AN ANALYSIS OF THE PRESIDENT'S CONCERNS AND THE DRAFT NATIONAL TOBACCO LEGISLATION

On September 17, 1997, President Clinton challenged Congress to pass sweeping tobacco legislation that would significantly reduce underage tobacco use, and implement and build on the proposed settlement agreed on in June by the tobacco industry, many state attorneys general and private class action plaintiffs. The President announced that there are 5 key elements as set forth below that must be addressed by any national tobacco legislation.

Legislation has been drafted to implement the proposed settlement, and that draft legislation also addresses the concerns voiced by the President. What follows is a statement of the President's concerns (from the White House press release of September 17, 1997), with references to the provisions in the draft legislation which address those concerns.

One preliminary note is required: the Memorandum of Understanding which embodies the proposed settlement provides for the execution of a contractual agreement to be called the National Tobacco Control Protocol ("the Protocol"), which will include many of the agreed upon changes in the tobacco industry's corporate culture, restrictions on advertising and the like. The Protocol is provided for in the draft legislation at section 612. Where concerns of the President are anticipated to be addressed in the Protocol, that fact is so indicated in the following table.

THE PRESIDENT'S CONCERNS	WHERE ADDRESSED IN THE DRAFT LEGISLATION
1. A Comprehensive Plan to Reduce Youth Smoking, Including Tough Penalties If Targets Are Not Met. The central goal of tobacco legislation must be a comprehensive, nationwide effort to reduce teen smoking. The Administration is calling for:	See Section 2(a). Section 1008.
Tough Penalties and Price Increases to Reduce Youth Smoking: The Administration believes tobacco legislation must include stiff penalties that give the tobacco industry the strongest possible incentive to stop targeting kids. Legislation should set ambitious targets to cut teen smoking by 30% in 5 years, 50% in 7 years, and 60% in 10 years, and impose severe financial penalties that hold tobacco companies accountable to meet those targets. Tocay, the President called for a combination of industry payments and penalties to increase the price of cigarettes by up to $1.50 a pack over the next decade as necessary to meet youth smoking reduction targets.	Section 1009 Section 404

THE PRESIDENT'S CONCERNS	WHERE ADDRESSED IN THE DRAFT LEGISLATION
A Public Education and Counter Advertising Campaign: Legislation must provide for a nationwide effort to deglamorize tobacco, warn young people of its addictive nature and deadly consequences, and help parents discourage their children from taking up the habit.	Sections 506, 507, 508, 511
Expanded Efforts to Restrict Access and Limit Appeal: The Administration supports legislation codifying the FDA's efforts to reduce youth access to tobacco, and imposing even stronger restrictions on youth access and advertising consistent with the Constitution.	Sections 101, 621, 1001, 1002; 1005, 1006 Protocol
2. Full Authority for FDA to Regulate Tobacco Products. The Administration supports federal legislation that affirms efforts by the Food & Drug Administration (FDA) to regulate tobacco like any other drug or device and that provides FDA with sufficient flexibility to meet changing circumstances.	Sections 131, 132, 133

THE PRESIDENT'S CONCERNS	WHERE ADDRESSED IN THE DRAFT LEGISLATION
3. The Tobacco Industry Must Change The Way It Does Business. The President called for the tobacco industry to stop marketing and promoting tobacco to children, provide broad document disclosure–especially of those documents relating to marketing tobacco to children, and set up comprehensive corporate compliance programs that will reinforce the incentives created by youth smoking penalties.	Sections 111, 802, 1005, 1006, 1009; Protocol
4. Progress Toward Other Public Health Goals. Federal tobacco legislation provides an opportunity to meet other public health goals: the reduction of second-hand tobacco smoke, the expansion of smoking cessation programs, the strengthening of international efforts to control tobacco, and the provision of funds for health research.	Sections 301-306 Sections 401, 501, 506-509, 511
5. Protection for Tobacco Farmers and Their Communities. The Administration is committed to working with members of Congress in both parties to ensure that we protect the financial well-being of tobacco farmers, their families, and their communities.	Section 510

side by side

DRAFT **MARCH 17, 1998**

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

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

Provision	Harkin/Chafee (S ___)	Conrad (S 1638)	Hatch (S 1530)	McCain (S 1414)	Kennedy (S 1492)	Jeffords (S 1648) Revised
International tobacco control	-$100 million annually for global education efforts. -Terminates support for tobacco promotion overseas by the US Government. -$300 million to strengthen federal anti-smuggling activities, domestically and internationally	-$54 million in 1999 ($40 million in 2001) for governmental programs -$27 million in 1999 and $20 million in 2001 for non-governmental programs.	No provision	No provision	No provision	No provision
Medicaid	-Not clear	-4% of the overall settlement amount will go towards Medicaid outreach	No provision	No specified activity	No specified activity	No specified activity
Child Care and Development	-Not clear	-Expansion of CDCBG	No provision	No provision	-Expansion of CDCBG	No provision
Protection of Farmers	-$15 billion for compensation, income support and traditional assistance to tobacco farming families, and for economic development and related assistance	-$2.46 billion in 1999 (1.91 billion in 2001) for agricultural community revitalization	-$3.1 billion in year one; $6.2 billion in year three; and $16 billion over 25 years -Terminates the federal tobacco programs while making compensation to quota owners and tobacco farmers	-$2.1 billion annually from 1999 to 2008 and $500 million annually from 20009 to 2023 for tobacco quota buyouts and assistance to tobacco communities	-$3 billion annually for quota buyouts from 1999-2001 -$500 million annually in 1999 and 2000 then $800 million annually from 2001 to 2003, and $400 million in 2004, for tobacco community transition assistance block grants	No provision
Event Sponsorship	-Not clear	-$27 million in 1999 ($20 million in 2001) to compensate events, teams, or entries in events, who lose sponsorship by tobacco industry	No provision	-$75 million annually for 10 years to compensate events, teams, or entries in events	-Included in State tobacco block grants	No provision

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

Tobacco - Side 4n Side

Key to Comments:

FDA blue
DoJ red

S.1415

Universal Tobacco Settlement Act

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

[pp.4-6]

- Stating that "FDA found . . ." may negate the helpfulness of these findings; probably need to make it clear that Congress recognizes and adopts the particular findings.

