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Tobacco Bill Comparisons [2]

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McCAIN TOBACCO BILL (S. 1415) - DRAFT**MAJOR PROVISIONS¹**

ISSUE	COMMERCE COMMITTEE MARK
MARKETING AND ADVERTISING RESTRICTIONS	Calls for National and State protocols by which industry agrees to no outdoor advertising; no human images or cartoon characters, black and white text only advertising (except in adult periodicals and venues); no animal figures. No color ads on the back face of adult magazines. Limits advertising to FDA/FTC specified media. Restricts glamorization of tobacco. Any advertising that violates the statute or protocol is considered "false and misleading." Liability limits eliminated if tobacco companies challenge or are no longer bound by advertising restrictions. Places size, color, number, and placement restrictions on point-of-sale advertising and displays. Provides for no additional point-of-sale advertising for companies with higher market share. Preemption of further restrictions on advertising or package labeling requirements remains in the Federal Cigarette Labeling and Advertising Act (CLAA). Requires health warnings on advertisements.
WARNINGS, LABELING AND PACKAGING	Requires new, explicit warning labels in bold type. Requires alternating black on white; white on black warning labels for packages. Requires health warnings. Allows FDA to update warnings at any time based on science. Requirements for package warnings other than those set by FDA are preempted by the CLAA.
YOUTH ACCESS RESTRICTIONS	Federal prohibition of sales to minors under 18; requires photo ID if under age 27; requires face to face transactions; bans vending machines and self-service sales except in adult-only facilities, permits mail-order sales subject to FDA review. Administered by FDA.

ISSUE	COMMERCE COMMITTEE MARK															
VENDING MACHINE OWNER COMPENSATION	Bans the sale of tobacco products through the use of vending machines and authorizes a system to compensate the owners of such machines. No funding specified.															
CESSATION AND PREVENTION	No funding specified. Authorizes a National Community Action Program; National Cessation Research Program; National Tobacco Free Public Education Program; National Smoking Cessation Program; various studies; counter-advertising and creation of Tobacco Use and Cessation Board.															
UNDERAGE TOBACCO USE TARGETS	Sets reduction targets of underage use based on the number of years after enactment of the legislation. <table><thead><tr><th></th><th>Cigarettes</th><th>Smokeless</th></tr></thead><tbody><tr><td>3 yrs. --</td><td>15%</td><td>12.5%</td></tr><tr><td>5 yrs --</td><td>30%</td><td>25%</td></tr><tr><td>7 yrs --</td><td>50%</td><td>35%</td></tr><tr><td>10 yrs --</td><td>60%</td><td>45%</td></tr></tbody></table> No targets are set for underage use of other tobacco products, such as cigars, little cigars, roll-your-own, or pipes.		Cigarettes	Smokeless	3 yrs. --	15%	12.5%	5 yrs --	30%	25%	7 yrs --	50%	35%	10 yrs --	60%	45%
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ISSUE	COMMERCE COMMITTEE MARK
LOOK-BACK PENALTIES	Industry-wide penalties only (no firm-specific). Requires HHS to annually determine through surveys (beginning in 3rd year after enactment) the underage daily use of cigarettes and smokeless tobacco during the preceding year. Requires Industry to pay tiered monetary penalties (non-tax deductible) for falling short of youth reduction targets. 1-5 percentage points short: \$80 million per point. 6-10 percentage points short: \$160 million per point. 11 and above percentage points short: \$240 million per point. Yearly cap of 3.5 billion with no tax deductibility of penalty payments. Joint, several & strict liability for penalties. Provides legal actions for companies against another for financial liability. If any company misses its share of target by more than 20 points, company's liability cap is waived for 2 years or until goal is met, whichever is later, with due process. Liability cap is waived for criminal convictions of violations under this act.
USE OF PENALTY AMOUNTS	Transfers 90% of penalty receipts to grants for states/local governments to further reduce youth smoking. Secretary may retain up to 5% of penalty receipts for administration of the look-back assessment. The final 5% of receipts is for a compliance bonus to reward states and retailers who prevent youths (less than 5%) from successfully purchasing tobacco products. Secretary may withhold 5% of any state's grant if state fails to enforce compliance with youth access restrictions.

ISSUE	COMMERCE COMMITTEE MARK
STATE ENFORCEMENT OF YOUTH ACCESS LAWS	Compliance goals set (see above Use of Penalty Amounts) for state and tribal governments. Funding from settlement for enforcement efforts. Repeals the 1992 Synar Amendment, which was an earlier effort to set targets for the percentage of youths who successfully purchase tobacco products. Percentage of funding withheld for non-compliance is greater in Synar (ranging from 20- 40%, although difference in absolute dollar values are not known). This amendment is no longer needed because these requirements replace it.
LICENSING OF RETAILERS	Requires state, tribal and federal licensing program to be funded from settlement. FDA would draft model state program in consultation with state and local officials.
FDA REGULATION OF TOBACCO PRODUCTS AND NICOTINE	Recognizes FDA has broad authority over tobacco including advertising, youth access, and new products. FDA authority over tobacco is separate chapter of FD&C Act to assure FDA authority over tobacco will not affect FDA authority over other regulated products. Provides for FDA authority over youth access. FDA approval of new products. Any ban on nicotine, retail sales, or category of tobacco products would require Presidential notification to Congress and include two-year waiting period for Congress to act. If Congress does not act ban goes into effect. No FDA authority over farmers (e.g., would be no control over genetic manipulation of tobacco leaf). FDA rules must take into account the impact of actions on demand for unregulated contraband products.
CORPORATE CULTURE AND COMPLIANCE, LOBBYISTS AND WHISTLE BLOWERS	Calls for national and state protocols requiring an industry plan to comply with all new laws on the manufacture and distribution of tobacco. Protects industry whistle blowers. 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. Industry plan would include specific assessment mechanism and enforcement standards of industry plan to be included in the protocols.

ISSUE	COMMERCE COMMITTEE MARK
SMOKING RESTRICTIONS IN PUBLIC FACILITIES (ETS)	Restrict smoking in public facilities to enclosed 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, prisons, private residences and any building with any of the above facilities/functions in them. Allows states to opt out. Authorizes incentive grant program for states.
INDUSTRY PAYMENTS	Establishes National Tobacco Settlement Trust Fund. Calls for industry to pay \$10 billion up-front. Yearly payments required of industry: 1999 -- \$14.4 billion 2000 -- \$15.4 billion 2001 -- \$17.7 billion 2002 -- \$21 billion 2003 -- \$23.6 billion Each year thereafter, \$23.6 billion in real dollars (though the bill has a misprint and says the 2004 amount is \$21.0 billion.) Payments are volume adjusted -- increased if consumption volume increases and decreased if volume decreases from 2004 levels. Payments are tax deductible. Nominal Net Receipts (FY99-03) -- \$71.1 billion Implied Per-Pack Equivalents (Real 1999 \$): 1999 -- 65 cents per pack 2000 -- 70 cents per pack 2001 -- 80 cents per pack 2002 -- \$1 per pack 2003 -- \$1.10 per pack

ISSUE	COMMERCE COMMITTEE MARK
SPENDING FROM TRUST FUND	Most spending decisions are left to the floor of the Senate. Committee mark specifies funding for: 5-Year Funding FDA: \$2 billion States: \$26 billion (OMB estimate) Farmers: \$11 billion International: \$1 billion Total Spending: \$39 billion Receipts Less Spending: \$32 billion Although it is not clearly indicated in the bill, we understand that McCain intended to allow manufacturers to deduct 80% of the \$6.5 annual liability cap (see liability section below) from their annual payments. This could reduce the net receipts by an additional \$26 billion over 5 years. The bill also authorizes funding for NIH, CDC, and AHCPR research using language from the Conrad bill, which included \$17 billion for these activities.
FUNDING PRIORITIES	In absence of specific funding recommendations, the bill includes a “Sense of the Senate” amendment indicating that the funds raised by this act should be used to support the following priorities: 1. Tobacco use prevention and cessation. 2. Tobacco related health research. 3. Assist tobacco farmers and tobacco dependent communities. 4. Reimburse public health care financing programs for tobacco related costs, including Medicare. 5. Settle with and reimburse states for tobacco related health care costs and damages, including Medicaid. 6. Create a Tobacco Asbestos Trust Fund. 7. Provide funding for the Federal Black Lung Program. 8. Child Care 9. Clinical Trials at NIH. 10. Veterans.

ISSUE	COMMERCE COMMITTEE MARK
CONSENT DECREES AND NATIONAL PROTOCOL	Manufacturers and states enter into consent decrees that include many of the provisions of the Act, and include a waiver of Constitutional claims. Within 6 months of enactment requires each manufacturer to enter into a legally binding and enforceable contract (The National Tobacco Control Protocol) on both the federal and state level. Federal protocol to be executed with U.S. Attorney General in consultation with the Secretary of HHS. State protocol to be executed with State Attorney General in consultation with state Governor.
NON-PARTICIPATING MANUFACTURERS	Denies non-participating manufacturers liability protection and imposes user fees on them equal to the annual assessment paid by participating manufacturers. In addition, non-participating manufacturers must make annual payments into a reserve fund to settle liability claims; the amount is equal to 150% of the payment it would have paid under the bill if the manufacturer had actually been a party to the Settlement.
ATTORNEYS' FEES	All attorney's fees and costs paid by industry outside the payments made under this act. Three member arbitration panel in which plaintiff representative and defendant representatives pick a third member.

ISSUE	COMMERCE COMMITTEE MARK
CIVIL LIABILITY RESTRICTIONS	Establishes a \$6.5 billion cap on annual industry payments for individual liability claims against participating manufacturers. Permits suits by private plaintiffs (incl. class actions and third-party suits), and claims by the federal government, but preempts suits brought by states, local governments and Indian tribes. Permits punitive damages for past conduct (within the cap) and punitive damages for future conduct (outside the cap). Prohibits addiction and dependence claims. Creates a federal cause of action with concurrent jurisdiction in state and federal courts for tobacco-related health injuries. Requires courts to sever trials involving participating and non-participating manufacturers. Creates rebuttable presumptions that: 1) nicotine is addictive; and 2) certain specified diseases are caused by use of tobacco products. The bill does not appear to establish a fund of money from which judgements and settlements are paid (although this may have been intended). Instead, the bill requires the Secretary of the Treasury to keep a record of payments made and judgments and settlements. By rule, the Secretary is to establish a mechanism for ensuring that payments are made to all entitled in the year which the award was made or in a subsequent year. The press release accompanying the bill suggests that the drafters of the bill intended to include the 80% payment; the bill, as drafted, however, does not clearly establish such a fund and makes no reference to the 20%/80% model.
INDUSTRY DOCUMENT DISCLOSURE	Creates National Tobacco Document Depository Expands the availability of documents in a public depository for use by plaintiffs in actions against the industry and provides for efficient use of these documents. Requires manufacturers to deposit: 1) all deposition of corporate representatives; 2) depositions of all expert and fact witnesses; 3) answers to interrogatories in all cases; 4) court orders on substantive issues; 5) all documents provided in recent specified lawsuits; 6) all health research documents; 7) document indexes maintained by the industry. 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.

ISSUE	COMMERCE COMMITTEE MARK
AGRICULTURE AND RURAL COMMUNITY ASSISTANCE	Specifies \$11 billion over 5 years and \$25 billion over 25 years. Includes the LEAF Act sponsored by Senator Ford. Creates Tobacco Community Revitalization Trust Fund from payments by industry The fund pays for lost tobacco, quota, administrative costs of the tobacco program, to tobacco community Economic Development Grants, Farmer Opportunity Grant Program, and the Tobacco Worker Transition Program. Offers farmers opportunity to stop producing tobacco by selling their quotas. Provides tobacco farmers with educational and economic assistance to find another means of living. Provides general immunity for tobacco producers and warehouse owners.
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. Requires Indian tribes to collect any tobacco excise or sale taxes on non-members of the tribes. The Indian tribe shall remit such taxes to the U.S. Treasury, which shall, in turn remit the taxes to the State in which they were collected.
NO STATE OR LOCAL PREEMPTION	Allows state and local governments to impose any additional tobacco product control measures that are not inconsistent with the provisions of this Act. However, preemption is imposed in various sections of the Act for certain issues (e.g., packaging and labeling; advertising restrictions; product standards).
INTERNATIONAL TOBACCO CONTROL	Creates non-profit corporation and provides funds for international tobacco control programs. Prohibits use of federal funds by federal officials to promote U.S. tobacco exports or to seek to remove nondiscriminatory restrictions on tobacco products by foreign countries. Prohibits U.S. employees of tobacco companies from marketing to children overseas. Requires tobacco product exports to carry the same warning labels required on products sold in the U.S.

