NLWJC - Kagan
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Tobacco-Settlement: New Legislation-Hatch/Feinstein

Tob-nr-new bpi –
Hatch-Feinstein

Hatch-Feinstein
Tobacco Alternative

Total Cost: The total cost of the alternative, which is modeled after the June 20, 1997 Attorneys' General agreement and is drafted to obviate any constitutional concerns, is $428.5 billion over the first 25 years ($60 billion more than the settlement). Revenues are derived from fixed payments made by the tobacco industry according to a table in the bill.

Additional amounts could be made available from a strong look-back provision. The agreement will be executed through a binding and enforceable contract between the manufacturers, the States, the Federal government, and the *Castano* litigants.

Spending Allocation: Of the total amount, $204 billion is provided directly to the states through a population-based formula, with all Medicaid recovery waived. Forty percent of that amount will be available to the states for any purpose the state deems appropriate. Sixty percent will be made available to States in the form of a block grant.

States may receive funding under the block grant for tobacco-related expenses associated with the following programs: WIC; Maternal and Child Health; Children's health (SCHIP); Head Start; School lunch; Indian Health Service programs; Community and Migrant Health Centers; Family planning; HIV health care services; State-initiated smoking cessation programs; Child care; State-initiated public education campaigns; State-initiated programs for event sponsorship; and State-initiated elementary and secondary education reforms necessary to foster a tobacco-free learning environment.

Public Health: A $100 billion (over 25 years) National Institutes of Health Trust Fund for Health Research is established which reflects the settlement of punitive damages for past reprehensible behavior of the tobacco industry. In addition, the Secretary of Health and Human Services will implement a National Anti-Tobacco Product Consumption and Product Cessation Program which includes substantial public education. This program will receive $92 billion over a 25 year period, subject to any required adjustments for inflation, sales volume adjustments and

look-back penalties.

The bill will recognize the unique cultural and linguistic differences among minorities in America. Any anti-tobacco funding program for cessation, research, prevention, education and counter-advertising shall be culturally sensitive to ensure reduction of demand for tobacco products among minority youth.

FDA Authority: Authorizes the FDA to regulate manufacturing, labeling, packaging, misbranding, and adulteration. Authorizes FDA to recall products. Makes lawful FDA's current restrictions on youth sales (e.g., ID checks) (part of the "FDA Rule"). Authorizes HHS to impose additional restrictions on marketing and advertising if HHS determines that marketing and advertising have significantly contributed to the use of products by teenagers.

Requires manufacturers to submit to HHS information on tobacco ingredients (including nicotine content), scientific research documents, and marketing research documents. Requires FDA to issue standards for products that involve (A) the gradual modification of nicotine yields; (B) reduction or elimination of other harmful ingredients; (C) changes to reduce the likelihood of fires.

Requires Congress to disapprove any HHS rule to prohibit cigarettes or smokeless tobacco or the reduction of nicotine to zero. Authorizes HHS to issue standards for reduced risk tobacco products that reduce harm to individuals and the overall public health. Authorizes HHS to assess and collect fees for regulating tobacco products.

Liability Provisions: All Federal, state and local suits, including class actions, are settled; provided however, members of the class shall have the right to pursue their injury claims. All individual suits will be preserved and allowed to proceed, except for those making addiction or dependency treatment claims. Individual suits are allowed for physical harm relating to use of tobacco products, including compensatory damages and pain and suffering.

There is a cap on the payout for successful litigants of up to $1 million per year until the award is paid in total. Punitive damages for past conduct are settled in the bill in exchange for $100 billion to be deposited in a fund for biomedical research. Punitive damages for future conduct are allowed, but not for any claims

relating to addiction or dependence. At the court's choice, individual case consolidations are allowed. Total industry liability is capped at $5.5 billion a year.

Advertising and Marketing Restrictions: The alternative includes a provision that will encourage the companies to consent voluntarily to advertising restrictions, including Internet advertising. The FDA is given express authority, in consultation with the FTC, to impose restrictions on the advertising and marketing of tobacco. The proposal **bans** all outdoor advertising, all stadium/arena advertising, use of cartoon characters, Internet advertising accessible to minors, color and image advertising, etc., **except for** adult-only locations, adult magazines and newspapers (but not back covers).

City/County Provision: States are required, through an agreement with the local governmental entity within the state, to resolve any pending health-related civil action by or on behalf of local governments against tobacco companies commenced on or before June 20, 1997. This includes City of San Francisco and related cities and counties, Los Angeles County, Cook County, Erie County and New York City.