- Need to have more extensive findings on advertising issues. The following would be appropriate (essentially what's in the Conrad bill with minor edits):

  - In 1995, the tobacco industry spent close to $4,900,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

  - Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful.

  - Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.

  - Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

  - Children are exposed to substantial and unavoidable tobacco advertising, that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

  - Tobacco advertising increases the size of the tobacco market by increasing consumption of tobacco products including increasing tobacco sales to young

people.

- Children are more influenced by tobacco advertising than adults, they smoke the most advertised brands, and children as young as 3 to 6 can recognize a character associated with smoking at the same rate that they recognize cartoons and fast food characters.

- Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market.

- Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.

- Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

- International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones. Text only requirements, while not as stringent as a ban, will accomplish this purpose while preserving the informational function of advertising.

Sec. 3. Purposes.

[pp.7-9]

- A number of these findings are unnecessary and/or not consistent that changes that will be discussed below—

- (2) position currently is that specific advertising restrictions should not be in legislation; also, FDA's restrictions do not ban all outdoor advertising, and its black and white text only requirements encompass limits on cartoon characters and human figures.

- (3) This is a reference to a state-administered licensing program. The working group seems to support the concept of a federal registration system. Required state licensing programs may be unnecessary.

- (5) is unnecessary because the concept is encompassed by general FDA authority.

- (6) contains an unnecessary clause, "including the power to regulate the level of nicotine in such products," which is encompassed in general FDA authority.

- (7) A final decision has not been made as to whether companies will be required to publically disclose future laboratory research.

TITLE I--REGULATION OF THE TOBACCO INDUSTRY

Sec. 100. Definitions.

- Relation of these definitions to the Federal Food, Drug, and Cosmetics Act (FDCA) is unclear; some of the definitions are more narrow than FDCA usage. For example, under FDCA, "commerce" includes movement from a foreign country to the United States. The definitions could be a problem if FDA wished to adopt a broader definition of a particular term with respect to tobacco (such as manufacturer).

Subtitle A--Restriction on Marketing and Advertising

Sec. 101. Prohibitions on advertising.

- Codifies restrictions expressly into legislation. Constitutional concerns regarding advertising restrictions that go beyond FDA restrictions have been discussed with McCain staffers. To retain flexibility, it would be preferable to simply affirm FDA's authority to issue advertising restrictions rather than include specific restrictions in statute. In order to clarify the agency's authority in this regard, amend section 520(e) as follows:

  - Section 520(e)(1) is amended by striking "or use-" and inserting "or use, including restrictions on the access to and the advertising and promotion of, tobacco products-"

- To ensure that 1996 FDA regulations do not need to be re-promulgated, the legislation should include the following statement validating the regulations enacted by FDA—

  - "The regulations promulgated by the Secretary in the rule dated August 28, 1996 (Vol. 61, No. 168 F.R.), adding part 897 to title 21, Code of Federal Regulations, shall be deemed to have been properly promulgated under the Food, Drug and Cosmetic Act as amended by this title."

Specific comments on the particular restrictions

- Section 101(d)(3)(B) [p. 16]: The provision allowing the manufacturer with at least a 25% market share to have another sign at point-of-sale serves no public health interest, and would only further strengthen market leaders.

- Section 101(d)(4)(B) [p. 17] permits audio and video materials to be distributed (but not played) at point of sale. These materials will make their way to children. The FDA rule limits audio or video formats to words only with no music or sound effects and, for video, static black text only on a white background. Any audio with the video is limited

to words only with no music or sound effects. Materials may not be taken from the store. (These restrictions do not apply in adult-only facilities; the audio/visual materials may not, however, leave the adult-only facility).

- The enforcement authority for these provisions is unclear. This was discussed in the 2/27 letter. Advertising restrictions similar to the FDA tobacco rule restrictions can be enforced under FDCA enforcement provisions. If the language discussed above is enacted, the FDCA enforcement provisions would be operative.

Sec. 102. General restrictions.

- See comment for section 101.

- Restriction on glamorization [p. 20] goes beyond FDA rule; would be difficult to enforce; may raise constitutional issues.

Sec. 103. Format and content requirements for labeling and advertising.

- See comment for section 101.

- section 103(b)(1)(A)(ii), advertising in adult only locations [p. 21]: FDA rule requires items to be affixed to the facility. It is not sufficient to be attached to a fixture (this could include banners, etc. that could be removed easily by patrons). Should delete "or fixture."

Sec. 104. Statement of intended use.

- These provisions are in FDA rule; unnecessary if FDA's jurisdiction to regulate products as drug delivery devices is affirmed.

- In addition, the statements of intended use in the FDA rule employ BATF terms of reference for smokeless tobacco products. As a result, only two intended use statements for smokeless tobacco products should be permitted—

    Chewing Tobacco--A Nicotine-Delivery Device for Persons 18 or Older.

    Snuff--A Nicotine-Delivery Device for Persons 18 or Older.

Sec. 105. Ban on nontobacco items and services, contests and games of chance, and sponsorship of events.

- See comment for section 101.

Sec. 106. Use of product descriptors.

- FDA may find, based on available information, that it is not in the interests of public health to permit usage of the terms "light" and "low tar" even with disclaimers. FDA should retain existing authority to prohibit the use of such terms. Section 106(b) would permit FDA to continue to do this.

Subtitle B--Warnings, Labeling and Packaging

Sec. 111. Cigarette warnings.

- Not clear what part of government is responsible for these provisions; "[FDA] Commissioner" is supposed to do some things; FTC is to approve compliance plans; "Commission" is to do other actions. The language changes below refer to the HHS Secretary.

- Section 111(a)(2) [p. 27, lines 15-16], modify as follows (add words in bold)—

  - (2) ADVERTISING- It shall be unlawful for any manufacturer, ~~or~~ importer, ***distributor, or retailer*** of cigarettes to advertise or cause to be advertised . . .