ISSUE	COMMERCE COMMITTEE MARK
ANTI-TRUST EXEMPTION	Antitrust laws of the U.S. do not apply to the joint discussion, consideration, review, action, agreement, or understanding by or among any participating manufacturers, for the purposes of, and limit to -- (1) entering into and complying with the Protocol, Trust Agreement, or Consent Decree; (2) refusing to deal with a distributor, retailer, or other seller of tobacco products who distributes such products for sale to, or offers for sale or sells such products to, underage persons, or who otherwise fails to comply with the applicable requirements for the Act, the Protocol, or Consent Decree; or (3) submitting an application relating to a plan or program submitted to the U.S. Attorney General for approval that is designed to reduce the use of tobacco products by underage individuals.
MANDATED PASS THROUGH PAYMENTS	Requires industry to pass through 100% of payments to cigarette prices and to adopt industry plan to comply with law and protocol.
VETERANS	Includes an Amendment sponsored by Sen. Rockefeller that authorizes the Veteran's Administration to sue liable third parties for reimbursement of paying monthly disability compensation for tobacco-related diseases.

1. Bill as introduced in the Commerce Committee, 3/31/98. Includes Chairman's amendments and most major amendments. For simplicity, does not include the following amendments: 1) Hutchison's amendment to compensate competitors who must share technology; 2) Hutchison's amendment to require Congressional Review of FDA regulations; 3) Ford's amendment to clarify charts; 4) Kerry's amendment to allow states to use their own funds to supplement federal child care program; 5) Breaux's amendment to allow claimants to be paid by insurance companies if manufacturer cannot pay a claim; 6) Hutchison's amendment to allow states that have reached separate settlements with tobacco companies to opt in to the global settlement; 7) Ford's amendment to apply existing penalties to FDA if documents are released from the depository.

Draft prepared by OMB staff with comments from HHS and DOJ.

POLICY COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/18/98 -- UNEDITED

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

Make 3 files [mast 422a.wpd | mast 422b.wpd | mast 422?.wpd]

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	Definitions	6(17)	22	Definition of tobacco products	Include cigars and pipe tobacco in the list of tobacco products covered by this legislation.	TR
Policy	Notification	8	23	Notification section: it would be difficult to conclude that causation between the heightened restrictions on cigarettes and smokeless tobacco and increases in youth usage of cigars and pipes.	Lines 13-15, strike "a decrease in underage use of tobacco products resulting from the enactment of this Act has produced". Line 16, before the period, insert "has occurred".	FDA DOJ
Const'l	Challenges to the Act Advertising. ..Not Separable	9	24	Bill strips tobacco manufacturers of the liability limitations if they challenge the Act; raises significant constitutional concerns	Strike entire section	DOJ

A = to be negotiated

B = staff level policy

? = may not want to propose



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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	I: Healthy Kids Trust Fund	chap 3, sec 131	p. 42	Bill provides for increases in the Child Care and Development Block Grant of 1990 to increase funding for child care affordability, quality, and accessibility.	Strike entire section and replace with the "Child Care Quality Improvement Act of 1998" which is attached and has been sent to OMB for clearance. Appropriate funds in the bill in the amounts included in the President's Budget. Clarify that funds for child care subsidies are within the "State share" of the settlement, while other child care authorities are not tobacco-funded in the President's Budget. We are concerned that the lack of specificity makes understanding the level of financing and the type of programs under this section difficult. The language in the attached bill better defines the quality improvement, local collaboratives, and subsidy increases that are discussed in the bill. For more information, please contact Mary Bourdette at 690-6311 or Audrey Smolkin at 690-6553.	HHS/A SMB
Policy	I.A., FDA	101 FDCA 908©	59	As drafted, it may be very difficult to ever find that the defect is not in any tobacco product.	Line 11, after "not" insert "ordinarily" and strike "other".	FDA

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Policy	I.A., FDA	101 FDCA 910 (d)(3)	73	As drafted, it may be difficult to apply this standard.	Line 23; strike "other" and insert "is ordinarily caused by".	FDA
Policy	I.A., FDA	101 FDCA 913 (a)(2)(B)	79 (& 13 of 4/1 doc)	Requiring agreement on protocols may limit agency's ability to protect health, and is not consistent with the FDCA generally.	Page 13 (of 4/1 document), line 12 after "Secretary," insert "includes"; Line 13, add a period after "product"; Strike lines 14-16, and insert "If such studies are required, the manufacturer may consult with the Secretary regarding protocols for such studies.".	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
B Policy/Legal	I.A., FDA	101 FDCA 915 (b)(1)(B)	87	The advisory committee is to include 2 individuals as representatives of the tobacco manufacturing industry. This advisory committee will be reviewing confidential and trade secret information from the companies. Given that there are so few manufacturers, the employer of a committee member under (B) will have a competitive interest in that information, and conflicts of interest are likely to arise.	Redistribute member allocation differently and/or include representatives of other groups.	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Const'l	I:B Advertising	122 (a)(1)(B)	96	The provisions prohibiting all outdoor advertising (Sec. 122(a)(1)(B)) goes beyond the FDA regulation and raises significant constitutional concerns	Strike, or, if included at all, this provision should be made conditional	DOJ
Const'l	I:B Advertising	12 (a)(1)(F)	97	Ban on Internet advertising raises constitutional concerns, and may be unnecessary in light of current law and other provisions of the bill (including subsection (a)(6)(B), which addresses accessibility to minors).	Strike subsection (F)	DOJ
Const'l	I: Advertising	122 (a)(2)	98	Subsection (2) should be clearly limited to commercial speech and should contain an adult exception	In subsection (2), insert "brand-name" before "product identification"; insert "that individuals under the age of 18 are permitted to view" after "video game"; insert "by a manufacturer or distributor or retailer" after "has been made"	DOJ

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Const'l	I: Advertising	122 (a)(3)	98	Subsection (3) should be clearly limited to commercial speech and the adult exception should be more clearly specified	Strike "promoting the image or use" and insert "advertising"; strike "appeals to" each time that it appears; insert "are permitted to view" after "18 years" and after "individuals" at the end of the subsection.	DOJ
Const'l	I: Advertising	123 (b)(1)	101	The provisions that allow manufacturers that have larger market share to have more advertising undermine the narrow tailoring of the advertising restrictions	Strike "which has less than . . . (as determined by the Secretary" in the first line and strike "which has less than . . . location." at the end	DOJ
Const'l	I: Advertising	123(d)	102	Subsection (d) should include the exception for advertising in locations where minors are not permitted	Strike "where tobacco products are offered for sale" at the end of subsection (d) and insert in its place "where individuals under the age of 18 are permitted."	DOJ

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Policy/legal	I.B., protocol	121-123	96-103	It may be inappropriate (on policy and legal grounds) to include so many FDA requirements (see above). Also, several of the specific requirements are inconsistent with FDA requirements, and, as a result, would undermine FDA authority. It is unclear what happens if FDA changes a requirements and it would be difficult to comply with both requirements.	Specific concerns/issues— Page 96-97, section 122, strike item (a)(1)(C), lines 21 - line 2. [this allowance for disclaimers is not permitted under the FDCA, as amended] Page 97, strike item (a)(1)(F), lines 11-17. [Internet ban raises Constitutional issues] Page 97, item (a)(1)(G), line 23, strike "or fixture". [otherwise, is broader than FDA regulations] Page 98, item (a)(1)(G), line 6, strike "and" and insert "or". [otherwise, more lenient than FDA regulations] Page 99, item (a)(5), lines 12-23, strike all, or strike lines 15-23, and in line 14, strike "follows:" and insert "required by the Secretary by regulation." [this item adopts FDA's existing requirement for established name and intended use statements on packages. FDA may at some point, decide to promulgate revised requirements that are different; yet the companies would still be required under the protocol to also include the old (and possibly	FDA Page 102, section 123, item (d), strike lines 7-12. [this provision is the opposite of what FDA regulations permit].

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	II A- Reduction and under age Tobacco use		103-119	This Title contains significant problems with reduction targets, assessment methodology, structure and amount of payments by manufacturers, and methodology to assess progress and determine attainment or non-attainment of goals. These problems make the Title unworkable.	Strike entire Title and replace with language which administration incorporates the following principles: • targets for smokeless tobacco should match those for cigarettes; other tobacco products should also be included in targets • manufacturer specific surcharges are needed to discourage youth tobacco use • surcharge levels must be raised significantly in order to have the desired effect on manufacturer behavior and youth tobacco use • removal of surcharge cap as proposed by McCain • development and implementation of a tobacco use surveillance system which will provide data sufficient to implement the lookback and penalty provisions and better monitor tobacco use patterns and the impact of prevention programs • required percentage reductions determined based upon point estimates without regard to CIs • funding sufficient to support the development and implementation of tobacco use surveillance	CDC DOJ

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Policy <i>[was in technicals]</i>	II. Reductions in Underage Tobacco Use	202 (a)	P. 104	Tobacco use under this section is gauged by estimates of "daily use". Such a measure misses tobacco use that occurs regularly, but less than "daily".	Revise Sec. 202 (a) by substituting "within the past 30 days" in place of the term "daily use". Data on tobacco use by youth show that some youth use several different brands or products on a routine basis, but none of them on a daily basis. Data on these patterns of tobacco use would not be capture if the "daily use" measure is retained.	OMB
Policy	IIA	202	104-105	Does not specifically allow measurement of underage tobacco use measure based on past month use.	Past month tobacco use should be basis of measurement system. Measuring daily use of tobacco omits valid information about routine tobacco use by young people that occurs regularly but not on a daily basis.	ASPE
Policy <i>(A)</i>	II:A: Reductions in Underage Tobacco Use	201-202	104 - 110	Does not include manufacturer-specific goals and penalties.	Manufacturer specific goals and surcharges (in addition to industry-wide) are needed to discourage youth tobacco use. To be effective, a tobacco reduction system must direct financial incentives both to individual manufacturers and to the industry as a whole to meet youth tobacco use reduction targets.	HH5 OMB
Policy <i>(A)</i>	IIA ²	202	106	Does not provide high enough maximum surcharge in any one year (surcharges capped at \$3.5 billion).	If surcharges are capped, cap should be substantially higher to ensure that companies have strong incentives to discourage youth tobacco use.	HH5

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Policy <i>duplicate</i>	IIA. Reductions in Underage Tobacco Use	202 (b) (3)	P. 106	A \$3.5 B cap on all industry penalties is too low; it should be raised to provide sufficient incentive for the industry to change its behavior.	Revise cap upward [~~\$6B (40 cents per pack) or some higher number,] or remove the cap altogether. Under the \$3.5 billion cap, companies could simply view the penalties as cost of doing business and make only minimal changes in behavior.~~ HHS estimates that the \$3.5 billion cap would be equivalent to roughly \$.15 per pack, based on current sales of 24 billion packs per year.	OMB
Policy	IIA. Reductions in Underage Tobacco Use	202 (c)	P. 107	Penalties imposed on tobacco manufacturers are joint, several, and strict obligations, allocated by market share. Penalties should also be imposed on specific firms.	Revise Sec. 202 (c) and related sections so that penalties are firm-specific and industry-wide. ~~Company-specific penalties provide strong incentives for each company to discourage youth tobacco use.~~	OMB HHS
Policy	IIA	202(e)	108	Penalty funds transferred to states may supplant Federal funds: Secretary shall transfer 90% of penalty receipts to states governments.	Clarifying language should be added to ensure that transfer of receipts to states should not supplant current Federal grants and/or contract agreements to state and local governments.	ASPE

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Policy A	IIA: Reduction in Underage Tobacco Use	202(f)(2) changed to 202(g)(2)	109	Contribution rights	This section places the burden of proof on the government, rather than on the tobacco manufacturer. The whole idea of the lookback penalty is to hold manufacturer's liable for missing their youth reduction targets. If we add the additional hurdle of requiring the government to prove that the companies targeted children, then we eviscerate this approach.	TR
Policy A	IIA	203©	111	In any action taken by the Secretary against a manufacturer, the court must determine whether the manufacturer failed to comply with the Act's provisions regarding underage tobacco use or took material action to undermine the achievement of the required percentage reduction.	A subjective assessment about industry behavior should not be added to the objective test of whether or not targets are met. Such a subjective assessment would necessitate much closer federal government review of all of the business and marketing practices of the industry in order to determine whether the industry or specific manufacturers substantially contributed to youth use above the targets. Placing such a burden on the government would likely delay the imposition of surcharges and would leave the lookback system subject to endless litigation over industry behavior.	