Look-Back Provision: Sets out reasonable national goals for youth smoking reduction. For cigarettes, measured from the baseline year, the goals will be a 30% reduction in use in 2004 and 2005; a 50% decrease in 2006, 2007, and 2008, and a 67% reduction thereafter. Separate goals are set for smokeless tobacco. If the Secretary of HHS determines that these goals have not been met in any year following year 5, she is authorized to impose a surcharge on manufacturers up to $5 billion per year. If the goals continue not to be met after 10 years, the surcharge payments will be increased to $10 billion per year. At the total discretion of the Secretary, the look back may be abated all or in part.

Document Depository: A National Tobacco Document Depository is established as a resource for litigants; this will disclose previously non public or confidential documents by tobacco manufacturers. The Depository is based on voluntary agreement of the tobacco companies.

Attorneys' Fees: An arbitration panel will be appointed by the Trust Fund

trustees, the participating manufacturers, State Attorneys General who were signatories to the June 20, 1997 memorandum of understanding, and private attorneys who are signatories to the June 20, 1997 memorandum of understanding. The arbitration panel will make awards based on enumerated criteria subject to an annual amount equal to a 5% cap of industry payments (attorneys' fees, however, will be paid by manufacturers outside of this bill.)

Agricultural Transition: The bill provides assistance to transition farmers away from tobacco by adding certain provisions from the LEAF bill (Ford) to the Lugar bill. The bill will terminate the existing tobacco quota program, but will require the purchase back of these quota rights for $8 per pound for quota owners ($4 per pound for lessees). In addition, $1.4 billion will be paid to states over 7 years in a block grant and $1.44 billion will be available over 25 years for farm families in Farmer Opportunity Grants and $500 million over 25 years in Worker Transition Payments for displaced workers.

Environmental Provision: Standards to reduce involuntary exposure to tobacco smoke are included, based on the 6/20/97 agreement. The bill precludes preemption of any other Federal, State or local law in this area.

Anti-Smuggling: A title is included specifically to address concerns that any price increases in tobacco products will lead to increased contraband. This provision provides new criminal penalties for trafficking in contraband tobacco products, new labeling requirements and other requirements for tracking of tobacco products in interstate commerce, and a substantial enhancement of Federal, State and local law enforcement resources devoted to tobacco smuggling.

7/17/98

Tob-mr-mow Lgis-
Hatch-Feinstein

Hatch-Feinstein: ***Tobacco Alternative Talking Points***

Total Cost:

* Hatch-Feinstein costs $428.5 billion over the first 25 years ($60 billion more than the settlement and $88 billion less than McCain). Revenues are derived from fixed payments made by the tobacco industry according to a table in the bill.

Spending Allocation:

* Of the total amount, $204 billion is provided directly to the states through a population-based formula, with all Medicaid recovery waived.

* 40% of the $204 billion will be available to the states for any purpose the state deems appropriate.

* 60% will be made available to States in the form of a block grant for the following programs:

  WIC; Maternal and Child Health; Children's health (SCHIP); Head Start; School lunch; Indian Health Service programs; Community and Migrant Health Centers; Family planning; HIV health care services; State-initiated smoking cessation programs; Child care; State-initiated

public education campaigns; State-initiated programs for event sponsorship; and State-initiated elementary and secondary education reforms necessary to foster a tobacco-free learning environment.

Public Health:

* $100 billion (over 25 years) for National Institutes of Health Trust Fund for Health Research, which reflects the settlement of punitive damages for past reprehensible behavior of the tobacco industry.

* Provides $92 billion over a 25 year period and requires the Secretary of Health and Human Services to implement a National Anti-Tobacco Product Consumption and Product Cessation Program which includes substantial public education.

FDA Authority:

* Authorizes the FDA to regulate manufacturing, labeling, packaging, misbranding, and adulteration. Authorizes FDA to recall products.

* Makes lawful FDA's current restrictions on youth sales (e.g., ID checks) (part of the "FDA Rule"). Authorizes HHS to impose additional restrictions on marketing and advertising if HHS determines that marketing and

advertising have significantly contributed to the use of products by teenagers.

* Requires manufacturers to submit to HHS information on tobacco ingredients (including nicotine content), scientific research documents, and marketing research documents. Requires FDA to issue standards for products that involve (A) the gradual modification of nicotine yields; (B) reduction or elimination of other harmful ingredients; (C) changes to reduce the likelihood of fires.