- ADD at the end of Section 111(a)(2) [p. 28, line 11], the following—

  - "(3) ADDITIONAL WARNINGS.--Beginning on the date that is 18 months after the date of enactment of this subchapter, the Secretary may substitute for, or require warnings in addition to, those otherwise required under subparagraphs (1) and (2) if the Secretary determines that such warnings would be more effective in deterring the use of cigarettes."

- Section 111(b)(1) [p. 28, lines 12-16], modify as follows (add words in bold)—

  - (1) LOCATION- Each label statement required by paragraph (1) of subsection (a) shall be located on the upper portion of the front and rear panels of the cigarette package (or carton) ***directly on the package underneath the cellophane or other clear wrapping*** and occupy not less than 25 percent of such ~~front~~ panel.

- Section 111(b)(3) [p. 29, lines 5-8], modify as follows (add words in bold)—

  - (3) EXCEPTION—The provisions of paragraph (1) shall not apply in the case of a flip-top cigarette package (offered for sale on the date of enactment of this Act) ***manufactured or distributed prior to January 1, 2000*** where the front portion . . .

- Section 111(c)(1) [p. 29, lines 14-17], modify as follows (add words in bold)—

  - (1) LOCATION- Each label statement required by paragraph (2) of subsection (a)

shall ***appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area and shall*** occupy not less than 20 percent of the area of the advertisement involved.

- Section 111(d) [p. 31, line 6, - p. 33, line 15], DELETE and replace with—

  - "(3) FORMAT.--The label statements under paragraph (2) of subsection (a) shall be black when the background is white and white when the background is black, and shall be in the point size required under this subparagraph. The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first down stroke of the capital 'W' of the word 'WARNING' in the label statements."
  "(4) LANGUAGE REQUIREMENT.--The label statements required under paragraph (2) of subsection (a) shall be in English, except that—
    "(i) in the case of an advertisement that appears in a newspaper, magazine, periodical or other publication that is not in English, such statements shall appear in the predominant language of the publication; or
    "(ii) in the case of any other advertisement that is not in English, such statements shall appear in the same language as that principally used in the advertisement."

"(d) ROTATION OF LABEL STATEMENTS.--
"(1) LABELING.--The label statements specified in paragraph (2) of subsection (a) shall be randomly displayed in each 12 month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which such product is marketed in accordance with a plan submitted by the manufacturer, importer, distributor or retailer and approved by the Secretary."
"(2) ADVERTISING.--The label statements specified in paragraph (2) of subsection (a) shall be rotated quarterly in alternating sequence in advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer, importer, distributor or retailer and approved by the Secretary."
"(3) APPROVAL OF PLANS.--The Secretary shall review each plan submitted by a manufacturer, importer, distributor or retailer of cigarettes under this paragraph and approve such plan if the plan will provide for the equal distribution and display on packaging and the rotation required in advertising under this paragraph and if such plan assures that all of the labels required under subparagraphs (1) and (2) will be displayed by the manufacturer, importer, distributor or retailer at the same time."

- DELETE Section 111(e) [p. 33, lines 16-19]. Exports are addressed in Section 117 [pp. 39-40].

Sec. 112. Smokeless tobacco warnings.

- Section 112(a)(2) [p. 34, lines 14-16], modify as follows (add words in bold)—

- (2) ADVERTISING- It shall be unlawful for any manufacturer, ~~or~~ importer, ***distributor, or retailer*** of smokeless tobacco products to advertise or cause to be advertised . . . .

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ADD at the end of Section 112(a)(2) [p. 35, line 4], the following—

- "(3) ADDITIONAL WARNINGS.--Beginning on the date that is 18 months after the date of enactment of this subchapter, the Secretary may substitute for, or require warnings in addition to, those otherwise required under subparagraphs (1) and (2) if the Secretary determines that such warnings would be more effective in deterring the use of smokeless tobacco products."

- Section 112(b)(1) [p. 35, lines 5-8], modify as follows (add words in bold)—

  - (1) LOCATION- Each label statement required by paragraph (1) of subsection (a) shall be located on the ***two*** principal display panels of the product and occupy not less than 25 percent of ~~such~~ ***each*** panel.

- Section 112(c) [p. 35, lines 22-24], delete (1) after (d) (conforms to changes above)—

  - "(c) ADVERTISING AND ROTATION- The provisions of subsections (c) and (d)~~(1)~~ of section 111 shall apply to advertisements for smokeless tobacco products and the rotation of the label statements required under subsection (a)(1) on such products."

- DELETE Section 112(d) [p. 36, lines 3-7]. Exports are addressed in Section 117 [pp. 39-40].

- After 112(e) [p. 36, line 11], ADD the following—

  - (f) OTHER TOBACCO PRODUCTS—The Secretary may prescribe such regulations as may be appropriate to establish warning labels for other tobacco product packaging, labeling, and advertising.

Sec. 113. Ingredients.

[pp. 36, lines 12-17]

- This refers to a proposed new provision of the FDCA; the requirements of proposed FDCA section 119 do not need to be repeated here. Should delete.

Sec. 114. Enforcement, regulations, and construction.

[pp. 36-37]

- At minimum, a violation of section 113 (a proposed new FDCA provision) should not be enforced by FTC but by FDA.

- Suggest deleting sections 114(a)-(c), and have provisions be enforced under FDCA. Warning statements are a concept encompassed by FDCA. Given the public health purpose of these statements, they are appropriately administered and enforced by FDA.

Sec. 115. Preemption.

[p. 38, lines 1-14]

- Delete "or in any advertisement" in subsections (a), (b) [lines 6 and 12-13].

Sec. 116. Reports.

Sec. 117. Exports.

- Warning statement requirements would not be required for exports. Is there a policy issue?

Sec. 118. Repeals.

Subtitle C--Restriction on Access to Tobacco Products

Sec. 121. Requirements relating to retailers.

Sec. 122. Manufacture, sale, and distribution.

[pp. 40-44]

Sec. 121. Requirements relating to retailers
Sec. 122. Manufacture, sale, and distribution

- These provisions codify the FDA access restrictions. To retain flexibility (and simplify this legislation), it may be preferable to simply expressly affirm FDA authority to enact access restrictions and recognize the 1996 regulations. See comments on section 101, above.