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Policy <i>Does technical 106 take care of it</i>	IIA	204	116	The underage cigarette use baseline may underestimate youth use. Baseline is based on an average number of daily youth smokers over the past 5-10 years.	The baseline should not be based on a 5-10 year average or on a daily measure of tobacco use. The use of such an average along with a daily measure of tobacco use will tend to understate youth smoking because many youth smoke but are not daily users and the prevalence of youth smokers has increased over the last decade.	ASPE
Policy <i>A</i>	II	204	117	Does not separately specify "non-attainment percentage for cigarettes" for new manufacturers.	The non-attainment percentage should be defined separately for new manufacturers. Insert: "In the case of a new manufacturer, the term non-attainment percentage means the number of percentage points yielded by the percentage points by which the percent prevalence of underage use of the manufacturer's product exceeds the percentage of underage children in the de minimis level."	
Policy	Title IIB ⁹ State Enforcement Incentives	212	Frist Amendment, p.5	Bonus funding to retailers	Consider dropping language on p. 5, line 16 on sharing funding with compliant retailers. Although providing incentives for retailer compliance is commendable, in the context of inadequate funding for public health and other programs, this use of funding is questionable.	DOJ
Policy	Title IIB ⁹ State Enforcement Incentives	213	Frist amendment, page 6	Noncompliance - withholding of funds	Increase amount on page 6, line 14 to higher than 5%, perhaps up to 20% or higher.	DOJ

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
B Policy	Title IIC and Title XI	221 222 223 1172 1173 1174	126-134 and 357-362	Inconsistencies in language regarding prevention, cessation, and other programs.	Sections 1172-1174 are misplaced and duplicate programs in sections 221-223. The language in 1172-4, which are similar to provisions in the Conrad bill, is preferable.	CDC
2 6 Policy	Title II	221	127	Eligibility of individuals for cessation funding	Strike Section 221 (b)(2) starting on line 13. The bill should not set up a new bureaucracy to provide cessation benefits. Instead, benefits for those without private insurance should be made available through Medicaid, Medicare, community health centers, and the public health system. The majority of funding should be used to stimulate the health care delivery system to provide cessation services by giving incentive grants to health care systems and to conduct provider training, guideline development and health services research.	DOJ
B Policy	Title IIC	222	129	Board to direct media/public education campaign.	Strike all language on the Public Education Board. On page 131, line 19, language on Secretary establishing a program, with the Board entering into contracts, is confusing. The media campaign should be directed by a government program either designated by the Secretary or specified in the bill to enhance coordination between the media campaign and prevention programs administered by the Secretary.	DOJ

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	II. C Reductions in Underage Tobacco Use	235	P. 134	Sec. 235 provides for a State licensing program funded by a block grant to each state.	Substitute the Administration's proposed Federal licensing program. The Administration's plan is self-financing, and does not depend on funds from the settlement.	OMB

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	II.C. reductions in underage use	235	134-137	As drafted, this could be inconsistent with FDA regulatory efforts. In particular, the penalties are too vague, and would allow States to obtain funds even if their program had minimal penalties. Would be preferable to allow the Secretary to establish minimum standards.	Strike (a)(2)(A), page 134, line 16, - page 135, line 2, and replace with the following language— “(2) STATE AGREEMENT REQUIRED.-- In order to receive a block grant under this section, a State shall have in place a program that meets or exceeds (as determined by the Secretary the requirements of the Model State Program Described in paragraph (3)).” Strike (B) and (C), page 135, line 3, - page 136, line 16, and replace with the following— “(3) MODEL PROGRAM.--Not later than 12 months after the date of enactment of this subchapter, the Secretary shall promulgate a model State program that is consistent with the restrictions on access promulgated by the Secretary on August 28, 1996 (Vol. 61, No. 168, Federal Register).” <u>ALTERNATIVE REPLACEMENT</u> if more specificity with respect to the model program is desired in the statute— “(3) MODEL PROGRAM.--Not later than 12 months after the date of enactment of this subchapter, the Secretary shall promulgate a model State program. Such model State program shall at a minimum-- “(A) provide for the collection of licensing fees by the	FDA program;

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	II.C. reductions in underage use	235	134-137	continuation	"(B) prohibit retailers from selling or otherwise distributing tobacco products directly to consumers in a State unless such retailers have in effect tobacco licenses issued or renewed in accordance with State or local laws; "(C) provide for the notification of every person in the State who is engaged in the distribution at retail of tobacco products of the license requirement and of the date by which such person shall have obtained a license in order to continue to distribute such products; "(D) prohibit licensed retailers from selling or otherwise distributing tobacco products to minors, consistent with the age restrictions promulgated by the Secretary on August 28, 1996 (Vol. 61, No. 168, Federal Register); "(E) provide for penalties of up to \$50,000 for each violation of the requirements under such program relating to the sale or distribution of tobacco products without a license and for appropriate penalties for other violations of laws relating to youth access to tobacco products;	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	II.C. reductions in underage use	235	134-137	continuation	"(F) require retailers to comply with the applicable requirements of this section and any regulations relating to this section; "(G) provide for the suspension or revocation of a license in the case of a retailer that repeatedly sells or distributes tobacco products to individuals in a manner inconsistent with the age restrictions promulgated by the Secretary on August 28, 1996 (Vol. 61, No. 168, Federal Register), or otherwise in violation of State or local law; and	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	II.C. reductions in underage use	235	134-137	continuation	"(H) provide for penalties that are consistent with the following: "(I) RETAILERS.--In the case of a retailer who distributes a tobacco product to a minor in a manner inconsistent with the age restrictions promulgated by the Secretary on August 28, 1996 (Vol. 61, No. 168, Federal Register), the regulations shall provide for the application of a civil money penalty of at least— "(I) \$250 for the 1st violation; "(II) \$500 for the 2nd violation; "(III) \$1,500 for the 3rd violation; "(IV) \$5,000 for the 4th violation; and "(V) \$10,000 for the 5th and subsequent violations. "(ii) EMPLOYEES OF RETAILERS.--In the case of an employee of a retailer who distributes a tobacco product to a minor in a manner inconsistent with the age restrictions promulgated by the Secretary on August 28, 1996 (Vol. 61, No. 168, Federal Register), the regulations may provide for the application of a civil money penalty of— "(I) \$25 for the 1st violation; "(II) \$50 for the 2nd violation; and "(III) \$150 for the 3rd and subsequent violations. "(iii) MINORS. In the case of a minor who purchases or attempts to purchase a tobacco product (other than a minor engaged in an authorized sting or a law enforcement	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	III	301	141	This section does not make provision for warnings on cigars or little cigars, even though youth use of cigars is now at 24%.	Page 141 strike line 20 and replace with: "neath the cellophane or other clear wrapping or, if cellophane or other clear wrapping is the only wrapping, then the label statement shall appear prominently directly on that wrapping." (allows for warnings on individually wrapped cigars)	CDC
Policy	III, Tobacco product warning and smoke constituent disclosures	301 FCLAA 4(b)(3)	145	Provision restricts all disclosures in advertising to 20 percent of the ad. The section refers not only the mandated health warnings but also to tar and nicotine disclosures and any "other disclosures required" under the Act. This is too restrictive. It will reduce the size of the mandated health warning every time FDA adds any required labeling disclosure and restricts the size of any required FDA disclosures to a preset amount of the ad.	Line 3-4, after "disclosures" insert "required under this section."	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	III	302	146	Regulatory authority to revise warnings is narrow and is inconsistent with the broader authority provided for revision of smokeless warning labels	Page 146 strike lines 17 to 21 and replace with " the text, format, size, placement, or any other aspect of the warning label statements required by subsection (a) of this section, and to require other relevant information on cigarette packages."	CDC
Policy	III	302	146	Definitions in Cigarette Labeling and Advertising Act should be amended to be consistent with definitions in bill	Page 146 following line 21 add: "Sec. 303. Definitions. Section 3 of the Federal Cigarette Labeling and Advertising Act is amended by striking subsections (1), (4), and (7) and replacing with the following: (1)The term "cigarette" means - (A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, (B) any roll of tobacco wrapped in any substance containing tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A), and includes cigarette tubes and cigarette sticks; and (4) The term "package" means a pack, box, carton, or container of any kind or, if no other container, any wrapping including cellophane, in which cigarettes and little cigars are offered for sale, sold, or otherwise distributed to consumers.	CDC

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Policy B	III, Tobacco product warning and smoke constituent disclosures			The preemption problems of FCLAA are not addressed (15 USC 1334). Under FCLAA, the federal government is preempted from putting additional health warning requirements on the package, and States are also preempted from imposing advertising restrictions based on smoking and health. In addition, this provision has been construed by courts to preempt certain tort actions. This should be addressed by deleting the preemption portions of the FCLAA.	Insert a new section as follows— "Section 5(b) of the Federal Cigarette and Labeling and Advertising Act (15 USC 1334(b)) is amended by striking the entire subsection. Section 5(a) of the Federal Cigarette and Labeling and Advertising Act (15 USC 1334(a)) is amended by striking the "(a)" and inserting at the end before the period, "by any State or local authority".	FDA
Const'l A	III: Reporting of constituents	311(b)	154	To avoid takings concerns, the Secretary could be required to maintain proprietary information on a confidential basis		DOJ

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
A Policy	IV: National Tobacco Settlement Trust Fund	401(1)	155	Provides \$196.5 billion for State Litigation Settlement Account.	On page 155, strike \$196,500,000,000. Specify annual payment to States. In 2004, these should not increase by more than the increase in the industry payment.	HHS/AS MB
A Policy	Title IV: National Tobacco Settlement Fund	401 (d)	P. 156	The bill states that "Amounts in the trust fund shall be available in each calendar year, as provided by appropriations act."	Spending section of the bill is not complete. As a general rule, the final bill needs to make spending provisions mandatory for those specified in the Budget as mandatory (e.g. Class Size) and discretionary for those specified in the Budget as discretionary (e.g. NIH).	OMB
A Const'l	IV: Initial Payment	402 (a)(1)	157	Unless the initial payments are structured as preconditions to the receipt of federal benefits, this provision could raise bill of attainder concerns; we assume that the bill does this, but the definition of "participating manufacturer" needs to be made more clear	This will be part of DOJ's suggested edits of the "conditional" parts of the bill which are designed to reduce the bill's vulnerability to constitutional challenge	DOJ

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
A Policy	IV: National Tobacco Settlement Trust Fund	402(b)	158	Provides industry payments of \$23.6 billion in year 5, and \$21 billion in year 6 and later.	Currently, the bill proposes to decrease industry payments by \$2.6 billion at the same time the payments to States would increase by \$1.5 billion, decreasing the Federal share by \$4.1 billion. <u>The Federal share should not decrease.</u>	HHS/AS MB
<i>Done in technicals</i> Policy	IV: National Tobacco Settlement Trust Fund	402 (b)	P. 158, as amended by technical package	The bill includes an annual payment for the 5th year of \$23.6 billion and for the 6th year of \$21.0 billion. ~~The sixth year payment should be inflated from the fifth year.~~	Revise the language so the level in the 6th year and subsequent years is inflated from the previous year.	OMB
B Policy	IV: National Tobacco Settlement Trust Fund	402	159	Ford Amendment to ensure equitable treatment of small tobacco companies	This subsidization of small companies will provide a competitive advantage to imports unless it is clarified that this refers to total production of that manufacturer, not just to U.S. domestic sales. Even in this case, it may be difficult to impose on imports because it may be difficult to measure their total non-US production.	TR

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	IV. National Tobacco Settlement Trust Fund	402 (g)	P. 160	Participating tobacco manufacturers shall use its best efforts to pass through annual payments under the settlement agreement.	Do not attempt to monitor pass throughs and, therefore, strike Sec. 402 (g). Monitoring requires knowing what prices would have been in absence of this legislation.	OMB TR
Policy	IV.	403	162	liability credits	delete if they appear in the final committee print. page 162, line 3 through 163 line 17.	HHS/A SMB
Policy	IV. National Tobacco Settlement Trust Fund	408 (c) (1)	P.171	The Tobacco Trust Fund is placed off-budget under the McCain bill.	Placing the tobacco trust fund off-budget is objectionable. From a budgetary standpoint, all budget receipts and outlays should be included within the President's budget. In addition, from a policy standpoint, if funding is off-budget, it is not part of the Paygo scorecard, which makes the funds a much less flexible source of funding for the Administration's priorities. Strike Section 408 (c) (1).	OMB

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	IV: National Tobacco Settlement Trust Fund	410(a)	172	Provides that not less than 90 percent of surcharge payments should be awarded to State and local governments and public health agencies, and 10% can be used for Federal purposes.	Policy should state that funding levels should be decided by appropriators when amounts of surcharge payments are known.	HHS/A SMB

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	Title V: Standards to reduce involuntary exposure to tobacco smoke.	Sec 501 (2)(A) "General"	Page 174	As stated, law could exempt buildings with commercial/ retail/ light industrial establishments on first floor but residential on all other floors. It could also exempt buildings primarily used for commercial/ retailing/ light industrial purposes but which have one or two apartments (e.g. caretaker's unit). The intent may be to apply restrictions only to the nonresidential portion of the building. However, this may be misinterpreted to exempt entire buildings with any residential units.	Strike or amend "other than any building or portion thereof regularly used for residential purposes." Recommend clarifying language to close loophole and specify that when public facilities are shared with residential space, each must be on a separate ventilation system similar to those identified for smoking areas.	CDC/ OMB

