issued informally under the notice-and-comment procedure established by the Administrative Procedure Act (APA; 5 U.S.C. 551 *et seq.*). The agency publishes a notice of proposed rulemaking in the Federal Register, permits interested persons to submit comments, and incorporates in the final rule a concise statement of the rule's basis and purpose. These regulations are reviewed under the "arbitrary, capricious, abuse of discretion" standard. Under this standard, a reviewing court would uphold an agency's action if it is rational, based on a consideration of the relevant factors, and within the scope of the authority designated to the agency by Congress. The settlement, however, would require FDA to undertake a formal rulemaking subject to the APA. This would involve trial-type hearings

at which parties present evidence and conduct cross examinations. Furthermore, the "substantial evidence" standard required by the settlement may be more stringent than the "arbitrary, capricious, abuse of discretion" standard employed in informal rulemaking.

^d This presumably refers to the Small Business Regulatory Fairness Enforcement Act of 1996 (P.L. 104-121), under which Congress has 60 session days to block a regulation by passing a joint resolution of disapproval. This procedure may be applied to any rule that results in an annual effect on the economy of at least \$100 million.

^e A Part 12 hearing refers to a formal evidentiary public hearing under FDA regulations (21 C.F.R. 12), involving presentation of evidence, cross examination, and other trial-type procedures. Requiring that an agency base its action on a "preponderance of evidence" is, according to some analysts, extremely unusual.

^f The term "less hazardous tobacco products" refers to innovative products such as smokeless cigarettes, as opposed to chemically modified existing products.

^g Under current law, the industry is required to provide annually to the Secretary of Health and Human Services a list of all the additives used in the manufacture of tobacco products. The Secretary is granted no authority to regulate additives that are suspected of being hazardous.

^h The Tobacco Institute is the industry's Washington DC-based lobbying organization, and the Council for Tobacco Research provides industry funds for biomedical research.

ⁱ The Synar Amendment to the Public Health Service Act requires states to enforce their laws prohibiting the sale of tobacco products to individuals under age 18. States must conduct annual random, unannounced inspections of retail outlets to ensure compliance with the law. States risk losing federal substance abuse block grant funds for failure to comply. Under the settlement, a state would lose up to 20% of its Medicaid reimbursement funds (see Title VI) if after 10 years its enforcement program failed to reach a 90% compliance rate.

^j On March 25, 1994, the Occupational Safety and Health Organization (OSHA) proposed an indoor air quality regulation that would restrict smoking to separately ventilated, designated smoking rooms. The smoking restriction would apply to all industrial and non-industrial buildings under OSHA's jurisdiction, including restaurants and bars.

^k The settlement negotiators intend that funding provided to the states would be sufficient to extend health insurance to uninsured children.

^l Arithmetically, an increase of 62 cents per pack would raise \$15 billion in additional revenue, based on (1996) cigarette sales of 24.165 billion packs. However, this estimate does not take into account any wholesale or retail price mark-up.

^m This 25-year total includes \$60 billion in lieu of punitive damages for the tobacco industry's past conduct.

ⁿ By the ninth year, the total annual damages paid by the industry is capped at \$5 billion per year.

Tobacco
Side by Side

TABLE 1a: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Regulation of Tobacco Industry, Tobacco Products, and Product Use			
	Title I	Titles II & IV	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. 101] Restricts use of non-tobacco trade or brand names for tobacco products; limits advertising to FDA-specified media; restricts glamorization of tobacco. [Sec. 102] Restricts advertising in non-adult facilities and publications to black-on-white format. [Sec. 103] Requires statement of intended use on advertisements. [Sec. 104] Prohibits non-tobacco merchandise and brand-name sponsorship. [Sec. 105]	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	Requires new, explicit warning labels in bold type. [Sec. 111-112] Preempts labeling by state and local governments. [Sec. 115] Exempts tobacco product exports from labeling requirements. [Sec. 117] Repeals existing federal tobacco product labeling laws. [Sec. 118]	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]	Requires new, explicit warning labels in bold type. 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; bans self-service sales except in adult-only facilities; allows mail-order sales subject to FDA review. [Sec. 121-122]	Similar provisions to S. 1414, except that vending machines are permitted in adult-only facilities. [Sec. 401]	