Subtitle D--Licensing of Retail Tobacco Sellers

Sec. 131. Establishment of program.

Sec. 132. Requirements.

Sec. 133. Penalties, revocations and suspensions.

Sec. 134. Federal licensing of military and other entities.

[p. 44-52]

Sec. 131. Establishment of program
Sec. 132. Requirements
Sec. 133. Penalties, revocations and suspensions
Sec. 134. Federal licensing of military and other entities

- These provisions would, in effect, shift enforcement of the FDA access restrictions to individual state programs. FDA believes that a comprehensive federal enforcement strategy is necessary.
- There have been extensive discussions within the administration (DPC, HHS/FDA, DOJ, Treasury) to finalize a federal approach to "licensing" that would achieve this goal as well as provide necessary controls over the chain of distribution. Legislative language is being drafted now.
- The penalty scheme is based on violations within a 2 year period; FDA's current enforcement strategy does not impose any time restrictions on the schedule for escalating penalties.

Subtitle E--Regulation of Tobacco Product Development and Manufacturing

Sec. 141. Reference.

Sec. 142. Treatment of tobacco products as drugs.

[pp. 52-55]

Sec. 141. Reference
Sec. 142. Treatment of tobacco products as drugs

- These provisions should be deleted and replaced with the provisions for express affirmation of FDA authority.

  - To express affirm FDA jurisdiction, and amend the definitions of drug and device to specifically include nicotine in tobacco as a drug and tobacco products as devices, the following is needed—

    Drug: Section 201(g)(1) is amended by striking"; and (D)" and inserting ";(D) nicotine in tobacco products; and (E)"

    Devices: Section 201(h) is amended--in paragraph (2) by striking "or" at the end; in paragraph (3), by striking "and" at the end and inserting "or"; and by inserting after paragraph (3), "(4) a delivery component of a tobacco product; and"

- Consistent with the traditional FDCA approach of defining regulated products rather than specific products within the category, it would be only necessary to define "tobacco products," e.g.—

  "201(kk) The term 'tobacco product' means any product made or derived from tobacco leaf made for human consumption."

  - If desired, the following clause could also be included, but is not necessary:

  ", including, but not limited to, cigarettes, cigarillos, cigarette tobacco, cigars, little cigars, pipe tobacco, and smokeless tobacco, and roll-your-own tobacco."

- Thus, p. 52, line 20, — p. 55, line 4, should be deleted and replaced with the above.

Sec. 143. Health and safety regulation of tobacco products.

[pp. 55-83]

- Should not create a separate chapter for tobacco products; tobacco products should be subject to regulation as drugs and devices. (Specific comments on proposed sections follow).

Section 901

- Incorporates definitions of Sec. 100; some of the definitions are more narrow than current FDA provisions or interpretations. FDA could face unnecessary obstacles if it wished to promulgate a broader definition of a particular term (such as manufacturer).

Section 902: purpose

- Unnecessary.

Section 903: regulations

- FDA already has this authority under section 701.

Section 904: minimum requirements

- Already have misbranding and adulteration authority in sections 501, 502.

Section 905: performance standards [pp. 57-60]

- Already have this authority under section 514; may wish to include authority for FDA to issue performance standards prior to classification (because classification is a lengthy

process and the issuance of performance standards requires notice and comment rulemaking).

- The following would provide such authority—

  "The Secretary may adopt a performance standard under section 514(a)(2) for a tobacco product regardless of whether the product has been classified under section 513."

- If there is a desire to specify what the standards could encompass, the following could be added, but is not necessary—

  "Such standards may include--
  "(1) the reduction or elimination of nicotine yields of the product;
  "(2) the reduction or elimination of other constituents or harmful components of the product; or
  "(3) standards relating to any other requirement pursuant to section 514(a)(2)."

  "(b) TOBACCO CONSTITUENTS.--The Secretary may require that a manufacturer test, report and disclose tobacco and tobacco smoke constituents, including labeling and advertising disclosures relating to such constituents, including, but not limited to, tar and nicotine."

- In particular, the agency opposes the limitations on its authority in 905(f), (g) [p. 61]. Developments in nicotine replacement products or nicotine analogues may make these options appropriate at some point in the future.

Section 906: scientific advisory committee [pp. 61-63]

- Already have provision under current FDCA section 904 to establish advisory committee (and there are requirements in various operational device provisions to consult with an advisory group). Not opposed to special provisions for a tobacco scientific advisory group, provided that there is no requirement of tobacco industry representation.

Section 907: nicotine and other constituents [pp. 63-68]

- Unnecessary and unduly burdensome.

- The approach that would be more consistent with the public health would be to codify the approach explained in the preamble to the FDA Tobacco Rule, 61 Fed. Reg. 44412-13, in the device provisions:

  - Section 513(a) is amended in paragraph (1)(B), by inserting after the first sentence

"For a device which is a tobacco product, the assurance in the previous sentence need not be found if the Secretary finds that special controls achieve the best public health result."; and in paragraph (2) by redesignating subparagraphs (A), (B) and [C] as clauses (i), (ii), and (iii), respectively; by striking "(2) For" and inserting "(2)(A)For"; and by adding at the end "(B) For purposes of paragraph (1)(B), subsections (c)(2)(C), (d)(2)(B), (e)(2)(A), (f)(3)(B)(i), and (f)(3)(C)(i), and sections 514, 519(a), 520(e), and 520(f), the safety and effectiveness of a device that is a tobacco product need not be found if the Secretary finds that the action to be taken under any such provision would achieve the best public health result. The finding as to whether the best public health result has been achieved shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account-[i] the increased or decreased likelihood that existing customers of tobacco products will stop using such products; and (ii) the increased or decreased likelihood that those who do not use tobacco products will start using such products."

- Recall Authority: Section 518(e)(1) is amended by inserting after "adverse health consequences or death," the following—

  "and for tobacco products that the best public health result would be achieved,"

Section 908: reduced risk [pp. 68-73]

- Suggest deleting entire section.