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
B Policy	Title V	Sec 501 (2)(B) "Exclusions "	Page 174- 5	Exclusions listed in legislation are difficult to alter as public demand for expanded restrictions on indoor smoking become evident.	Recommend listing exclusions as part of regulation, not in the legislation itself, to allow for more progressive restrictions as public opinion accepts or demands greater smokefree indoor spaces.	CDC/ DOL
B Policy	Title V	Sec 501 (2)(B) "Exclusions "	Page 174- 5	Similar to Sec 501, (2)(A) "General," Page 174 regarding buildings with multiple use spaces, in this case restaurants.	Recommend clarifying language to close loophole and specifying that when public facilities are shared with residential space, each must be on a separate ventilation system similar to those identified for smoking areas.	CDC/ DOL
A Policy	Title V	Sec 501 (2)(C) "Fast Food Restaurants "	Page 175	Fast food restaurants are narrowly defined as McDonald's type facilities and does not include "family style" restaurants such as Olive Garden, Old Country Buffet, and Cracker Barrel which may not cater "largely to individuals under 18 years of age," but which are frequented by families with children.	Recommend that family style restaurants be covered by the restrictions and not exempted under the restaurants exception.	CDC/ DOL

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	Title V	Sec 502 (b)(1)(A) "Combustion of Tobacco"	Page 176	Does not include tobacco heating devices such as Eclipse.	Recommend including tobacco heating as well as tobacco combustion devices.	CDC/ DOL
Policy	V	501(3)	175	Only lessees that exercise control over their leased space should be held responsible.	Amend the term "responsible entity" as follows: "... with respect to any public facility, the owner of such facility except that in the case of any such facility or portion thereof that is leased to a lessee that exercises control over the leased space, including the ventilation system, such term may also mean the lessee.	DOL
Policy	V	502(b)(1)	176	Need to ensure that smoke from outside areas does not enter the public facility through air intake vents, or open windows or doors. Also need to ensure that smokers do not light up prior to entering designated smoking areas.	Amend to read as follows: "(A) prohibit the smoking of cigarettes, cigars, and pipes, and any other combustion of tobacco within the facility and on the facility property within the immediate vicinity (e.g., 20 feet) of the entrance to the facility or any air intake vent, including open windows or doors. Lighting of tobacco products shall also be prohibited within the immediate vicinity of entrances to specially designated smoking areas."	DOL

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	V	502©	176-177	Rewritten for clarity and specificity, and to protect nonsmokers from having to enter specially designated smoking areas before most of the contaminants have dissipated.	Amend to read as follows: "A specially designated smoking area meets the requirements of this subsection if (1) physical barriers are installed to separate such an area from surrounding smoke-free areas; 2) the area is under negative pressure compared to surrounding smoke-free areas; 3) all the air from the area is exhausted directly to the outside, through exhaust ducts under negative pressure, to ensure that air from the area does not recirculate or drift to other areas within the public facility; 4) nonsmoking individuals, including cleaning and maintenance workers, do not have to enter the designated smoking area for any purpose while smoking is occurring in the area, or for at least one hour after smoking in the area has ceased. Smoking shall not be allowed in the designated smoking area if the exhaust ventilation system is not operational."	DOL

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	V	502	177	Workers in the hospitality industry experience higher than average exposures to ETS, resulting in severe adverse health effects, and need some protections. Although it may not be feasible to eliminate exposures for these workers, the risks can be reduced by implementing controls.	Insert new paragraph as follows: "Smoking in Eating, Drinking and Gaming 502 (d) Facilities. (1) Where smoking is allowed in eating, drinking, and gaming facilities, the following protections shall be phased in: (A) restrict smoking to a specific area - within 6 months; (B) separate smoking and nonsmoking areas with physical barriers and keep smoking areas under negative pressure - within 24 months; © install additional engineering controls to reduce ETS exposures within the smoking areas (e.g., floor-to-ceiling displacement ventilation systems, local exhaust ventilation, and "clean-air islands," at fixed work stations) - within 36 months; and; (D) design and install improved ventilation systems in new construction and major renovations - within 5 years.	DOL

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	V	502	179	Due to the size and number of existing hotel guest rooms used as smoking rooms, and the difficulty of retrofitting existing guest rooms, requirements intended to protect nonsmokers in hotel guest rooms will only apply to new construction and major renovation.	Insert new section as follows: "(e) New Construction and Major Renovation 502 (e) of Hotel Guest Rooms. For all newly constructed and renovated hotel guest rooms: (1) Hotel guest rooms designated as "smoking" rooms shall be connected to a separate ventilation system from that servicing the rest of the building. (2) This separate ventilation system shall include additional engineering controls to reduce ETS exposures within the smoking rooms. Such controls, e.g., filtration, will allow recirculation of the air within that specific ventilation system. (3) Nonsmoking individuals shall not be required to enter a smoking room for at least one hour after smoking has ceased.	DOL

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	V	503(b) & ©	177-178	Need to clarify the difference between actions brought by private citizens and enforcement actions taken by OSHA against employers.	Amend to read as follows: "CITIZEN ACTIONS AND ENFORCEMENT . . . (b) Notification and Venue. Any person aggrieved by a violation of a smoking restriction provision shall notify the alleged violator. If the violation has not been corrected after 60 days from the date of notification, and the alleged violator is not an employer subject to the OSH Act, the aggrieved person may file an action in any United States District Court for the district in which the defendant resides or is doing business to enjoin any violation of this title or to impose a civil penalty of any such violation in the amount of not more than \$5,000 per day of violation. The district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce this title and to impose civil penalties under this title to require compliance."	DOL
Policy	V	~~new~~ 503©	174-179	In order to fully realize the intent of Congress in enacting this Title, there must be a clear enforcement mechanism for the smoking restrictions.	Amend to read as follows: "If an alleged violator is an employer subject to the Occupational Safety and Health Act and is endangering employees protected by the OSH Act, the Secretary of Labor will enforce the smoking restriction provisions of this Title as a mandatory occupational safety and health standard in accordance with the OSH Act . The 60-day notice requirement in paragraph (b) applies only to suits by aggrieved persons; employers violating this Title are subject to administrative enforcement by OSHA without such notice necessarily being given."	DOL

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	V	504	174-179	Need to clarify language to ensure that more protective regulations are not preempted by this Title.	Amend to read as follows: "Nothing in this title shall preempt or otherwise affect any other existing or future federal, State, or local law or regulation which provides greater protection from the health hazards of environmental tobacco smoke. States shall not be permitted to preempt or prevent localities from enacting protections against environmental tobacco smoke that are more protective than those provided for in this section. Moreover, nothing in a statute covering smoking restrictions should preempt any existing or future federal, State or local law or regulation that addresses other indoor airborne workplace hazards, e.g., Legionella."	DOL

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy and Technical	VI: Indian tribes	603 (d)(3)	183	Subsection establishes eligibility for assistance requirements in the enforcement of the tobacco manufacture, distribution or sale regulations	(d)(3) removes "tribal organizations" as eligible to carry out responsibilities of this section. This change would be consistent with use of 18 USC 1151 definition of Indian country. However, (d)(3)(A) still retains both "tribe or tribal organization", an inconsistency with changes in this subsection.	IHS / HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy and Technical	VI: Indian tribes	603(f)(1)	187	This is the Eligibility for Public Health Grants section, which authorizes grants to tribes and tribal organizations for anti smoking plans approved by the HHS Secretary.	Subparagraph (f)(1)(A) was changed to eliminate the term "tribal organization" and language directing grants to be "in an amount equal to the amount determined under paragraph (3)". This change could be perceived as conforming technical change, similar to changes in the FDA regulatory section. However, public health grants do not require that a tribal entity be responsible for civil regulatory action. IHS utilizes both direct IHS services and the Indian Self-Determination Act contracts to deliver care and this provision would not have the flexibility to permit non-contracting tribes, or tribally supported organizations to continue to provide health care to those affected Indian communities. <u>IHS Recommendation:</u> Language is needed to insert the definition of tribe or tribal organization, pursuant to the Indian Self-Determination Act, as eligible grantees. Subparagraph (f)(1)(B) needs to be reinstated (it was struck by the Gorton Amdt.) It had clarified that funds going directly to tribes (i.e., other than IHS funding) was within the State share. The original McCain bill indicated that funds for a tribe would be deducted from the amounts otherwise available to the State in which the tribe is located.	IHS / HHS The application should be to the trustees of the National Tobacco Settlement Trust Fund, not to the Secretary.

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy and Technical	VI: Indian tribes	603(f)(2)	187	This section authorized HHS grants to those tribes and tribal organizations whose anti-smoking plans have been approved by HHS in conformity with section 603(e).	A "technical" change deleted the term "tribal organization" as an eligible grant recipient. Again, this original provision failed to recognize that the Indian Health Service provides direct care, as well as by by contracts under the Indian Self-Determination Act. The Indian Self Determination Act recognizes the right of tribes to make determination on which mechanism is most appropriate for providing their health care services: IHS, tribally operated or a multi-tribal organization delivery system. Deletion of "tribal organization" further narrows who may be a recipient for grants, leaving potential gaps in coverage. <u>IHS Recommendation:</u> Language is needed to insert the definition of tribe or tribal organization, pursuant to the Indian Self-Determination Act, as eligible grantees. Language should be inserted that recognizes that IHS will have principle responsibility for administering section 603, which would also ensure that the Indian Self-Determination contract or grant mechanism may be utilized to fund such activities, concurrent with other IHS funding public health initiatives.	IHS /HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy and Technical	VI: Indian Tribes	603(f)(3)	188	This section provides that any tribal grant amount shall be determined by the ratio of total Indian reservation residents relative to the total State population involved, and the amount allocated to that affected state.	Change to this section again eliminates "tribal organizations" as eligible grant recipients. <u>IHS Recommendation:</u> See IHS Comments in preceding section. Language is needed to insert the definition of tribe or tribal organization, pursuant to the Indian Self-Determination Act, as eligible grantees. Language is needed to clarify that IHS may be responsible for services on behalf of those tribes with approved plans. Language is needed to ensure that states do not count Indian citizens for services when IHS does assume responsibility, pursuant to a tribally approved plan..	IHS / HHS
Policy and Technical	VI: Indian tribes	603(f)(4)	188	This section identifies those purposes such tribal grant monies may be used for.	Changes adopted would eliminate the term "tribal organizations" as recognized to receive such funding. <u>IHS Recommendation:</u> Language is needed to clarify that IHS may be responsible for services on behalf of those tribes with approved plans, as required under section 603(e).. Language is needed to prevent such grant monies being counted as "offsets" to the tribes or IHS's annual appropriations.	IHS / HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy and Technical	VI: Indian tribes	603(h)	189	This section identifies how monies received from the trust fund for tribal purposes may be utilized.	This language states that monies will be provided to IHS, and through the Indian Self Determination Act contract or grant mechanisms, to tribes for reduction of tobacco consumption and other related purposes, and identifying a potential listing of health purposes. <u>IHS Recommendation:</u> Language needs to be inserted that recognizes that, for tribes who do not desire to administer such activities under a contract, that IHS be eligible to provide such services on their behalf: Line 13, "...shall be provided to the Indian Health Service and <u>available</u> through the Indian Self Determination Act..." Line 15: The amendment to strike "tribal organization" should be reinstated, particularly since such deletion is inconsistent with the use of the Indian Self Determination Act authority which precedes it. Language should be provided that recognizes, whether IHS administers directly or by a Indian Self-Determination Act contract or grant, that these monies may be used concurrent with existing IHS public health activities addressing unmet health needs (as required by PL 93-437) Language should be provided that ensures that, where monies are used for facility construction purposes, that these purposes be in keeping with the established resource allocation methodology to avoid the problem of building infrastructure without the necessary accompanying infrastructure (staff,	ISH/HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	VII. Civil Liability	701	vii :3	Definition of Participating Manufacturer	Need to ensure that the definition of "participating manufacturers" includes any manufacturer that sells tobacco in the U.S., so that companies importing cigarettes into the U.S. must pay the annual assessment as well.	OMB
Policy	VII: Civil Liability	708	VII: 24	Fee on Nonparticipating Manufacturers	Are USTR and State confident we can impose this fee on nonparticipating foreign manufacturers without violating our trade agreements.	TR
Policy	VII, civil liability	702(A) (3)	VII: 7	The provisions affecting retailer, distributors, wholesalers, and importers are anti-competitive, and may not be in the public interest.	Strike provisions.	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	VII, civil liability	705	VII: 12	Public health groups have expressed concern about litigants being precluded from having cases in state courts. Some state and local courts are more receptive to these cases than federal courts.	Look into whether removal to federal court is legally and Constitutionally required.	FDA
Policy	VII, civil liability	705©	VII: 13	Barring claims based on addiction and dependence is inconsistent with the rest of this Title (on page 43, a provision states that in any actions brought, there will be a presumption that nicotine is addictive).	Strike lines 10-13.	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
A Const'l, Policy, & Technical	VII			DOJ is currently working on a rewrite of this Title this is intended to address constitutional concerns in a manner that would still serve the goals announced by Senator McCain. It should be noted that these provisions in the current bill are very unclear and that some of DOJ's "technical" changes may turn out to be substantive, such as the creation of a liability fund that is carried over from year to year.	Substitute DOJ proposal when completed	DOJ