* Requires Congress to disapprove any HHS rule to prohibit cigarettes or smokeless tobacco or the reduction of nicotine to zero. Authorizes HHS to issue standards for reduced risk tobacco products that reduce harm to individuals and the overall public health. Authorizes HHS to assess and collect fees for regulating tobacco products.

Liability Provisions:

* All Federal, state and local suits, including class actions, are settled; provided however, members of the class shall have the right to pursue their injury claims.

* All individual suits will be preserved and allowed to proceed, except for those making addiction or dependency treatment claims. Individual suits are allowed for physical harm relating to use of tobacco products, including

compensatory damages and pain and suffering. No punitive damages allowed.

* There is a cap on the payout for successful litigants of up to $1 million per year until the award is paid in total.

* Punitive damages for future conduct are allowed, but not for any claims relating to addiction or dependence.

* At the court's choice, individual case consolidations are allowed.

* Total industry liability is capped at $5.5 billion a year.

Advertising and Marketing Restrictions:

* The alternative includes a provision that will encourage the companies to consent voluntarily to advertising restrictions, including Internet advertising.

* The FDA is given express authority, in consultation with the FTC, to impose restrictions on the advertising and marketing of tobacco.

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magazines and newspapers (but not back covers).

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* States are required, through an agreement with the local governmental entity within the state, to resolve any pending health-related civil action by or on behalf of local governments against tobacco companies commenced on or before June 20, 1997.

  This includes City of San Francisco and related cities and counties, Los Angeles County, Cook County, Erie County and New York City.

Look-Back Provision:

* Requires 30% reduction in use in 2004 and 2005; a 50% decrease in 2006, 2007, and 2008, and a 67% reduction thereafter. Separate goals are set for smokeless tobacco.

* Penalties for failing to meet the requirements are $5 billion per year for the first 5 years and $10 billion per year by the 10th year.

* At the total discretion of the Secretary, the look back may be abated all or in part.

Document Depository:

* A National Tobacco Document Depository is established as a resource for litigants; this will disclose previously non public or confidential documents by tobacco manufacturers. The Depository is based on voluntary agreement of the tobacco companies.

Attorneys' Fees:

* An arbitration panel will be appointed by the Trust Fund trustees, the participating manufacturers, State Attorneys General who were signatories to the June 20, 1997 memorandum of understanding, and private attorneys who are signatories to the June 20, 1997 memorandum of understanding. The arbitration panel will make awards based on enumerated criteria subject to an annual amount equal to a 5% cap of industry payments (attorneys' fees, however, will be paid by manufacturers outside of this bill.)

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Hatch - can vain & can't keep subsidy.

Tom Brown - You need Ford, Hollings, Boyd.

quota owners ($4 per pound for lessees). In addition, $1.4 billion will be paid to states over 7 years in a block grant and $1.44 billion will be available over 25 years for farm families in Farmer Opportunity Grants and $500 million over 25 years in Worker Transition Payments for displaced workers.

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* This provision provides new criminal penalties for trafficking in contraband tobacco products, new labeling requirements and other requirements for tracking of tobacco products in interstate commerce, and a substantial enhancement of Federal, State and local law enforcement resources devoted to tobacco smuggling.

7/17/98

Tob - ott - now bill —
Hatch-Feinstein

Prepared by Hatch staff 6/23/98

Hatch-Feinstein Comprehensive Tobacco Legislation
Price Per Pack Points

- Neutral experts, such as CBO and CRS, have pointed out the difficulty of projecting with mathematical precision how much cigarette and other tobacco prices will rise as a result of comprehensive tobacco legislation.

- But there is reason to believe that, in combination with other forces present in the tobacco products market (e.g., states taxes, wholesaler and retailer mark-up, liability exposure, etc.), the Hatch-Feinstein bill will meet and exceed the President's stated goal of increasing the price of cigarettes by up to $1.50 per pack over ten years.

- For example, a preliminary analysis by one Wall St. analyst, Martin Feldman of Salomon Smith Barney, indicated that the Hatch-Feinstein proposal would result in an average real retail price per pack of $3.65 in year six of the program.

- Assuming an average price per pack today of about $1.95 per pack, in year 6 Hatch-Feinstein would, according to Mr. Feldman's preliminary projections, results in an increase in the price per pack -- measured in 1997 dollars -- of about $1.70 per pack.

- The Hatch-Feinstein bill, according to Mr. Feldman's preliminary analysis, exceeds the President's ten year per pack price increase goal in year 6.