- The provision allowing reduced risk claims are very problematic. FDA has authority under FDCA to address these issue. If Congress wishes to make express this authority, the following provision would do so—

  - MISBRANDING.--Section 502 (21 U.S.C. 360) is amended by adding at the end the following:

    "(u) The regulations promulgated in accordance with this chapter with respect to devices that are tobacco products shall, at a minimum, require that a tobacco product be deemed to be misbranded if the labeling of the package of the product, or any claim of the manufacturer in connection with the product, states or implies (as determined by the Secretary) that the product presents a reduced health risk unless it is demonstrated to the satisfaction of the Secretary that the product will achieve the best public health result, taking into account all relevant factors including, but not limited to, the probability of the increased number of new users of tobacco products and the reduced probability that existing users of tobacco products will quit."

- The provisions for development of reduced risk technology contain authority that FDA has under the FDCA and authority that goes beyond the FDCA. FDA is available to discuss these issues further. Mandatory cross-licensing would create disincentives to research and development efforts. At minimum, licensing should not be mandatory. In addition, FDA does not have experience in setting patent license fees. Commerce might be a more appropriate authority to set such fees.

- The provision requiring the Secretary/PHS manufacture reduced risk products would require HHS involvement in an entirely new area, and could expose the government to tort liability.

Section 909: good manufacturing practices [pp. 73-78]

- Have gmp authority in device provisions, section 520(f). Already have regulations for device gmps that were the result of several years of rule-making. Industry could comply with these existing regulations (in fact, industry has been consultations with private gmp consultations on this issue). At some later date, FDA will likely promulgate tobacco-specific gmp regulations for some areas. But that is not the same as starting with a new statutory provision.

- If there is a concern about agricultural producers, see proposed 909(d) [p. 77], the FDCA could be amended to include the following—

  "AGRICULTURAL PRODUCERS. The Secretary may not promulgate any regulation directed towards devices that are tobacco products under this chapter that has the effect of placing regulatory burdens on tobacco producers (as such term is used for purposes of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) and the Agricultural Act of 1949 (7 U.S.C. 1441 et seq.)) in excess of the regulatory burdens generally placed on other agricultural commodity producers. This section shall not be construed to limit the regulatory requirements that may be imposed on producers who are also manufacturers under this Act."

Section 910: ingredients [pp. 78-82]

- FDA has authority under FDCA to issue regulations related to ingredient review and regulation. The agency is available to work with the Committee to develop appropriate statutory provisions, similar to those proposed, that would eliminate need for rulemaking. Appropriate changes are discussed below.

- Section 910(a)(1)(A): the exclusion of reconstituted tobacco from submission requirements is a significant omission; the fact that the tobacco is reconstituted can reveal information concerning the nicotine content and delivery of a product. Modify as follows—

  - "(A) a list of all ingredients, ***constituents***, substances, and compounds (other than

tobacco~~,~~ ***or*** water ~~or reconstituted tobacco sheet made wholly from tobacco~~) that are added to the tobacco (and the paper, ~~or~~ filter, ***or packaging*** of the product if applicable) in the manufacture of the tobacco product, for each brand of tobacco product so manufactured; and

- "(B) a description of the quantity of the ingredients, ***constituents,*** substances, and compounds that are listed under subparagraph (A) with respect to each brand of tobacco product."

- Other information appropriate for disclosure to the agency—

  "(C) the nicotine content of the product, measured in milligrams of nicotine;

  "(D) for each brand or variety of cigarettes— (i) the filter ventilation percentage (the level of air dilution in the cigarette as provided by the ventilation holes in the filter, described as a percentage); (ii) the pH level of the smoke of the cigarette; and (iii) the tar, nicotine, and carbon monoxide delivery level under Federal Trade Commission parameters and any other smoking conditions established by the Secretary, reported in milligrams of tar, nicotine, and carbon monoxide per cigarette;

  "(E) for each brand or variety of smokeless tobacco products— (i) the pH level of the tobacco; (ii) the moisture content of the tobacco expressed as a percentage of the weight of the tobacco; and (iii) the nicotine content— (I) for each gram of the product, measured in milligrams of nicotine; (II) expressed as a percentage of the dry weight of the tobacco; and (III) with respect to unionized (free) nicotine, expressed as a percentage per gram of the tobacco and expressed in milligrams per gram of the tobacco; and

  "(F) any other information determined appropriate by the Secretary."

- The Secretary should have authority to promulgate regulations on this issue (consistent with existing authority under the FDCA—

  - "METHODS.--The Secretary shall have the authority to promulgate regulations to establish the methods to be used by manufacturers in making the determinations required under paragraph (1)."

- Section 910(b) [p. 79]: Manufacturers have 5 years to submit their assessments of ingredients, etc.. This would allow them to flood FDA with information shortly before the 5 year period ends. FDA has to act within 90 days or else the ingredient is deemed approved. FDA should be able to require information earlier, on a staggered basis. Appropriate language would be—

- "The Secretary shall develop a procedure for the submission of safety assessments of such ingredients, constituents, substances, or compounds that staggers such safety assessments within the 5-year period."

- Section 910(b)(2), basis of assessment: the "the minds of competent scientists" concept in the second element, (B), is not currently in the FDCA, and would be hard to measure (particularly). Should delete (B) (p. 79, line 22, - p. 80, line 2). Replace with—

  "(B) demonstrate that there is a reasonable certainty among experts qualified by scientific training and experience who are consulted, that the ingredient, constituents, substance, or compound will not present any risk to consumers or the public in the quantities used under the intended conditions of use."

- Section 910(c)(2) [p.80]: 90 days is a short period of time to complete review, particularly given that the ingredient is deemed approved if this deadline is not met, section 910(c)(2)(C). Some other bills allow 180 days and allow the Secretary to later disapprove an ingredient if the deadline is not met. The following edits would address these concerns—

  - "(A) GENERAL REVIEW- Not later than 90 days after the receipt of a safety assessment under subsection (b), the Secretary shall review the findings contained in such assessment.