TABLE 1a: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Licensing of Retailers	Mandates state licensing of tobacco retailers and stipulates penalties, including license suspension and revocation, for non-compliance. [Sec. 131-134]	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 as follows: Defines tobacco products as drugs and Class II devices. Establishes strict regulatory requirements for reducing or eliminating nicotine and other tobacco product constituents, which include formal rule-making with judicial review, and demonstrating that the modified product reduces health risks and does not create a black market. Requires testing, reporting, and disclosure of tobacco smoke constituents. Establishes DHHS 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. [Sec. 142-143]	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]	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]
Corporate Culture and Compliance, Lobbyists, and Whistleblowers	Mandates industry plan to comply with all new laws on the manufacture and distribution of tobacco. Protects industry whistleblowers. Requires lobbyists to comply with the Act and agree not to support or oppose any federal or state legislation without consent of manufacturers. Disbands the Tobacco Institute and the Council for Tobacco Research. [Sec. 151-156]	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]	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]

TABLE 1a: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Reduction in Underage Tobacco Use			
	Title II	Title III	Title I
Underage Tobacco Use Targets	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. 202-204]	Same provisions as S. 1414. [Sec. 4, 312-314]	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	Fines manufacturers up to \$2 billion per year if reduction in underage tobacco use does not meet targets. Allows manufacturers to recover up to 75% 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. [Sec. 205-206]	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]	Requires manufacturers to pay a non-compliance fee of up to \$1.00 for each unit of tobacco product sold if reduction in underage tobacco use does not meet targets. No comparable provisions to recover non-compliance fees. [Sec. 101]

TABLE 1a: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Environmental Tobacco Smoke			
	Title III	Title VI	Title III
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) to enclosed, separately ventilated, designated smoking areas. Specifies that employees may not be required to enter smoking areas. Exempts restaurants (other than fast food), bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco outlets, and prisons. Allows state and local governments to enact stricter laws. [Sec. 301-306]	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]	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 IV	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 for 25 years: 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, and remaining at \$15 billion a year thereafter. Total payments = \$368.5 billion. Annual payments subject to inflation adjustment. Authorizes manufacturers to raise prices to cover cost of payments. [Sec. 402]	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. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Authorization of Trust Fund Expenditures	Authorizes expenditures from Trust Fund to award block grants to states and support national tobacco control programs (see Title V). [Sec. 401]	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			
	Title V	Title V	Title I
State Reimbursement (Medicaid)	Establishes a separate Public Health Trust Fund within the Settlement Trust Fund (see Title IV) to award block grants to states based on an allocation formula (to be determined). [Sec. 501-503] Block grant funds may be used for Medicaid reimbursement and to provide health insurance to uninsured minors. [Sec. 504] Allows DHHS Secretary to withhold block grant funds if states do not use them in accordance with section 504. [Sec. 505]	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]	Allocates 43% (i.e., 65 cents) of the annual revenues from the \$1.50 per pack excise tax, or approx. \$15 billion a year, as follows: reimburses state Medicaid accounts and allows each state to retain its federal matching share provided the funds are used for existing child health and welfare programs (similar to S. 1530); provides approx. \$2.3 billion a year for national and state counter-advertising and smoking cessation programs; establishes tobacco victims compensation fund (approx. \$5 billion a year). [Sec. 101]
Federal/State/Local Programs and Research	Establishes and authorizes funding for (i) the National Smoking Cessation Program, (ii) the National Reduction in Tobacco Usage Program, (iii) the National Tobacco-Free Public Education Program, (iv) the National Event Sponsorship Program, (v) the National Community Action Program, and (vi) the National Cessation Research Program. [Sec. 511-517]	Allocates a total of \$8 billion annually. \$4 billion goes to fund biomedical research at the National Institutes of Health, and the remaining \$4 billion is used 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]	Allocates 57% (i.e., 85 cents) of the annual revenues from the \$1.50 per pack excise tax, or over \$15 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 1a: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Consent Decrees, National Protocol, Non-Participating Manufacturers, Attorneys' Fees, and State Enforcement of Youth Access Laws			
	Title VI	Title II & III	
Consent Decrees and National Protocol	Requires manufacturers and states to enter into consent decrees that include many of the provisions of this Act, and that also include a waiver of constitutional claims. Within 6 months of enactment, requires manufacturers to enter into a legally binding and enforceable contract (the National Tobacco Control Protocol) developed by DHHS Secretary, which embodies the terms of this Act. [Sec. 611-612]	Requires manufacturers and states to enter into consent decrees that include many of the provisions of this 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 each state's Governor, which embodies the restrictions on advertising, promotion, and lobbying (described earlier in table). [Sec. 201]	
Non-Participating Manufacturers	Denies non-participating manufacturers liability protection (see Title VII), and imposes user fees on them, as well as annual payments into a reserve fund to settle liability claims. [Sec. 613]	Same provisions as S. 1414. [Sec. 243, 259]	
Attorneys' Fees		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. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
State Enforcement of Youth Access Laws	Requires states to enforce laws prohibiting the sale or distribution of tobacco products to minors, and 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. [Sec. 621-623]	Expands on Synar Amendment ² 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 IIC	
Legal Immunity	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. Limits the total damages paid by the industry each year to 33% of the annual payment to the Trust Fund. [Sec. 701-703]	Same provisions as S. 1414. [Sec. 255-258] In addition, requires each state to adopt these civil liability provisions as state law in order to receive Title V funds (see Sec. 501). [Sec. 261]	