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	VII	710	VII:29	Establishes tort trust fund that is funded on an annual basis	The purpose of this trust fund is unclear; Strike sec 710.	HHS/ASMB
Policy	VIII: Accountability Panel	Title VIII	191	This Title creates confusion as to the standard that the Secretary must meet in order to impose look-back surcharges and potentially give the companies an enormous loophole	Strike Title VIII (as amended into Title II)	DOJ
Const'l	IX: Use of funds for exportation		275?	The limitations on the President's ability to negotiate with foreign governments raise separation of powers concerns	Clarify that such restrictions are merely precatory.	DOJ

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	IX: Document Disclosure	901-911		The document disclosure provisions are similar, but not identical to the administration's proposal, which was adopted, almost entirely, by Harkin-Chafee-Graham; DOJ believes that the administration proposal is more clear and is more likely to function as intended.	Substitute administration proposal or section 404 of S.1889	DOJ/ FDA
Policy	IX, document disclosure	902	202	Requirement to disclose currently existing documents should apply to all manufacturers who market in the United States.	Strike lines 9-12.	FDA

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	IX, document disclosure	903 (b)(7)(B)	205	Listing of categories of documents is too narrow.	Insert section 404(d)(1) from S. 1889.	FDA
Const'l	IX: Document Disclosure	911(3)	220	Takings risk raised by the definition of "trade secret."	The definition appears to require implementation of a uniform federal standard of information that is entitled to protection as a trade secret, which may afford less protection than otherwise applicable state law. The risk could be reduced by aligning the uniform federal standard with the most restrictive existing state law standards.	DOJ
Policy	X. Long-Term Economic Assistance for Farmers	1012 (c)	P.229	Sec. 1012 of the McCain bill sets Trust Fund contributions at \$2.1 billion per year for FY 1999-2008, and at \$0.5 billion per year from 2009-2023.	The bill is very generous to farmers. As an alternative, tobacco farmers and their communities could be helped if the assistance to quota holders were limited to actual losses in the value of their quotas (estimated at up to \$2 billion total), with the remainder of funds made available for economic development (or for other purposes in the bill.) The \$25 billion included in the bill would compensate farmers for long-term domestic smoking trend reductions that are independent of the Settlement (flue-cured production is expected by USDA to fall 39 percent by 2005 and by 58 percent by 2009 without any settlement.)	OMB

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	X	1012	55E	Reduces total industry payments if funds from the Tobacco Settlement Trust Fund to assist farmers	Strike 1012(c)(1)(B), which reduces payments if the Tobacco Community Revitalization Trust Fund receives any funds from the Tobacco Settlement Trust Fund. Conform (1) by revising it to read ".....be equal to the amount of the contribution to the Trust Fund for the fiscal year required under paragraph (2)."	HHS/ASMB
Policy	Title XI	2801(2)(A)	315	bill specifies considerations by IOM in studying reduction of youth smoking	line 5, insert "and cessation" after prevention	HHS
Policy	XI, misc.	1106 PHSA 2802	316	The Commissioner of Food and Drugs should be on the National Task Force.	Line 18, insert a new paragraph (2): "(2) the Commissioner of Food and Drugs;" and renumber existing paragraphs.	FDA
Policy	Title XI	2803	318	Research and Surveillance funding	Separate the funding for surveillance and research to ensure that sufficient resources for surveillance are provided to monitor the lookback and penalty system, and to better monitor tobacco use patterns and impacts of prevention programs.	TR

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	Title XI	2803	319	Trigger would stop new funds to CDC for research and surveillance if agency's appropriation is less than in the previous year.	Delete or alter the trigger to remove the possibility that all new funding to CDC under the act would be contingent upon maintaining the agency's annual ~~appropriate~~ level. Maintain concept that funds from the act do not supplant existing agency funds, including those related to tobacco.	ASPE/ HHS

appropriation

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XI -Misc.	1106(a) (2804(a) and 2804(c) of the PHS Act)	320	<u>Funding and Expenditure of Funds</u> : Bill provides \$2.5 billion to NIH. The Director of NIH "shall provide funds to conduct or support epidemiological, behavioral, biomedical, and social science research (including the training of researchers) related to the prevention and treatment of tobacco addiction, and the prevention and treatment of diseases associated with tobacco use.	Amend § 2804(a) by adding the following at the end of the sentence on line 21 "to be allocated by the Director of NIH to its components, proportional to the funding received in annual appropriations acts." Strike § 2804(c) in its entirety. NIH would not support any proposal which would provide that increases for the fiscal years beyond FY 1998 are earmarked for any particular type of research. This leaves no flexibility to increase funding for research on the many devastating diseases and disabilities affecting our citizens. Because of the likelihood that most or all of any increases in the NIH budget would come from revenues generated by tobacco legislation, particular attention must be paid to how the money is designated. The bill would not provide funds for research on diabetes, Alzheimer's disease, spinal cord injury, cystic fibrosis, sickle cell disease, infectious diseases such as AIDS and hepatitis, or many other diseases. Moreover, given the nature of science and human biology, it would be difficult to adequately define the full spectrum of tobacco-related research today, and nearly impossible to define it for the future. Sixty percent of the NIH research portfolio is basic research that is aimed at understanding the fundamental aspects of living organisms. We cannot know in advance what findings from basic research	HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XI - Misc.	1106(a) (2804(d) of the PHS Act)	320	<u>Guaranteed Minimum:</u> Bill provides that 33% of the funds be set-aside for epidemiological, behavioral, and social science research related to the prevention and treatment of tobacco addiction.	Strike entire subsection. (2804 (d))	HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XI - Misc.	1106(a) (2804(e) of the PHS Act)	320	<u>Limitation:</u> Bill provides that funds set-aside for addiction research pursuant to section 2804(d) not be used to support neurobiological research, or research in which the behavior of an organism is observed for the purpose of determining activity at the cellular or molecular level, unless that research is necessary to study one of the purposes articulated in 2804(f).	Strike entire provision. (2804(c)) This provision is particularly problematic for NIH. In addition to earmarking funds to be spent on tobacco-related activities, this provision puts even greater limitations on NIH, by prescribing the <u>type</u> of research for which the funds may be used. If enacted, this would be the first time that Congress has put any limits on NIH's ability to do neurobiological research. Although this would still enable NIH to do this type of research if a determination were made that such research was necessary, this is a precedent-setting limitation that could open up the door to further encroachments on NIH's ability to set its own research agenda based on its scientific expertise.	HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
A Policy	XI - Misc.	1106(a) (2804(f) of the PHS Act)	321	<u>Nature of Research:</u> Bill provides that funds made available under the 33% set-aside be used to conduct or support a list of 11 activities.	Strike the provision in its entirety for the reasons articulated above. (2804(f))	HHS
B Policy	XI - Misc.	1106(a) (2804(g) of the PHS Act)	322	<u>Coordination:</u> Bill provides that the Director of NIH shall coordinate with the Task Force, and other agencies, in order to avoid duplicative efforts, by establishment of an Office of Tobacco Related-Research.	Strike lines 7-8 for the reasons set forth below.	HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XI - Misc.	1106(a) (2804(h) of the PHS Act)	322	<u>Office of Tobacco-Related Research:</u> Bill provides for the establishment of an Office of Tobacco Related Research that would coordinate and collaborate with other agencies, identify tobacco-related projects to be conducted by the research institutes, recommend to Congress the allocation of tobacco-related funds, and establish an information clearinghouse.	Strike the provision in its entirety. (2804(h)) There is no need for an office if the funds are not earmarked. However, any tobacco-related activities can be coordinated through the Office of Disease Prevention. By statute, the Associate Director for Prevention is responsible for "the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities..." Section 402(f) of the PHS Act.	HHS

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Const'l	XI: Center on Global Health and Tobacco	1132 (b)(4)	332-333	The composition of the ACT Board raises appointments clause and separation of powers concerns	Delete subsections (b)(4)(A), (B), and (C) and provide for appointments by the President with the advice and consent of the Senate.	DOJ
Policy	Title XI Subtitle C: "International Provisions"	Sec 1132 American Center on Global Health and Tobacco	Page 334	Again, the membership does not specify member's relationship to the tobacco industry.	Line 11= Recommend adding after "activities," "provided those individuals do not have direct or indirect, formal or informal, links with tobacco companies or any companies or entities affiliated with tobacco companies."	CDC

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	Title XI: Subtitle C: "International Provisions"	Sec 1132 "American Center on Global Health and Tobacco" (c) "Funding"	Page 334-5	The funding source appears duplicated for ACT. Under Sec 1131(a)&(b) \$150 million is available for use by ACT from the "International Trust Fund for the American Center on Global Health and Tobacco," derived from license fees collected under Sec 1121. Under Sec 1132(c)(1)&(2) a "Global Public Health and Education Resource Account" is created from general funds available under the "National Tobacco Settlement Trust Fund." The Global	Recommend clarifying this process.	CDC

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XI	Sec 1133 "Prohibit ions on use of Funds to Facilitate the Exportati on or Promotio n of Tobacco " (a) "In General"	Page 340-1	The prohibition on use of federal funds to promote or encourage the export, promotion etc. of tobacco may not be as broad as it first appears. The prohibition only applies to use of federal funds by any "officer, employee, department, or agency of the United States." This language would appear to allow funds to be used for this purpose by anyone else, including tobacco manufacturers or producers. For example, federal funds provided	This might be resolved by simply amending lines 1 and 5 on page 341 (Sec 1133(a)(1)[line 1]&(2)[line 5]) to read, respectively, "to <i>directly or indirectly, intentionally or unintentionally</i> promote or encourage the export . . ." and "to <i>directly or indirectly, intentionally or unintentionally</i> seek, through negotiation or otherwise . . ."	CDC

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
		Section 1133 continued		(Cont'd) directly to tobacco farmers to subsidize the cost of crops produced for export, thereby making U.S. products more cost-competitive in foreign markets, could be allowed under this provision. Similarly, tax deductions available to tobacco companies for foreign marketing expenditures could escape this provision.		CDC

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XI	Sec 1133 "Prohibitions on use of Funds to Facilitate the Exportation or Promotion of Tobacco" (b) Exception	Page 341	The definition of "arbitrary or unjustifiable" in subsection (c) may not provide sufficient protection of foreign regulation that legitimately treats imports unfavorably. An example would be a country seeking to ban tobacco products that have the potential to expand market size by appealing to new subsections of the population, such as filtered and/or flavored cigarettes that women and children are attracted to. While the country could	Such treatment of foreign products may violate international trade agreements but, with the various public health exemptions that exist, it might not. Domestic legislation should not restrict the health activities of foreign governments any more than existing international agreements already do. Monitoring of conflict of domestic legislation with international agreements is provided for in Section 1134.	CDC

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
		Sec 1133 continued		(Cont'd) apply to all filtered and flavored cigarettes, whether domestic or foreign, if the only companies offering filtered and flavored cigarettes were foreign, those companies would likely claim <i>de facto</i> discrimination		CDC
Policy	XI	1143	P. 345	The requirements for tracking of tobacco products under Sec. 1143 are unnecessarily burdensome.	Modify requirements of Sec. 1143 for the posting and returning of bonds at the shipment level are unnecessarily burdensome to both exporters and to the Federal government, particularly in light of the labeling requirement for export of tobacco products.	OMB

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XXVIII. National Efforts to Reduce Youth Smoking	1144	P. 347	The tobacco product permits program, while similar to Treasury's regulatory proposal, does not provide for: (1) retailer registration, and (2) assessment of fees to recover program administration costs.	Adopt the Administration's proposed language instead, where retailers must register with Treasury and pay a fee. The Administration's proposal would hold registrants accountable for violations of the terms and conditions of the permit.	OMB

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XI: Antitrust Exemption	1161	355	The bill provides a limited antitrust exemption that is too broad and may allow the manufacturers to collude in a manner inconsistent with the Act's goals; in addition, the exemption requires the Attorney General to oversee reduction of youth smoking plans; oversight by the AG is not desirable	Strike the entire section	DOJ