    "(B) APPROVAL OR DISAPPROVAL- Not later than ~~90~~ ***180*** days after the completion of a review under subparagraph (A), the Secretary shall approve or disapprove of the safety of the ingredient, ***constituent,*** substance, or compound that was the subject of the assessment and provide notice to the manufacturer of such action. ***The Secretary may, for good cause, extend the period for such review.***

    "(C) INACTION BY SECRETARY- If the Secretary fails to act with respect to an assessment during the ~~90~~-***180***-day period referred to in subparagraph (B), ~~the safety of the ingredient, substance, or compound involved shall be deemed to be approved.~~ ***the manufacturer of the tobacco product involved may continue to use the ingredient, constituents, substance, or compound involved until such time as the Secretary makes a determination with respect to the assessment.***

- Section 910(d) [p.81], disclosure: it is not clear how the public health would be served by having tobacco products meet only the food standards for public disclosure of ingredients (rather than regulations pursuant to device law). A way to address this would to include a provision that provided—

  - "a package of a tobacco product shall disclose all ingredients, constituents, substances, or compounds contained in the product in accordance with regulations promulgated under section 701(a) by the Secretary."

- Section 910(d)(2) [pp. 81-82]: the food labeling standard is not appropriate.

- Section 910(d)(3) [p.82]: Section 301(j) of the FDCA would prohibit FDA from disclosing this information. Need to add a clause after "Notwithstanding paragraph (1)"--

  - "or section 301(j),"

- Section 910(e), confidentiality [p. 82]: this is unnecessary. FDA already has statutory provisions, regulations, and procedures to protect trade secret information. In addition, the prohibition on using this information to establish a performance standard would significantly reduces its use and would detract from the agency's ability to reduce the risks of these products. FDA has experience in using procedures in rulemaking to ensure trade secrets are protected.

- If these provisions are enacted, would also need to add misbranding and prohibited act provisions to provide enforcement mechanisms.

Section 911 [p. 83]:

- As discussed above, these provisions should apply. Should delete this section.

Subtitle F--Compliance Plans and Corporate Culture

Sec. 151. Compliance plans.

Sec. 152. Compliance programs.

[pp. 83-99]

Sec. 151. Compliance plans
Sec. 152. Compliance programs

- Issue: could these provisions be used as defenses in enforcement FDCA actions?
- The provision regarding retail establishments (d) may raise anti-trust/anti-competitive concerns [p. 87]

Sec. 153. Whistleblower protections.

Sec. 154. Provisions relating to lobbying.

Sec. 155. Termination of certain entities.

Sec. 156. Enforcement.

[pp.94-99]

- These provisions will be difficult to police. Also, there may be First Amendment concerns.

- Not clear what part of HHS is enforcing this, section 156(b) [p.95]. Depending on the component responsible, it may already have regulations for hearings. Separate procedures should not be required.

- Also, there is an item "(f) Scarlet Letter Advertising" that has no text.

TITLE II--REDUCTION IN UNDERAGE TOBACCO USE

Sec. 201. Purpose.

Sec. 202. Determination of underage use base percentages.

Sec. 203. Annual daily incidence of underage use of tobacco products.

[pp. 101-104]

- Daily use may not provide the most accurate/useful measure. Other studies based their numbers on usage over the past 30 days.

Sec. 204. Required reduction in underage tobacco use.

Sec. 205. Application of surcharges.

Sec. 206. Abatement procedures.

[pp. 110-112]

- The provision allowing any attorney general to be heard at an abatement hearing might significantly prolong the process. Also, this provision might be inconsistent with the way the funding provisions of this legislation is drafted. There may be legal concerns with essentially giving the AGs such an express interest in the money coming in from the companies (i.e., to the extent we wish to condition recipient of the money on particular state actions).

TITLE III--STANDARDS TO REDUCE INVOLUNTARY EXPOSURE TO TOBACCO SMOKE

Sec. 301. Definitions.

Sec. 302. Smoke-free environment policy.

Sec. 303. Citizen actions.

Sec. 304. Preemption.

Sec. 305. Regulations.

Sec. 306. Effective date.

TITLE IV--PUBLIC HEALTH AND OTHER PROGRAMS

Subtitle A--Public Health Block Grant Program

Sec. 401. Public Health Trust Fund.

[p. 118, line 18]

- Having the Commissioner be trustee of the fund (along with the Secretary) may not be entirely consistent with FDA's mission; also, may not serve intended purpose as the Commissioner reports to the Secretary.

Sec. 402. Block grants to States.

Sec. 403. Allotments.

Sec. 404. Use of funds.

Sec. 405. Withholding of funds.

Subtitle B--Other Programs

Sec. 411. National Smoking Cessation Program.

Sec. 412. National Reduction in Tobacco Usage Program.

Sec. 413. National Tobacco-Free Public Education Program.

Sec. 414. National Event Sponsorship Program.

[pp. 133-136]

- Does HHS have an interest in doling money out to groups that lose sponsorship after the ban on brand name sponsorship goes into effect?

- Section (c) refers to a section 401(d)(5) with respect to the amounts of money available for this section. There is no section 401(d) in this legislation

Sec. 415. National Community Action Program.

[p. 219]

- This provision should be amended to make clear that this "general immunity" does not apply to "an active tobacco producer, tobacco-related growers association, or tobacco warehouse owner or employee" who is **also** a "tobacco product manufacturer, distributor, or retailer."

[pp. 220-222]

- These appear to be generally acceptable; need to review more carefully (some of them may be insufficient, but FDA would taken individual circumstances into account in taking enforcement action).

Sec. 902. Native Americans.

Sec. 903. Preemption.

[p. 227]

- Suggest modifying 903(a)--
  - (a) GENERAL PREEMPTION- Except as otherwise provided for in this section, nothing in this Act shall be construed as prohibiting a State from imposing requirements, prohibitions, penalties or other measures to further the purposes of this Act that are ***equal to or*** in addition to the requirements, prohibitions, or penalties required under this Act. . . .

- Not clear whether it is the legislation's intent to exempt tobacco products from FDCA section 521, 21 U.S.C. § 360k, which preempts any state or local requirement with respect to a device which is different from, or in addition to, any requirement applicable under the FDCA to that device, or relates to the safety or effectiveness of the device. Under the FDCA, states and localities may apply for exemptions from preemption.