TABLE 1a: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Industry Document Disclosure			
	Title VIII	Title VII	Title I
National Tobacco Document Depository	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. 802]	Similar provisions to S.1414. [Sec. 701-703]	Similar provisions. [Sec. 101]
Agriculture and Rural Community Adjustment			
	Title IX (S. 1310, Ford)	Title VIII	Title IV
Funding	Tobacco Community Revitalization Trust Fund of \$28.5 billion. [Sec. 911-912]	Tobacco Transition Account of \$16 billion. [Sec. 101, 811, 841-842]	Trust Fund (from higher excise taxes) expected to spend \$13 billion on this Title. [Sec. 101, subsection 2815]
Farmer compensation	Payments to tobacco farm quota owners (up to \$8/lb) and tenants for production losses from baseline levels (totaling about \$15.8 billion). Quota and no-net-cost price support loan programs maintained. [Sec. 921]	Quota owner buyout (\$8/lb) and tenant compensation (\$1.20/lb) (totaling about \$14.7 billion with 100% participation). Mandatory end to quota program and 3-year phase out of price support loan program. [Sec. 812-814]	Quota buyout offer to owners (\$4/lb) and tenant compensation offer (\$4/lb) (\$9.2 billion exposure with 100% participation). Quota and price support loan programs continue. [Sec. 411-414]
Other USDA tobacco activities	All costs for extension services, crop insurance, loan program administration, leaf grading and inspection, and other activities associated with tobacco production will be paid from Trust Fund (totaling about \$2.5 billion). [Sec. 922]		

TABLE 1a: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1414, S. 1530, AND S. 1492)

Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Community & Worker Economic Assistance	Annual community economic development grants for 25 years (totaling \$8.3 billion). [Sec. 923] Assistance for displaced industry workers (not more than \$500 million). [Sec. 931] Education grants for tobacco farm families (about \$1.4 billion). [Sec. 932]	Annual community economic development grants for 3 years (totaling \$300 million). [Sec. 821] Assistance for displaced industry workers (not more than \$500 million). [Sec. 816] Education grants for farm families (about \$1.4 billion). [Sec. 817]	Annual community economic development grants for 6 years (totaling \$3.8 billion). [Sec. 431]
Immunity Provisions	Agriculture sector immune to penalties for lack of manufacturer compliance with national settlement legislation. [Sec. 941]		
Native Americans, State and Local Preemption, International Tobacco Control, Antitrust Exemption, and Asbestos			
	Title X	Title IX	Title I
Native Americans	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 eligibility for public health funding (see Title V). [Sec. 1002]	Provides that the requirements of this Act relating to the manufacture, distribution, and sale of tobacco products apply on tribal lands. Considers tribes as states for the purposes of this Act. Provides IHS with \$200 million a year from Trust Fund for Indian health programs (see Title I). [Sec. 901]	
Preemption	Allows state and local governments to 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 do not conflict with the regulatory provisions in this Act. [Sec. 401]	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]
International Tobacco Control			
Antitrust Exemption		Provides participating manufacturers with limited exemption from federal and state antitrust laws. [Sec. 903]	

TABLE 1a: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1414, S. 1530, AND S. 1492)			
Topic	S. 1414 (McCain)	S. 1530 (Hatch)	S. 1492 (Kennedy)
Asbestos		Allocates \$200 million per year to pay asbestos claims of smokers. [Sec. 101]	