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XXVIII. National Efforts to Reduce Youth Smoking	1150	P.355	The McCain bill would authorize appropriations to carry out Subtitle E -- Prevention of Tobacco Smuggling, as opposed to the Administration's self-financing program.	Adopt the Administration's proposal with fees, and delete the authorization of appropriations section.	OMB
Const'l	XI: Provisions related to minorities	1171(b)	357	Subsection (b) raises equal protection concerns under the Fifth Amendment and the equal protection principles established in the Adarand case	Strike the requirement that funds go to minority institutions or institutions that provide health care to minorities.	DOJ

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	XI.F., misc.	1173	360	The amount of money to be available for counter-advertising is unclear. Counter-advertising is a critical component of the program, and sufficient funding needs to be allocated for this purpose.	Include adequate funding floor in the legislation.	FDA
Policy	Amendments	Snowe - 1181	N/A	Asbestos, black lung, Medicare	From the sense of the Senate amendment on the use of funds, delete "including Medicare" from (1). Delete (5) on Tobacco Asbestos Trust Fund and (7) on funding for Black Lung. Renumber accordingly. These uses would divert resources from public health programs.	HHS/ASMB

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Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Technical/ legal	Amendments	Burns	N/A	The amendment indicates that it should be placed in Title XI. The amendment lacks enforcement mechanisms. Vending machines are encompassed under the FDA rule, and the restriction is enforceable through the FDCA.	Add to Title I.A., a new FDCA section 917— "Section 917. BAN ON SALE THROUGH VENDING MACHINES. The Secretary shall promulgate regulations to prohibit the sale of tobacco products through the use of vending machines."	FDA
Policy	Amendments	Burns	N/A	Buys out tobacco vending industry in first two years.	Delete amendment – diverts resources from public health programs.	HHS/ASMB
Policy	Amendments	Rockefeller	N/A	Reimburse VA for the cost of disability entitlements due to tobacco-related diseases.	Administration has proposed legislation eliminating disability compensation for illnesses acquired <u>after</u> service. This \$10 B (CBO)/ \$17 B (OMB) proposal has been earmarked to offset transportation highway costs in the Budget Resolution. The Rockefeller amendment would also reimburse costs of tobacco conditions initiated <u>during</u> service. Administration position and cost impact pending.	OMB

POLICY COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/18/98 --UNEDITED

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

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Policy	Amendments	Rockefeller VA issue		Authority for VA to sue tobacco firms	Impact is unclear; there may be concerns once impact is known.	HHS/ASMB
Policy	Amendments	Inouye		Asbestos trust fund	Strike amendment -- diverts resources from public health programs.	HHS/ASMB
Policy	Amendments	Gorton		Require Indian tribes to collect Federal and State tobacco tax	Provision would run counter to a Supreme Court ruling in 1991 stating that the doctrine of sovereign immunity bars states from suing tribes to collect taxes. The amendment would remove incentives for tribes and states to enter into tax collection agreements. Such agreements are in force between roughly 200 tribes and 18 states.	OMB

POLICY COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/18/98 --UNEDITED

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

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Const'l	Consent Decrees	N/A	N/A	The Bill, as drafted, does not make clear the role of the Master Settlement Agreement, the consent decrees, and the protocol. The terms are not used consistently, and it is unclear what is conditional on what. DOJ is currently redrafting relevant sections to insulate the bill as much as possible from constitutional attack	See DOJ edits when completed	DOJ

POLICY COMMENTS ON SENATE COMMERCE COMMITTEE BILL -- 4/18/98 --UNEDITED

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

Type of Change	Bill Title	Section Number	Page Number	Description of Issue	Proposed Change	Agency
Const'l	Consent decrees	N/A	N/A	The Bill itself does not contain political speech restrictions, but, to the extent that it requires companies to enter into agreements that contain such restrictions, the bill raises very serious constitutional problems	Restrictions on political speech contained in proposed consent decrees, settlement agreements, or protocols should be eliminated.	DOJ
Policy				Medicaid outreach	Proposal from the President's Budget needs to be included.	HHS/ASMB
Policy				Medicare clinical trials	Proposal from the President's Budget needs to be included.	HHS/ASMB

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
Overall Position	Congress should reject the settlement and legislate a strong tobacco policy. It does not need the industry's help or permission to do this.	Settlement is a landmark effort that would generate far more \$ for public health activities than Congress would ever appropriate. Preferable to the uncertainty and delay of litigation.	Settlement is a great start for providing revenues for public health programs. No single piece of federal legislation will solve America's tobacco problem.	Settlement is not perfect but could help to significantly reduce tobacco use.	Settlement will not protect the public health. Industry can manipulate gaping loopholes.
Priority Issues	<u>5 Goals:</u> 1. unhampered FDA regulation of nicotine 2. prohibition of industry efforts to target kids 3. stiff penalties for targeting kids 4. smoke-free public places 5. excise tax to fund education and cessation programs	-Strengthen FDA jurisdiction over tobacco products -Increase Look Back penalties fivefold -No immunity	-Authority for FDA to develop performance standards as it sees fit that will apply from the effective date of the act -\$2 increase in price per pack -Equal treatment in certain respects of smokeless and pipe tobacco and cigars.	-Complete authority for FDA over tobacco products and nicotine -No immunity for past wrongdoing -Harsher Look Back penalties	-No changes or limits on FDA authority -No immunity or limits on industry's future liability
FDA Regulation	-Make explicit FDA's unlimited authority to regulate and phase out nicotine and remove other ingredients that contribute to the initiation of and dependence on tobacco products -Time limits or moratoriums on FDA activity should be flexible to accommodate advances in science, information, and health policy.	-FDA should be able to use same procedures (notice and comment) and standard of review (arbitrary and capricious) that generally apply under FDCA. -Instead of enumerating FDA powers, industry should specify limitations on FDA's authority--this way the inference is in favor of FDA authority	-Authority for FDA to develop tough performance standards that aim to reduce or eliminate any constituent, including nicotine and that apply from the effective date of the act -No formal rulemaking -Eliminate heightened standards of proof and FDA's black market obligation	-Complete authority over tobacco products and nicotine -Eliminate excessive bureaucracy -More resources -Concerned about formal rulemaking and black market requirements	-No changes to FDA authority - No formal rulemaking requirement -No obligation to prove unlikelihood of black market - Industry should not be allowed to designate any ingredient a confidential trade secret.

Look Back	-Adopt stronger targets: 15%-30% from years 1-5, and then 40%-65% from years 5-10. -No cap on penalties for failure -Increase penalties: if industry misses target by 5 points, it should pay 5 times the sanction -Assess compliance and penalties on a company-by-company basis	-No automatic pass through -No tax deductibility -Penalties should be assessed against each individual company based on its on reductions in underage use -Increase penalties from \$80 million to \$400-\$450 million to force industry to internalize social costs of underage use -Eliminate \$2 billion cap -Eliminate 75% rebate; add a \$80 million credit for each extra percentage point of reduction -Give FDA authority to tighten targets after 10 years	-Increase penalties -Eliminate 75% rebate -Eliminate \$2 billion cap -Reduction targets for smokeless should be same as for cigarettes, because it's more popular with teenage boys.	Penalties in the settlement should establish the floor--make them more severe. Amounts should be adjusted annually to reflect the most current data on teen smoking.	-Individual company accountability for reduction -Additional nonfinancial penalties like more ad restrictions -Define "reasonable available measures" in detail, so industry can't get the 75% rebate easily
Document Disclosure	Industry must disclose all documents that: -reveal public relations, advertising, marketing, promotion, and political activities -are improperly shielded by attorney-client privilege -reveal all technical and health/safety data -indicate industry strategies for targeting kids and minorities -show health effects of ETS	No recommendation. Dr. Lonnie Bristow has said that the 3-judge panel procedure is acceptable.	-Streamline 3-judge panel procedure -Industry must show why a document should not be disclosed -FDA must have all information relevant to the public health and the development of reduced risk tobacco products.	Full and open disclosure of all documents that relate to health issues	Streamline/eliminate overly time-consuming, bureaucratic review mechanisms like the document-by-document review of privileged records by industry lawyers.

Immunity	Congress does not know enough of their secrets to grant the industry immunity. Preserve all avenues of litigation, both civil and criminal.	Immunity to class action suits and punitive damages is a major drawback of the settlement. Class actions draw attention to industry deceit, whereas individual suits focus on plaintiff's personal responsibility. Punitives are the major source of large recovery for plaintiffs--without them, there is no incentive for individual suits. Free of the fear of liability, industry won't change its bad behavior.	No recommendation.	No immunity to either companies or their agents for past wrongdoing.	-Adamantly opposes any immunity or limits on the industry's liability -No cap on damages -Requiring public to accommodate corporate wrongdoing sets a dangerous precedent.
Size of Payments/ Price per Pack	-To really reduce children's use and overall consumption and raise revenues, price per pack should go up at least \$2. -Financial punishments should not be considered ordinary business expenses and tax deductible -Demand more money--the industry will boom under the current settlement as it is already targeting 18-24 year-olds.	Increase of at least \$1 per pack should be produced. This increase would result in a 15% reduction in overall consumption and a 33% in youth consumption.	-Payments are too small--either the payments or excise tax should produce a \$2 increase in price per pack. -Tax deductibility of payments makes things too easy for industry and decreases federal revenues.	Add provisions to prevent the industry from declaring bankruptcy.	Tax provisions that make every penny tax-deductible make things too easy for the industry.
ETS	<u>Ban smoking in:</u> -all work sites -all places of public assembly -outdoor areas where people assemble, like service lines, arenas -schools- inside and outside -all forms of public transportation, including flights going in and out of U.S. -all federal workplaces, including branches of military and VA hospitals	No recommendation. By enacting the Smoke-Free Environment Act of 1993, the settlement would achieve more than would stand alone legislation.	No recommendation. It is good that the provision would not preempt more stringent state or local laws restricting smoking in public places.	No preemption of stronger local and state clean air policies. OSHA standards are the minimum that must be met.	Settlement doesn't protect restaurant, bar, and hospitality workers who are most at risk for passive smoking disease.

Farmers	-Blue-ribbon panel should recommend short- and long-term strategies to reduce tobacco states' and communities' dependence on the crop. -Industry should finance an economic assistance and development fund to help tobacco farmers and non-farm industry workers find alternatives. -More settlement funds should go to farmers and less to trial lawyers.	Congress should use settlement funds to establish a public program to purchase tobacco farmland or tobacco crop allotments from farmers who want to leave the tobacco market.	No recommendation.	Set aside a portion of excise taxes to provide tobacco-producing communities with economic development assistance and opportunities for crop diversification.	No recommendation.
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Comprehensive Tobacco Proposals

March 12, 1998

Research, Public Health & Other Program
Investments

PROVISION	JUNE 1997 PROPOSED SETTLEMENT	MCCAIN (S1415) Universal Tobacco Settlement Act	JEFFORDS (S1648) “Preventing Addiction to Smoking Among Teens Act” (PAST Act)	HATCH (S1530) Placing “Restraints on Tobacco’s Endangerment of Children and Teens Act” (PROTECT Act)	KENNEDY (S1492) “Healthy and Smoke Free Children Act”	CONRAD (S 1638) “Healthy Kids Act”	HARKIN/CHAFEE/ GRAHAM (Tentative)	PRESIDENT’S BUDGET
RECEIPTS								
Total funding available and source of revenues.	Provides \$368.5 billion in <i>gross</i> payments over 25 years, including \$68.5 million by 2003, subject to adjustments for inflation, volume reduction, credits for settlement of individual cases, and penalties. Net receipts probably would be significantly less as Treasury and JCT generally estimate that increased excise taxes and related payments reduce other receipts somewhat.	Refers to a Settlement Trust Fund. No specific revenue source or amount is provided, and except for a Tobacco Community Revitalization Trust Fund, no specific funding levels are given for programs authorized. Another version of the bill (S1414) creates a National Tobacco Settlement Trust Fund in the U.S. Treasury. The trustees of the Trust Fund shall be the Commissioner of FDA and the Secretary of HHS. S1414 includes revenue and spending amounts consistent with the June 1997 Settlement, except does not provide payments in perpetuity beyond 25 years, and provides \$28.5 billion for growers. Other variations are noted below.	Funding made available from Tobacco Settlement Trust Fund, fees and penalties. No details are provided in the bill about total funding assumed available from Tobacco Settlement Trust Fund.	Establishes a Trust Fund from payments made by tobacco manufacturers. Trustees would be the Attorney General, and Secretaries of Treasury and HHS. Fund would have two accounts – State and Federal. Portions of the total funds are earmarked in the Federal Account for assistance to farmers, asbestos-related litigation, and new program to enhance Native American Health. Remaining funds are split equally between the State and Federal Accounts. Provides \$408 billion over 25 years (\$79 billion over five years) including an initial payment of \$10 billion.	Estimates based on a \$1.50 per pack increase in three installments, using the JCT estimates of the Conrad bill. Includes net revenues of \$67 billion over 5 years. All funding assumed to begin in 1999.	Estimates based on a \$1.50 per pack increase in three installments and a \$15 billion up-front payment (not tax deductible) that is assumed to occur in FY 99. Proponents estimate 25 year total at \$500 billion in net new receipts. Since 1999 includes a \$15 billion initial payment, funding decreases in 2000. Funding generally stabilizes in 2001, the last year with a sizeable assessment increase.	Estimates based on a \$1.50 per pack increase in two installments (\$1.00 the first year’s \$.50 the second year). Increases would be achieved through annual industry payments totaling \$20 billion in year one and \$25 billion annually thereafter, adjusted for inflation. Also requires industry to make an initial payment of \$10 billion.	Provides \$9.8 billion for 1999; \$65.5 billion total by 2003 in tobacco legislation receipts.
RESEARCH (See Next Page)								