The Hatch-Feinstein bill is a somewhat strengthened version of the original (June 20th) agreement between the state attorneys general and the tobacco companies. As compared with the June 20th agreement, the bill includes: (1) slightly higher base payments; (2) stronger lookback surcharges; (3) provisions to protect tobacco farmers (essentially adopting Lugar); and (4) a spending plan that largely mirrors the one that we and Sen. McCain devised. Though still considerably smaller than the McCain bill, the Hatch bill would lead to a fairly significant price increase -- about 69 cents per pack from annual payments and 25 cents per pack from lookbacks -- which would produce a significant (approximately 40%) decline in youth smoking.

One serious shortcoming of the Hatch bill is its FDA provisions, which fail to provide the FDA with all the authority it is claiming under current law (a claim, of course, now in litigation). The bill's lookback provisions, though much strengthened from the settlement, are also subject to criticism, principally on the ground that they do not include a company-specific component and are abatable on a showing of good conduct. Less significantly, the bill contains a limited antitrust exemption and leaves all enforcement of its environmental smoke standard (which is quite strong) to the states. Finally -- but most important from the standpoint of trying to amass votes -- the bill includes all the liability protections of the settlement to which the public health community objected: a $5.5 billion annual cap on liability combined with a ban on punitive damages and class actions.

Comparison of McCain Manager's Amendment,
McCain as Amended, Hatch and Settlement
June 30, 1998

	McCain Manager's Amendment	McCain as Amended	Hatch	Settlement
Total Payments over 25 Years* (real 99$)	$408 billion (after volume adjustment and price caps**). Payments continue after 25th year.	$408 billion (after volume adjustment and price caps**). Payments continue after 25th year.	$291 billion after volume adjustment (Originally reported as $428.5 billion, and $408 billion in bill, but these exclude volume adjustment). 25 years only.	$267 billion after volume adjustment ($368.5 billion if no drop in consumption). Payments continue after 25th year.
Net Available Receipts* (nominal $ over 5 years).	$59 billion	$59 billion	$47 billion	$40 billion
Price Increase*	$1.10 per pack	$1.10 per pack	66 cents per pack	64 cents per pack

* OMB estimate
** McCain proposed to add price caps, which were not included in original legislative language

	McCain Manager's Amendment	McCain as Amended	Hatch	Settlement
Lookback Surcharges -- Industry	$80 million for each percentage point missed for the first five points missed, $160 million for each percentage point missed (for 6-10 points missed), $240 million for each percentage point missed (for 11 points or more missed). Penalties are capped at $4 billion per year.	$40 million for the first five percentage points by which the industry misses the youth smoking reduction target, and $120 million for each point missed thereafter. Penalties are capped at $2 billion. (Durbin amendment).	Years 1-5: $100 million for each percentage point missed for the first five points missed, $200 million for each percentage point missed (for 6-10 points missed), $300 million for each percentage point missed (for 11 or more points missed). Penalties are capped at $5 billion per year. After year 5: $250 million for each percentage point missed for the first five points missed; $500 million for each percentage point missed for 6 points missed or above. Penalties are capped at $10 billion per year. The proposal's so-called "double-counting adjustment" means that the actual surcharges imposed are in most years substantially below the amounts per percentage point presented (e.g., the effective charge is about $140 million per point, not $500 million). Companies may have these surcharges abated if they acted in good faith and complied with the law.	$80 million for each percentage point by which the industry misses the youth smoking reduction target. Penalties are capped at $2 billion annually. Companies may have these surcharges abated if they acted in good faith and complied with the law.

	McCain Manager's Amendment	McCain as Amended	Hatch	Settlement
Lookback Surcharges -- Company Specific	$1000 per teen by which the company misses its youth smoking reduction target. This figure (which is equivalent to about $64 million per percentage point) represents twice the forgone profits of hooking a teen. No cap on penalties.	$80 million per percentage point for the first 5 percentage points, and $240 million per percentage point thereafter. This figure represents approximately 2.5 times the forgone profits for the first five percentage points, and about 7.5 times the forgone profits for the next 19 percentage points. Penalties are capped at $5 billion. (Durbin amendment.)	None.	None.
Youth Smoking Reduction Targets	Reduce youth smoking by 60% over 10 years.	Reduce youth smoking by 67% over 10 years.	Reduce youth smoking by 60% over 10 years.	Reduce youth smoking by 60% over 10 years.

	McCain Manager's Amendment	McCain as-Amended	Hatch	Settlement
FDA Authority	Provides full authority in a separate title.	Provides full authority in a separate title.	Provides authority in a separate title with significant limitations. Bill contains many procedural hurdles and other barriers that would constrain FDA's ability to regulate tobacco products: congressional approval is required if FDA wants to reduce nicotine levels to zero or ban a tobacco product; FDA must take into account numerous additional considerations before making decisions; FDA limited to regulation of nicotine and ingredients and could not require modification to product design or parts, such as the filter, to reduce health risks; FDA would not have premarket approval authority for new or unconventional products; agency could not require manufacturers to conduct additional testing for ingredients; disclosure requirements are weak because they allow companies to use general terms to describe ingredients.	Provisions are based on device law, but with significant limitations. Imposes numerous new procedural and substantive burdens on the agency: required to make numerous additional findings before issuing a performance standard; required to use formal rule-making procedures, which are resource-intensive and lengthy (including an ALJ hearing); parties could immediately petition FDA to seek review of whether a modification has resulted in the creation of a significant demand for contraband, irrespective of whether judicial review of the standard itself is complete. FDA could not ban nicotine for at least 12 years, and additional findings are required. Ingredient review and disclosure provisions are based on standards for food (rather than drugs or devices), and give manufacturers 5 years to submit information, but if FDA does not act within 90 days, the ingredient is approved.