* 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. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
Regulation of Tobacco Industry, Tobacco Products, and Product Use			
	Titles II, VII and VIII	Titles II, VII and VIII	Titles I and 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]	Prohibits outdoor tobacco product advertising; prohibits use of human or cartoon images in advertising; prohibits Internet advertising; restricts point-of-sale advertising. Restricts use of non-tobacco trade or brand names for tobacco products; limits advertising to FDA-specified media; restricts glamorization of tobacco. Restricts advertising in non-adult facilities and publications to black-on-white format. Prohibits non-tobacco merchandise and brand-name sponsorship. [Sec. 101]
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. Exempts tobacco product exports from labeling requirements. [Sec. 101] Supercedes/repeals existing federal tobacco product labeling laws. [Sec. 102]
Youth Access Restrictions	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machine and self-service sales except in adult-only facilities; permits mail-order sales subject to FDA review. [Sec. 202]	Same provisions as S. 1638. [Sec. 202]	Prohibits sales to minors; requires photo ID if under age 27; requires face-to-face transactions; bans vending machine and self-service sales except in adult-only facilities; permits mail-order sales subject to FDA review. [Sec. 202]

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
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]	Mandates state licensing of tobacco retailers and stipulates penalties, including license suspension and revocation, for non-compliance. [Sec. 202]
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 access to, and the advertising and promotion of, 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-comments rulemaking that may include the reduction or elimination of nicotine or other harmful constituents. Requires testing, reporting, and disclosure of tobacco smoke constituents. Requires disclosure of amounts of all non-tobacco ingredients in each brand. Requires ingredients to be included on the product label. Establishes DHHS scientific advisory committee. [Sec. 201-205]	Same provisions as S. 1638. [Sec. 201-205]	Amends Federal Food, Drug, and Cosmetic Act as follows: Creates new FDA authority to regulate tobacco products. Permits FDA to issue regulations through notice-and-comments rulemaking to reduce or eliminate nicotine or other harmful constituents, subject to congressional review/approval. Encourages tobacco companies to develop and market reduced risk tobacco products. 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. Authorizes assessment and collection of \$100 million annually in fees to fund FDA regulation. [Sec. 101]
Corporate Culture and Compliance, Lobbyists, and Whistleblowers	Protects industry whistleblowers. [Sec. 802]	Same provisions as S. 1638. [Sec. 802]	

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
Reduction in Underage Tobacco Use			
	Title III	Title III	Title II
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]	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. 202]
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]	Fines manufacturers up to \$500 million per percentage point short of the target for underage use of cigarettes targets. Allows manufacturers to recover 75% 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 to exceed reduction targets. [Sec. 202]

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Razio)	S. 1648 (Jeffords)
Environmental Tobacco Smoke			
	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 require OSHA to issue within 12 months a final indoor air quality regulation, which includes smoking restrictions in industrial and nonindustrial worksites. [Sec. 301]
Tobacco Trust Fund			
	Title I	Title I	Title II
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/pack in first year, \$1.00/pack in second year, and \$1.50/pack in third year 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 increasing 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]	The Act assumes the establishment of a Tobacco Settlement Trust Fund under separate legislation.

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
Authorization of Trust Fund Expenditures	Authorizes annual expenditures from Trust Fund (see below). [Sec. 101]	Authorizes annual expenditures from Trust Fund (see below). [Sec. 101]	Authorizes annual expenditures for 10 years from Tobacco Settlement Trust Fund (see below). [Sec. 202]
Distribution/Allocation of Trust Funds or Excise Tax Revenues			
	Title I	Title I	Title II
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]	

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
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) to 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) to 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]	Requires CDC to allocate annually to states up to \$440 million to promote state and community tobacco control programs. Allocates annually to states up to \$1.5 billion for tobacco cessation programs, including efforts to encourage health plans and insurers to provide coverage for cessation treatment. Mandates an Institute of Medicine report to provide recommendations for tobacco-related research. Creates interagency National Tobacco Task Force to address tobacco-related research priorities. Allocates up to \$345 million annually to CDC for tobacco-related surveillance, epidemiology, and prevention. Allocates \$2.5 billion annually to NIH for tobacco-related research. Allocates \$500 million annually for counter advertising. [Sec. 202]

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
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]	

TABLE 1b; COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
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. Established penalties for retailers, their employees, and minors for sales to minors. [Sec. 205]	Same provisions as S. 1638. [Sec. 205]	Requires states to enact a law consistent with the provisions of a model state law described in the Act, or risk losing funding provided by this section. Grants CDC enforcement authority. States must meet compliance target of 90%. Model state law includes retailer licensing, state inspections and enforcement, fines for retailers, their employees, and minors for sales to minors. Allocates \$65 million annually to states from the Trust Fund. [Sec. 202]
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]	