- Generally, the retail price per pack estimates made by Wall Street analysts, like Mr. Feldman, have been higher for two reasons:

- First, proponents of the Commerce Committee bill, and many press accounts, have focused solely on the $1.10 per pack required to be made to the Treasury, not on how these payments interacted with other forces in the market (e.g., manufacturers price increases, state and local tobacco taxes, wholesaler and retailer mark-ups, liability exposure, etc.) to set a retail price.

- Second, those such as the Department of Treasury, projecting the $1.10 per pack increase made different assumptions than many Wall Street analysts concerning the increases in state tobacco taxes, wholesaler and retailer mark-ups, liability exposure, and the extent to which look-back penalties will apply.

- For example, according to the Treasury Department under the Commerce Committee legislation the youth reduction targets will be met and look back payments will not be triggered. In contrast, according to the Feldman preliminary analysis referred to above, the full lookback penalty ($5 billion per year in years 6-10 and $10 billion per year thereafter) would be triggered.

- If the year 5 required payment under the Commerce Committee bill, $23.6 billion, were compared with a representative $17.6 billion annual payment required by Hatch-Feinstein, a simple straight-line analysis comparison to the $1.10 per pack figure of the Commerce Committee bill represents about $0.82 per pack under Hatch-Feinstein. [In order to be consistent, this projection employs the Treasury's assumption that no lookback penalty will be triggered.]

- Since it is the price at the cash register, not the amount of fees that are paid to the Treasury, that directly influence consumer behavior (and especially teenagers' purchasing decisions), it is important and proper to weigh all the relevant components of price, not just the payments to the Federal Treasury.

- The Commerce Committee bill requires a payment of $1.10 per pack to the Treasury and this compares with about an $0.82 per pack payment to the Treasury under Hatch-Feinstein. It may be useful to compare these to the Treasury payments with projections of real prices at the retail level: Mr. Feldman of Salomon Smith Barney projects a real retail price of $3.65 per pack in 2004 under Hatch-Feinstein compared with an estimate of $4.60 per pack under the Commerce Committee bill.

Tab - ref - new legis - Hatch-Feinstein and Tab - ref - FDA jurisdiction

P-20 Hatch - FDA

Bruce - Diffs btw this + Man Amend.

1. std - "maximize best benefits to pub health" (derived from Katzen EO)

our old one: "best - for public health"

std now in is from FDAct

2. No premkt approval - v. performance stds

theory - perf. std operates prospectively.

they couldn't mkt new product unless petitioned to change perf std.

can amend perf stds - even after 24 mos. 163, 11 14-19

BS: new product may meet perf std -

still, we would want to do premkt approval.

so we can ensure, e.g., that labeling is approp.

BS: agency never really able to ch thru perf stds

Olt: this gives you abil to say what products are permiss or now -

BS: we can't anticipate in this way.

also: prospective or retroactive?

who has burden of proof?

BS: talking abt product that only comes on mkt once every five or so yrs.

~~FDA~~ 3. Regs - codified all regs that were on access but NOT advert regs.

also: FDA can regulate ads to advert. from day of this bill -

What is std for reg auth on advert?? "significant contribution to youth smkg" -

→ meant to mimic comm std

On access — codify reg.

then, FDA has continuing reg auth. - 701a - for whatever reason.

BS - says has to be some wh time

But intent: broad auth to modify access.

4. Pos. act of Cong — IRY

banning a class / eliminating nicotine (totally)

5. Considerations — 182-83

A, B, C - from rule

tech feasibility

accepted by + affordable to adult consumers.

6. Filters, etc. too?

Seems so.

Bill S.

7. Record inspection -

8. Civil $ penalties

9. Deh of tobacco products (OK)

10. Imports?

Tob-sct-new legis-
Hatch-Feinstein 4

July 21 Hatch/Conrad mtg.

DiFi: Philos diff - best way - get willingness of tob - otherwise, you in ct.

Discussion re spending for states - OH says. "block grants OK w/ me"
Repubs should like Conrad; Dems Hatch!

OH - on FDA, think we've written letter providing -
bec we req FDA to come up w/ perf stds.
also: our advert is btr bec cos. are on board.
"think we can work out."

ETS - Don't know enuf, should be able to resolve.

Lookbacks - trouble. PM will never do co-specific.
OH: provide for abatement by HHS on co-specific basis.
RT: hard to do const...
JB: lots of auth for FDA... } OK, OK

Conrad - abate down to 0
critically imp't - not be something that future gov tob. Powers...