	McCain Manager's Amendment	McCain as Amended	Hatch	Settlement
Advertising and Access Provisions	Affirms advertising and access provisions in the FDA rule and adds additional advertising restrictions through a consent protocol.	Affirms advertising and access provisions in the FDA rule and adds additional advertising restrictions through a consent protocol.	Repeals advertising restrictions in 1996 Rule, but includes most of them in the consent protocol along with the additional restrictions contained in the settlement. (Some of the provisions, such as the limit on advertising in publications, are less restrictive than the FDA rule. Because they are contained only in the protocol, they will apply only to manufacturers, but not to distributors or retailers). The bill reaffirms the youth access restrictions, but denies the FDA the authority to modify them. Denies FDA the authority to impose civil monetary penalties for retailer violations of access restrictions; provides only for injunctive relief and criminal penalties.	Codifies FDA access and advertising restrictions, and adds some additional restrictions. Modifies several of the advertising restrictions such that they are less comprehensive than the FDA rule (e.g., permits unrestricted point of sale advertising in tobacco outlets, irrespective of whether children are permitted to enter; expands the type of visual imagery permitted; allows videos and audio advertising to be distributed to consumers). Cannot make any modifications to access restrictions for at least 5 years. FDA authority over content of advertising is unclear; unclear whether FDA could modify the advertising restrictions.

	McCain Manager's Amendment	McCain as Amended	Hatch	Settlement
Uses of Tobacco Receipts	Receipts would be divided as follows: 22% for medical research; 22% for public health efforts; 40% for the states (half unrestricted and half for designated purposes); and 16% for farmers.	After receipts are deducted from the tobacco trust fund for a tax cut and theVeterans health care amendment (see below), revenues would be divided as follows: 22% for medical research; 22% for public health efforts; 40% for the states (half unrestricted and half for designated purposes); and 16% for farmers. The Coverdell amendment expanded public health efforts to include anti-drug efforts (see below). Half of the restricted state funds must be used for child care (Kerry-Bond amendment).	Receipts would be divided as follows: Up to 36% as litigation credit. Depending on how big the credit is: 13-20% for medical research; 13-21% for public health efforts; 27-42% to the states (with little practical restriction on uses); and 11-17% for farmers.	Receipts would be divided as follows: Up to 33% credit against lawsuit settlement. Depending on size of credit: 6-9% for medical research; 17-25% for public health programs; and 44-66% to reimburse states for Medicaid outlays.
Public Health	$13B over 5 years (22%)	$9B over 5 years.	$6-$10B over 5.	$7-10B over 5.
Research	$13B over 5 years (22%). Mostly NIH, but includes CDC/AHCPR.	$9B over 5 years.	$6-$9B over 5	$2-$4B over 5.
State Funds	$24B over 5 years (half unrestricted and half for menu of seven programs).	$16B over 5 years, half restricted and half unrestricted, of which half of the restricted funds must be used for child care.	$12-$19B over 5. Forty percent of a state's funds are completely unrestricted. The other sixty percent is effectively unrestricted, although states must submit a plan showing how they will spend these funds on cessation and anti-smoking activities.	$18-$27B over 5. Unrestricted.

	McCain Manager's Amendment	McCain as Amended	Hatch	Settlement
Protections of Tobacco Farmers	Includes Sen. Ford's LEAF Act which continues a price support program and includes compensation (buyout option) for producers ($2.1 billion per year for 10 years; $28.5 billion over 25 years).	Includes Sen. Ford's LEAF Act which continues a price support program and includes compensation (buyout option) for producers (authorized at $2.1 billion per year for 10 years; $28.5 billion over 25 years, though the farmers allocation account is funded at $6B over 5 years). Also contains a competing proposal by Senator Lugar to end the tobacco program ($18 billion over 3 years for buyout).	Ends the tobacco program along the lines of the Lugar bill, but over a longer period of time. Provides $17 billion over 7 years ($19 billion over 25 years) to compensate farmers and fund economic development programs.	None.
Environmental Tobacco Smoke Provision	Includes provisions to protect against environmental tobacco smoke; allows states to opt out only if they have state laws that are equally protective. Exempts the hospitality industry (e.g., bars, restaurants).	Includes provisions to protect against environmental tobacco smoke; allows states to opt out only if they have state laws that are equally protective. Exempts the hospitality industry (e.g., bars, restaurants).	Includes provisions to protect against environmental tobacco smoke. There is no Federal enforcement mechanism, only state enforcement. The bill exempts bars, but not restaurants. The bill does not preempt stronger state or local laws.	Includes provisions to protect against environmental tobacco smoke. Exempts the hospitality industry (e.g., bars, restaurants).
Liability Protections for Industry:				
1. Liability Cap	$8 billion cap.	None (Gregg amendment struck the $8 billion cap).	$5.5 billion per year.	$5 billion per year.
2. Bar on Class Actions	None.	None.	Yes.	Yes.
3. Bar on Punitive Damages	None.	None.	Yes.	Yes.
4. Credit Against Base Payment	None.	None.	Yes. 80% credit (could be 36% of all uses).	Yes. 80% credit.
Antitrust Exemption	No	No	Yes -- limited.	Yes.

	McCain Manager's Amendment	McCain as Amended	Hatch	Settlement
Anti-drug Provisions	At their option, states could use their restricted funds for Substance Abuse Treatment and Prevention programs and Safe and Drug Free Schools.	At their option, states could use their restricted funds for Substance Abuse Treatment and Prevention programs and Safe and Drug Free Schools; authorizes a number of drug programs that will compete with public health funding for counteradvertising, smoking cessation, licensing and enforcement (Coverdell amendment).	None.	None.
Cap on Attorneys' Fees	Set by arbitration panel.	Set by court, but cannot exceed: $4000 per hour for actions filed before 12/31/94, $2000 per hour for actions filed between 12/31/94 and 4/1/97, $1000 per hour for actions filed between 4/1/97 and 6/15/98, and $500 for actions filed after 6/15/98.	Arbitration panel to determine attorneys' fees; total fees subject to cap of 5% of industry payments. Fees to be paid by manufacturers outside of the payments required under the bill.	None.

	McCain Manager's Amendment	McCain as Amended	Hatch	Settlement
Tax Cut	None.	Gramm amendment would provide tax relief to married couples earning less than $50,000, and a health insurance tax cut for the self-employed. Cost: $16 billion over 4 years, $30 billion over following 5 years, and one-third of tobacco trust fund revenues (plus other non-tobacco funds) thereafter. (If youth smoking targets are met and youth smoking declines by 67% over the next decade, the tax cut can use a larger share of the tobacco trust fund dollars.)	None.	None.