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
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]	Requires industry to submit to DHHS all health-related research documents. Secretary will determine whether privileged information be exempt from disclosure. [Sec. 101]
Agriculture and Rural Community Adjustment			
	Title IV	Title IV	
Funding	Establishes Tobacco Transition Trust Fund to receive payments from HEALTHY Kids Trust Fund: \$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: \$21 billion over first 10 years, then gradually phased out over 25 years. Requires Congress to enact legislation by Jan. 1, 2000, authorizing use of funds for assisting tobacco farmers and their communities. [Sec. 101, 402] Requires that cigarette manufacturers purchase a certain amount of tobacco grown in the United States. [Sec. 401]	
Farmer compensation			
Other USDA tobacco activities			
Community & Worker Economic Assistance			
Immunity Provisions			

TABLE 1b: COMPARISON OF TOBACCO SETTLEMENT BILLS (S. 1638, H.R. 3474, and S. 1648)

Topic	S. 1638 (Conrad)	H.R. 3474 (Fazio)	S. 1648 (Jeffords)
Native Americans, State and Local Preemption, International Tobacco Control, Antitrust Exemption, and Asbestos			
	Titles VIII and IX	Titles VIII, IX and X	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 and enforce additional measures to further the purposes of this Act. [Sec. 101]
International Tobacco Control	Creates 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 to remove 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			
Asbestos		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.

Title

Provisions

Marketing and Advertising

Incorporates the following provisions of the FDA rule: (i) Prohibits use of non-tobacco brand names for tobacco products unless such names were in existence as of 1/1/95 (897.16(a)); (ii) Restricts tobacco product advertising to FDA-specified media (897.30(a)); (iii) Restricts permissible tobacco product advertising to black text on a white background except for advertising in adult-only facilities and adult publications (897.32 (a-b)); (iv) Requires advertisements to include FDA-mandated statement, "Nicotine-Delivery Device for Persons 18 and Older" (897.32(c)); (v) Bans sale and distribution of non-tobacco items, services, and gifts, and brand-name sponsorship of sporting and other cultural events (897.34(a-c)).

Modifies and extends the FDA rule as follows: (i) Bans all outdoor tobacco product advertising and all brand-name advertising directed outside from a retail store (modifies 897.30(a-b)); (ii) Bans the use of human and cartoon images in tobacco advertising and packaging; (iii) Prohibits tobacco product advertising on the Internet unless designed to be inaccessible from the United States; (iv) Prohibits payments to glamorize tobacco use in media appealing to minors; (v) Prohibits payments for tobacco product placement in movies, TV programs, and video games; (vi) Establishes additional restrictions on point-of-sale advertising (e.g., regulates number of permissible advertisements).

Warnings, Labeling and Packaging

Amends the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 *et seq.*) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 *et seq.*) to require new warning labels on tobacco product packages and cartons, and on all tobacco advertisements. For cigarettes, the warnings would be in bold type and occupy 25% of the front of the package.⁴ 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.

SUMMARY OF PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
Restrictions on Access to Tobacco Products	Incorporates the following provisions of the FDA rule: (i) Sets a minimum age of 18 to purchase tobacco products and requires retailers to check photo ID of anyone under age 27 (897.14(a-b)); (ii) Requires face-to-face transactions for all tobacco sales, bans sale of individual cigarettes, and requires retailers to remove all displays and advertising that do not comply with this regulation (897.14(c-e)); (iii) Establishes a minimum package size of 20 cigarettes and bans the sampling of tobacco products (897.16(b)(d)); (iv) Bans self-service displays except in adult-only facilities (897.16(c)). Modifies and extends the FDA rule as follows: (i) Bans all vending machine sales; (ii) Permits mail-order sales, subject to proof of age and FDA review (modifies 897.16(c)); (iii) Mandates that tobacco products be placed out of reach of the customers (i.e., behind counter or under lock and key), except in adult-only facilities.
Licensing of Retail Sales	Mandates minimum federal standards for licensing tobacco product retailers. Retailers would face fines for selling tobacco without a license of at least \$1,000 per violation. Licensed retailers who sell to minors would face fines starting at \$500 and rising to \$25,000 for repeated violations. Retailers caught selling to minors 10 times within any two-year period could lose their license. Licensing fees would cover the administrative costs of issuing state licenses.
Tobacco Product Development and Manufacturing	Recognizes explicitly FDA's authority to regulate tobacco products. Classifies tobacco products as Class II devices² 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.³ Any such action would also be subject to congressional review under the Regulatory Reform Act of 1996.⁴ (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.⁵ 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.⁶ 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.