PROVISION	JUNE 1997 PROPOSED SETTLEMENT	McCAIN (S1415) Universal Tobacco Settlement Act	JEFFORDS (S1648) "Preventing Addiction to Smoking Among Teens Act" (PAST Act)	HATCH (S1530) Placing "Restraints on Tobacco's Endangerment of Children and Teens Act" (PROTECT Act)	KENNEDY (S1492) "Healthy and Smoke Free Children Act"	CONRAD (S 1638) "Healthy Kids Act"	HARKIN/CHAFEE/ GRAHAM (Tentative)	PRESIDENT'S BUDGET
NIH	Recommends \$25 billion, to be paid over 8 years (\$17.5 billion over the first five years), for a Public Health Trust Fund. Calls for a Presidential Commission to be appointed to include representatives of the public health community, Attorney General, <u>Castano</u> attorneys and others to determine the specific <u>tobacco-related</u> medical research. While funds are not specifically earmarked for NIH, a substantial portion of this could be expected to fund NIH activities.	No provision	Provides \$2.5 billion annually for ten years to NIH for tobacco-related research. Not less than 40% of funds are to be made available to NCI; not less than 30% to NIDA.	Establishes a NIH Trust Fund for Health Research which reflects the settlement of punitive damages. Provides \$2.1 billion in first year, \$4 billion in year five and thereafter, \$95 billion over first 25 years. Requires Directors or Administrators of NIH, CDC, FDA, SAMHSA, and ONDCP to devise National Tobacco and Other Abused Substances Research Agenda. Funds expended as follows: OD – 2% Facilities – 2% Communications – 1% Cancer – 10% ICDs – 85% in same proportions as annual NIH appropriations bill. Grants and contracts from the Trust are to be fully funded in the first year. Trust is to be excluded for budget enforcement purposes. § 521	Provides \$1.57 billion in 1999; \$4.53 in 2001 for basic research. While there is an assumption that most would be used at NIH, funding would also be available for NSF and other institutions, potentially including AHCPR and CDC. Operates as a trust fund outside of the appropriations process. Also provides \$160 million in 1999 (\$450 million in 2001) for child development research, much of which would be in NIH.	Total: Provides \$1.1 billion in 1999, increasing to \$4.5 billion in 2001, for NIH research activities. Total NIH funding peaks in 2002 at \$5 billion, then drops to \$3.6 in 2003. Cancer: \$80 million in 1999 (\$350 million in 2001) is earmarked for cancer research. Tobacco: \$80 million in 1999 (\$350 million in 2001) is earmarked for tobacco-related research focusing on relationship between tobacco use and diseases, and behavior research on the addictive effects of nicotine.	Establishes a National Fund for Health Research to provide resources over and above those provided to the NIH in the annual appropriations process. Provides \$3.2 billion annually, distributed to ICD in accordance with appropriation allocation formulas. Directs ICD to give appropriate priority to tobacco-related research.	The budget increases NIH \$1.15 billion in 1999. 2001 funding would be \$3.0 billion above 1998. Increases total \$17 billion over five years. While cancer research is expected to grow 10% in 1999, there is no legislative earmark proposed.
CDC	No recommendation	No provision	See surveillance below	No provision.	See NIH above	\$10 million in 1999, increasing to \$50 million in 2001 is provided for CDC prevention research.	Not clear. See Other HHS Research.	Budget provides \$25 million in 1999; \$138 million over five years for CDC prevention research.
AHCPR	No recommendation	No provision	To be determined by National Tobacco Task Force.	No provision	See NIH above	\$10 million in 1999, increasing to \$50 million in 2001.	Not clear. See Other HHS Research	Budget uses tobacco funding, through the RFA, for \$46 million in 1999 and \$254 million over five years. The program level increase is \$25 million in 1999 and \$147 million over five years.

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Cancer clinical trials	No provision	No provision	No provision	No provision	No provision	Provides \$250 million annually from 1999 to 2001.	Not clear.	Provides \$200 million in 1999; \$800 million total by 2001 for demonstration project.
Other HHS Research	Recommends \$100 million annually to fund research and development of methods for how to discourage individuals from starting to use and how to help individuals to quit using.	Similar to June Settlement, establishes “National Cessation Research Program.” S1414 provided \$100 million annually.	Provides \$750,000 for IOM study on the framework for a research agenda to be used by Task Force.	No provision	Provides \$100 million, adjusted for inflation, for use reduction and addiction prevention research.	Smoking Patterns: Provides \$268 million in 1999 (\$200 million in 2001) for smoking pattern research focusing on minorities and women. Not clear which agency is expected to conduct research.	Provides \$625 million annually for prevention and cessation research.	See other uses below.
Non-HHS research	No recommendation	No provision	No recommendation	No provision	See NIH above	No recommendation	Not clear	Budget allocates \$3.6 billion for research in 1999, of which \$1.2 billion funds increases in HHS programs. Over five years, the budget allocates \$25 billion for research, compared to HHS research increases that total \$17 billion. The remainder funds research in NSF, Agriculture, Commerce, Education, Energy, HUD, Interior, VA, and EPA.
PUBLIC HEALTH								
Public Health	No dedicated funds for public health programs; however, Attorneys General recommend to the President and Congress public health programs and funding levels.	No specific amounts are provided. Establishes “Public Health Trust Fund” created within National Tobacco Settlement Trust Fund for block grants to States. Also Establishes Federal public health programs consistent with June Settlement recommendations. S1414	Funding made available from Tobacco Settlement Trust Fund unless otherwise noted.	Provides \$1.1 billion in first year, \$4 billion in year six; \$92 billion over first 25 years for public health programs. Specific program funding is not provided, except for State block grants described below. § 522	Funding for some public health programs are derived as a percent of excise revenues.	Excluding IHS programs, and FDA outreach and enforcement, funding for public health programs are derived as a percent of excise revenues.	Provides funding for various public health programs described below.	Funding for a number of public health activities is not specifically addressed. Instead, there is an allocation for other uses (see below) that include a number of public health activities.

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State tobacco block grants	Programs are funded directly, described below. “Lookback “ Surcharge: Not less than 90% of surcharge funds will be transferred as grants to States and local authorities to fund additional efforts to reduce underage use.	No specific funding amount provided. S1414 provides \$25 billion, to be paid over 8 years (\$17.5 billion over the first five years), then \$2.5 billion annually thereafter to reimburse States for tobacco-related expenditures, <u>including the establishment of liability settlement fund</u>. All programs must be approved by Secretary. Lookback “ Surcharge: Same as June Settlement.	Programs are funded directly, described below.	No less than 50% of public health funds are to be made available to states for anti-tobacco use and cessation program block grants.	Provides \$1.1 billion increasing to \$1.8 billion, adjusted for inflation, by 2009. For cessation school/ community-based programs, information campaigns, event sponsorship. § 2812, 2826	Programs are funded directly, described below.	Provides \$193.5 billion over 25 years for States. Of these funds, 50% is to be used for tobacco prevention, education and cessation, and the expansion of existing public health or children’s health programs. Also see Other Funds for States. Provides \$500 million annually for “Performance Bonus Pool” for states that meet or exceed the reduction targets within their own borders. Baselines and targets would be developed by CDC	Programs are funded directly, described below.

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Cessation	Recommends for the first 4 years, \$1 billion, and thereafter, \$1.5 billion of the total amount paid by the tobacco industry shall be paid into a Trust Fund to be used to assist individuals who want to quit using tobacco to do so. Secretary shall promulgate regulations to govern establishment of criteria of and a procedure for the approval of cessation programs and devices for which payment may be made under the program.	Same as June Settlement. S1414 provides \$1 billion for the first 4 years, and \$1.5 billion of thereafter.	Provides \$1 billion increasing to \$1.5 billion in 2008, terminating in 2009, for <u>State and Community Cessation Programs</u> . Requires States to submit a plan for approval to the Secretary which may include provisions for science-based programs designed to assist individuals quit their use of tobacco products; training in cessation intervention methods for health plans and professionals; programs to encourage health insurers to provide coverage for cessation; planning administration, monitoring and evaluation. State plan must be consistent with cessation guidelines issued by AHCPR. § 2841-2849	Directs CDC to inform tobacco consumers of effective therapies for ceasing consumption. Such actions shall be consistent with AHCPR guidelines. Directs Secretary to establish a model smoking cessation program that may be used by States. No specific amount provided for these activities.	Included in State tobacco block grants described above.	Provides \$884 million in 1999; \$650 million in 2001.	Provides \$1.5 billion when fully implemented for programs designed to enhance existing employer-based initiatives, and those which target uninsured and under-served populations.	See other uses below

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Tobacco Use Prevention Programs (school & community based)	Recommends \$75 million for first two years, \$100 million in the third year, and \$125 million annually thereafter to fund state and local tobacco control community based efforts modeled on the ASSIST program, designed to encourage community involvement in reducing tobacco use. Recommends \$125 million for the first three years and \$225 million annually thereafter to the Secretary of HHS to accomplish the reduction of tobacco usage through media and non-media based education prevention and cessation campaigns; research and development and public dissemination of technologies and methods to reduce the risk of dependence and injury from tobacco usage; testing and evaluation of health effects of tobacco; and promulgation of rules necessary to carry out the provision of this Act.	Same as June Settlement. S1414 provides \$75 million for first two years, \$100 million in the third year, and \$125 million annually thereafter. Same as June Settlement. S1414 provides \$125 million for the first three years and \$225 million annually thereafter.	Provides \$145 million in 1999 and 2000 increasing to \$440 million in 2008, and terminated in 2009, for <u>State and Community Action Program</u>. Requires States to submit to the Secretary, acting through the CDC Office of Smoking and Health for approval a plan which may include provisions for evidence-based community initiatives for tobacco use prevention and control; infrastructure development modeled after ASSIST program; counter-advertising; school-based efforts to prevent tobacco use and addiction; planning, administration, monitoring and evaluation of these activities. § 2831-2839	Directs Secretary, through the CDC to develop model curricula to educate the public about the health risks associated with tobacco use. Materials should be designed to influence behavior of young Americans. Directs CDC to provide technical assistance to State and local public health and educational officials, and parent-teacher and other civic organizations in developing age effective anti-tobacco curricula. Establishes program to develop educational materials for chronic users. No agency or organization directed to develop program. No specific amount provided for these activities.	Provides \$60 million increasing to \$100 million in 2003 (adjusted for inflation) for CDC Tobacco Use Prevention Programs. Additional fund for States included in block grants described above.	Provides \$402 million in 1999 (\$290 million in 2001) for CDC tobacco use prevention programs including community and school-based education and prevention programs.	Provides \$1.4 billion to states for community and school-based prevention activities. A portion of these funds will assist minority and low-income communities.	Provides \$74 million in 1999 for CDC tobacco control programs. Also see other uses below.