SUMMARY OF PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
Good Manufacturing Practice Industry Documents Non-Tobacco Ingredients Corporate Culture and Compliance	Subjects tobacco companies to good manufacturing practice standards comparable to those applicable to other FDA-regulated industries (see 820.1(e)(f)). 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. 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.^a 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.^b 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).^c

SUMMARY OF PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
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.¹ Allows state and local governments to enact stricter laws.
V. Scope and Effect	The settlement includes all tobacco products sold in U.S. commerce, and also covers imports and U.S. duty free items. Preserves the legal authority of state and local governments to regulate further the sale and distribution of tobacco products. Retains the fiscal authority over tobacco products of the Bureau of Alcohol, Tobacco and Firearms, and the existing authority of the FTC, except for tar, nicotine and carbon monoxide testing (see Title I, sec. B).
VI. Programs and Funding	Mandates annual industry payments in perpetuity to reimburse states for Medicaid outlays for smoking-related illnesses,² 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.³ 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)⁴

SUMMARY OF PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
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.^a Allows industry to deduct 80% of its liability costs each year from the annual payment.
IX. Board Approval	The terms of the settlement are subject to approval by the Boards of Directors of the participating tobacco companies.

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

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

^c Most regulations are issued informally under the notice-and-comment procedure established by the Administrative Procedure Act (APA; 5 U.S.C. 551 *et seq.*). The agency publishes a notice of proposed rulemaking in the Federal Register, permits interested persons to submit comments, and incorporates in the final rule a concise statement of the rule's basis and purpose. These regulations are reviewed under the "arbitrary, capricious, abuse of discretion" standard. Under this standard, a reviewing court would uphold an agency's action if it is rational, based on a consideration of the relevant factors, and within the scope of the authority designated to the agency by Congress. The settlement, however, would require FDA to undertake a formal rulemaking subject to the APA. This would involve trial-type hearings

at which parties present evidence and conduct cross examinations. Furthermore, the "substantial evidence" standard required by the settlement may be more stringent than the "arbitrary, capricious, abuse of discretion" standard employed in informal rulemaking.

^d This presumably refers to the Small Business Regulatory Fairness Enforcement Act of 1996 (P.L. 104-121), under which Congress has 60 session days to block a regulation by passing a joint resolution of disapproval. This procedure may be applied to any rule that results in an annual effect on the economy of at least \$100 million.

^e A Part 12 hearing refers to a formal evidentiary public hearing under FDA regulations (21 C.F.R. 12), involving presentation of evidence, cross examination, and other trial-type procedures. Requiring that an agency base its action on a "preponderance of evidence" is, according to some analysts, extremely unusual.

^f The term "less hazardous tobacco products" refers to innovative products such as smokeless cigarettes, as opposed to chemically modified existing products.

^g Under current law, the industry is required to provide annually to the Secretary of Health and Human Services a list of all the additives used in the manufacture of tobacco products. The Secretary is granted no authority to regulate additives that are suspected of being hazardous.

^h The Tobacco Institute is the industry's Washington DC-based lobbying organization, and the Council for Tobacco Research provides industry funds for biomedical research.

ⁱ The Synar Amendment to the Public Health Service Act requires states to enforce their laws prohibiting the sale of tobacco products to individuals under age 18. States must conduct annual random, unannounced inspections of retail outlets to ensure compliance with the law. States risk losing federal substance abuse block grant funds for failure to comply. Under the settlement, a state would lose up to 20% of its Medicaid reimbursement funds (see Title VI) if after 10 years its enforcement program failed to reach a 90% compliance rate.

^j On March 25, 1994, the Occupational Safety and Health Organization (OSHA) proposed an indoor air quality regulation that would restrict smoking to separately ventilated, designated smoking rooms. The smoking restriction would apply to all industrial and non-industrial buildings under OSHA's jurisdiction, including restaurants and bars.

^k The settlement negotiators intend that funding provided to the states would be sufficient to extend health insurance to uninsured children.

^l Arithmetically, an increase of 62 cents per pack would raise \$15 billion in additional revenue, based on (1996) cigarette sales of 24.165 billion packs. However, this estimate does not take into account any wholesale or retail price mark-up.

^m This 25-year total includes \$60 billion in lieu of punitive damages for the tobacco industry's past conduct.

ⁿ By the ninth year, the total annual damages paid by the industry is capped at \$5 billion per year.