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Surveillance	Not specifically addressed.	Same as June Settlement.	For tobacco-related activities, provides \$290 million increasing to \$345 million by year 4 of provision then decreasing to \$145 million by year 10. Funds are to be used for tobacco-related surveillance, epidemiological studies, and the development of tobacco control prevention strategies, to be conducted by CDC in coordination with National Tobacco Task Force comprised of SG, and Dir. of CDC-OSH, AHCPR, NIH and other representatives.	Requires Secretary to use the Monitoring the Future Survey or such other comparable index, as determined appropriate by the Secretary , and that uses identical methodology . No specific amount provided for this activity. Surcharges imposed for failure to meet national goals are to be used to further the purposes of this Act. Manufacturers may apply for abatements equal to 100% plus interest of surcharges if good faith and compliance is proven. §311-3178	Requires child tobacco use surveys and other measures, though does not provide specific funding levels for these activities, but instead provides 25% of non-compliance fees to addiction and prevention research grants and for grants under the national tobacco usage reduction and education program which includes surveillance activities.	\$134 million in 1999; \$98 million in 2001.	Not clear	See other uses below.
Counter-advertising	Recommends \$500 million be spent annually in such multi-media campaigns designed to discourage and de-glamorize the use of tobacco products; to be carried out by an independent non-profit organization with a Board made up of prestigious individuals and the leaders of major public health organizations	Same as June Settlement. S1414 provides \$500 million to be spent annually.	Provides \$500 million annually for 10 years, for public health education and promotion. Contracts awarded to public and nonprofit private entities to carry out educational activities designed to reduce the use of tobacco. § 2861	Directs Secretary to carry out a mass media public education campaign. No specific amount provided for this activity.	Provides \$500 million annually, adjusted for inflation, for Federal counter-advertising campaign	Provides \$669 million in 1999; \$490 million in 2001, for media counter-advertising and non-media prevention and cessation campaign.	Provides \$750 million annually for a nationwide campaign with national, state and local components.	See other uses below

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Product regulation, enforcement of youth access restrictions and retailer outreach	Recommends \$300 million annually for the FDA to carry out obligations under this Act, including for grants to states to assist in enforcement.	Same as June Settlement. S1414 provides \$300 million annually.	Provides \$100 million for regulation and control of tobacco products. Funding derived from fee assessed on manufacturers based on their individual market shares. § 901-913 Provides \$65 million annually from 1999 to 2008, augmented by penalties and surcharges; allows rebates to manufacturers if national reduction targets are surpassed. Licenses retailers, requires photo ID’s, face-to-face transactions, location of products in areas where customers do not have access, no out of package distribution, no samples, imposes civil penalty on retailers and assesses surcharges on manufacturers if national targets are not met. § 2801-2817, 2821-2825	Directs Secretary to provides funds for the administration and implementation of the public health and regulatory provisions of the Act, including funds for the CDC and FDA. No specific amount provided for these activities.	Provides \$300 million, adjusted for inflation, for FDA tobacco outreach and enforcement activities.	Provides \$300 million annually for FDA outreach and enforcement activities including regulation on tribal lands, and to examine drug and cessation devices for effectiveness, and to approve effective cessation programs and devices.	Maintains FDA authority, but prohibits banning the sale of tobacco products to adults. Specific funding amount to FDA is not clear.	Provides \$134 million for FDA enforcement activities in 1999, increasing to \$292 million in 2003.
Alcohol & Drug Reduction	No provision	Same as June Settlement.	No provision	No specific provision. See research section described above for details on National Tobacco and Other Abused Substances research agenda.	No provision	Provides \$134 million in 1999; \$100 million in 2001.	Not clear.	See other uses below.

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International tobacco control	No provision	Same as June Settlement.	No provision	No provision	No provision	Provides \$54 million in 1999 (\$40 million in 2001) for governmental programs, and \$27 million in 1999 (\$20 million in 2001) for non-governmental programs.	Provides \$100 million annually for global education efforts. Terminates all support for tobacco promotion overseas by the US Government. Provides \$300 million annually to strengthen federal anti-smuggling activities, both domestically and internationally.	See other uses below.
PROGRAMS FOR NATIVE AMERICANS								
IHS programs	No specific provision	Same as June Settlement.	No provision	Provides \$200 million annually for anti-tobacco-related consumption and cessation activities including clinic and facility construction, renovation, and improvement; provider services; community sanitation associated with clinic construction and improvement; inpatient and outpatient services, or other programs provided through the IHS. § 101,901	No provision	Provides \$200 million annually for anti-tobacco-related consumption and cessation activities including clinic and facility construction, renovation, and improvement; provider services; community sanitation associated with clinic construction and improvement; inpatient and outpatient services, or other programs provided through the IHS. § 901	Not clear.	See other uses below.

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Other programs for Native Americans	States must reserve a portion of their Tobacco Block Grant funds for their Indian tribes under regulations determined by the Secretary of HHS. In response to a Tribe’s request, the Secretary may provide its share of the State’s Block Grant funding directly, reducing the amount which the State would have otherwise received. Requirements for the use of funds by Tribes is the same as it is for States. Appendix III	Same as June Settlement § 402, 403, 902	No provision	Provides that Tribes receive a portion of the funds provided for State Block Grants (see Other Funds for States). The Secretary of HHS shall reduce the amount made available for each State’s Grant according to the percentage of State residents who are Indians residing on reservations within its borders. Such funding shall be made available to Tribes as grants to further the purposes of the Act. Tribes shall be given flexibility to meet their unique health needs. § 101, 901	No provision	Provides that Tribes receive a portion of the funds provided for State Block Grants (see Other Funds for States). The Secretary of HHS shall reduce the amount made available for each State’s Grant according to the percentage of State residents who are Indians residing reservations (and other areas within the jurisdiction of Tribes) within its borders. Such funding shall be made available to Tribes as grants and shall be used to reimburse the Tribe for smoking related expenditures and to further the purposes of the Act. Tribes shall be given flexibility to meet their unique health needs. § 901	Not clear.	See other uses below.

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CHILDREN'S PROGRAMS (All are State programs, except Head Start)								
Medicaid	No Specified Activity	Same as June Settlement.	No Specified Activity	No provision	No Specified Activity	4% of the overall settlement amount will go towards Medicaid outreach. FY 99: \$0.82 B; FY01: \$0.64 B There are a number of changes to the Medicaid program, including: - Using Medicaid fund created by TANF to be used for Medicaid and CHIP outreach (Sec. 133(a)) - Expanding Entities Qualified to determine presumptive eligibility (Sec. 133(b)) - Allowing Immigrant children who enter after August 1996 into Medicaid and CHIP (Sec. 133(c)) The bill would give the secretary the ability to develop a baseline number of children enrolled in Medicaid. A bonus for enrolling children above a given baseline. (Sec. 133(d))	Not clear. See Other Funds for States.	Provides \$100 million in 1999. \$900 million over five years would be spent on outreach activities. There are a number of changes to the Medicaid program, including: - Using Medicaid fund created by TANF to be used for Medicaid and CHIP outreach. Increase size of fund by \$25 million and remove sunset. - Expanding Entities Qualified to determine presumptive eligibility. - Allowing Immigrant children who enter after August 1996 into Medicaid and CHIP. - Transferring Presumptive Eligibility Costs from CHIP to Medicaid.
Head Start	No provision	Same as June Settlement.	No provision	No specific provision. States may use their block grant funds in conjunction with and under a number of HHS programs including Head Start. See Other Funds for States described below. § 502	- Funding for Early Head Start FY 99: \$157 M; FY01: \$453 M. - Funding for Head Start: FY 99: \$392 M; FY01: \$1.13 B	No provision	Not clear. See Other Funds for States.	Head Start expansions (\$305 million in 1999) are funded through regular discretionary appropriations (not related to tobacco)

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Child Care and Development	No provision	Same as June Settlement.	No provision	No provision	- Expansion of CCDBG to increase availability and affordability of quality child care, <i>FY 99: \$314 M; FY01: \$0.9 B</i> - CCDBG Health and Safety <i>FY 99: \$314 M; FY01: \$0.9 B</i> - CCDBG School age care, <i>FY99: \$314 M; FY01: \$0.9 B</i> - Individuals with Disabilities Education Act funding <i>FY99: \$78 M; FY01: \$0.227 M</i> Research addressed above.	17% of the overall settlement amount will go towards Child Care and Childhood Development Block Grant. These funds can be used for CCDBG Affordability, Quality Improvement, and Services. (Sec. 131(a)) <i>FY99: \$3.49 B; FY01 \$2.70 B</i>	Not clear. See Other Funds for States.	Provides \$1.2 billion in 1999; \$7.5 billion total by 2003 for CCDBG (unrestricted). Additional child care activities are funded outside tobacco legislation.
Education Grants	No provision	Same as June Settlement.	No provision	No provision	No provision	Provides \$1.23 billion in 1999, \$950 million in 2001, \$4.9 billion over five years for education grants.	Not clear. See Other Funds for States.	Provides \$1.1 billion in 1999; \$7.3 billion over five years for class size initiative.
OTHER PROGRAMS								
Unspecified other uses	NA	NA	NA	NA	NA	NA	Not clear. See Other Funds for States.	Provides \$3.4 billion in 1999; \$22.3 billion total by 2003 for programs including cessation programs, farmers assistance, unrestricted State funds, counteradvertising, and support for other initiatives associated with national tobacco legislation.

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Other funds for States	Did not designate an annual amount for payments to States. Mississippi, Florida, and Texas settlements appear to assume States receive \$4 billion the first year, increasing to \$8 billion by the sixth year. The State settlements also appear to assume States would receive the entire \$10 up-front payment. Did not specifically address Federal share of Medicaid.	Same as June Settlement.	Not addressed	Establishes State Account and provides \$3.3 billion in year one; \$8 billion in year six and thereafter, and \$186 billion over first 25 years. Disburses funds in State Account in accordance with allocation formulas consistent with June Settlement. State is unrestricted in use of allocation, except for amount determined to be Federal Medicaid share. Allows State to keep Federal Medicaid share for anti-smoking or tobacco-related purposes. States must use the funds for anti-tobacco programs in coordination with existing Federal programs including child nutrition, MCH, CHIP, Head Start, IHS and Ryan White.	Total funds for States includes public health block grant, child care & Head Start funds, Medicaid funds. States also get 43% of net revenue, less funding for public health programs and compensation for victims, which starts providing funds the second year, and reaches \$2.3 billion in 2001. States may keep the Federal share of Medicaid recoveries if they are used for certain purposes.	Total funds for States includes grants from a number of public health programs, child care funds, education, and Medicaid programs plus payments of \$3 billion in 1999, \$2.3 billion in 2001. States not expected to repay Federal share of Medicaid recoupments. Total funding for States would exceed \$8.5 billion in 1999 and \$6.6 billion in 2001.	Provides \$193.5 billion over 25 years for States. Of these funds, 50% would be distributed to States to use for improving early education, child care, or other purposes at their discretion.	Includes \$2.4 billion in 1999 funding for child care, education, and Medicaid (\$15.7 billion over five years). Additional payments included under “unspecified other uses” above.
Protection of farmers	No provision	Establishes “Tobacco Community Revitalization Trust Fund” to be administered by Secretary of Agriculture. Provides \$2.1 billion annually from 1999 to 2008, and \$500 annually from 2009 to 2023, for tobacco quota buyouts and assistance to tobacco communities.	No provision	Establishes “Tobacco Transition Act,” and provides \$3.1 billion in year one; \$6.2 billion in year three; and \$16 billion over 25 years. Terminates the federal tobacco programs while making compensation to quota owners and tobacco farmers. Provides economic assistance to affected communities through block grants to states.	Provides \$3 billion annually for quota buyouts from 1999-2001. Provides \$500 million annually in 1999 and 2000, then \$800 million annually from 2001 to 2003, and \$400 million in 2004, for tobacco community transition assistance block grants.	Provides \$2.46 billion in 1999 (\$1.91 billion in 2001) for agricultural community revitalization. A separate authorizing bill is required for funding to remain available.	Provides \$15 billion for compensation, income support and traditional assistance to tobacco farming families, and for economic development and related assistance in tobacco communities.	See other uses above

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Event sponsorship	Recommends \$75 million annually for ten years to compensate events, teams or entries in events, who lose sponsorship by tobacco industry as a result of this Act.	Same as June Settlement. S1414 provides \$75 million annually for ten years.	No provision	No provision	Included in State tobacco block grants described above.	Provides \$27 million in 1999 (\$20 million in 2001) to compensate events, teams or entries in events, who lose sponsorship by tobacco industry.	Not clear.	See other uses above.
HI trust fund solvency	No provision	Same as June Settlement.	No provision	No provision	No provision	Provides \$570 million in 1999; \$390 million in 2001.	Not clear.	See other uses above.
Debt Reduction	No provision	Same as June Settlement.	No provision	No provision	No provision	Provides \$1.23 billion in 1999; \$950 million in 2001.	Not clear.	See other uses above.
Assistance to Sufferers	No provision.	See State tobacco block grants.	No specific provision. However, Senator Enzi, a co-sponsor, has proposed a smoker’s compensation fund.	Provides \$200 million annually beginning in year two for programs and activities carried out by Secretary of Labor relating to victims of asbestos-related injuries shown to have been exacerbated by tobacco use. § 101c3D	Provides \$780 million in 1999, increasing to \$2.26 billion in 2001, for victims assistance compensation fund.	Provides \$80 million in 1999; \$60 million in 2001.	Provides \$4 billion annually for a National Victim’s Compensation Fund.	See other uses above.

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State Plans/ Maintenance of Effort on New Spending	No Specified Activities	Same as June Settlement.	States must submit plans to spend tobacco funds.	States must submit plans to spend tobacco funds.	States must submit plans to spend tobacco funds. Additional funds provided under tobacco are to supplement not supplant existing expenditures. (Sec. 2811(c)(6))	State must submit plans for new spending. No specified maintenance of effort provision.	Not clear. See Performance Bonus Pool in State tobacco block grants described above.	

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