50¢ in five yrs.
OH - just add another 50¢ in a set period of time.
don't link it to smoking reduction
(he's trying to suggest his own bill already does this)
KC: You say yours goes to $1.50
But we don't agree.
BR - just 70¢ according to our assumps.
OH - if we really whip it, we can solve problem.

DiFi: Is your goal to have 2 rollbacks?

KC: In effect

OH: OK to have double rollback if all 4 comes out same way.

I think we can work it out.

OH: Keep $ out of marriage penalty.

KC: We did it this way to "de-federalize" - get enuf Repubs. Carper bec. we will (one same on left)

OH - We can get enuf Repubs on our spending.

Why?? (Need only 51 - Then rest will pile on.)

OH - Lott + POTUS go out together - we go out in support. Then we pass + House will have to act.

Farmers —

OH: Beef up $ in exchange for getting rid of subsidy.

→ give some to other farmers.

to $286.

KC: give some $ to other farmers.

Phase out subsidy over 10 yrs.

Liab -

OH: I want to avoid conference - put Liab in now

KC: We won't agree w/ Liab in your bill

OH: Prepared to compromise.

KC: Only a cap.

OH: How much?

Part of payment structure? (i.e., credit)?

KC: At end of day, could sell cap on liab - 8 or 7.5 b. But That is all.

We would enter into understanding - That's what comes out of conf.

OH: Have to settle Class action.

KC: Can't do.

centage points by which the manufacturer has reduced underage tobacco use in excess of the 45 percent reduction required under section 314.

(c) PROCEDURES.—The Trustees, in consultation with the Secretary, shall develop procedures to carry out this section.

TITLE IV—REGULATION OF TOBACCO PRODUCTS AND TOBACCO PRODUCT DEVELOPMENT

SEC. 401. REGULATION OF TOBACCO PRODUCTS AND TOBACCO PRODUCT DEVELOPMENT.

(a) DEFINITION.—Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301(g)(1)) is amended by striking "; and (D)" and inserting ", including nicotine-containing tobacco products that do not comply with chapter IX; and (D)".

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsection (j), by striking "or 721" and inserting "721, 902, 903, or 907"; and

(2) by adding at the end the following:

"(aa) The introduction or delivery for introduction into interstate commerce of any tobacco product that does not comply with the provisions of chapter IX.

"(bb) The failure by the manufacturer of a tobacco product to comply with a tobacco product health risk management standard, a good manufacturing practice standard, a tobacco product labeling, warning or packaging standard, or any other requirement of chapter IX.".

(c) SEIZURE.—Section 304(a)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 334(a)(2)) is amended—

(1) by striking "and (D)" and inserting "(D)"; and

(2) by inserting before the period the following: ", and (E) Any adulterated or misbranded tobacco product".

(d) RECORDS OF INTERSTATE SHIPMENT.—Section 703 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 373 et seq.) is amended—

(1) by striking "or cosmetics" each place that such appears and inserting "cosmetics, or tobacco products"; and

(2) by striking "or cosmetic" each place that such appears and inserting "cosmetics, or tobacco product".

(e) INSPECTIONS.—Section 704(a)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended—

(1) in subparagraph (A), by striking "or cosmetics" each place that such appears and inserting ", cosmetics, or tobacco products"; and

(2) in the second sentence, by striking "drugs or" each place that such appears and inserting "drugs, tobacco products or".

(f) PUBLICITY.—Section 705(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 375(b)) is amended by striking "or cosmetics" and inserting "cosmetics, or tobacco products".

(g) PRESUMPTION.—Section 709 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 379a) is amended by striking "or cosmetic" and inserting "cosmetic, or tobacco product".

(h) IMPORTS AND EXPORTS.—Section 801 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) by redesignating subsection (f) as subsection (g); and

(2) by inserting after subsection (e), the following:

"(f)(1) A tobacco product intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

"(A) accords to the specifications of the foreign purchaser;

"(B) is not in conflict with the laws of the country to which it is intended for export;

"(C) is labeled on the outside of the shipping package that it is intended for export;

"(D) is not sold or offered for sale in domestic commerce; and

"(E) contains in the language of the importing country, a warning statement as required in section 905, and the presence of such warning statement does not conflict with the laws of the importing country.

"(2) Paragraph (1) does not apply to any tobacco product which is intended to be manufactured, exported or packaged for sale or distribution to members or units of the Armed Forces of the United States.".

SEC. 402. REGULATIONS CONCERNING CIGARETTES AND SMOKELESS TOBACCO.

(a) CONSTRUCTION.—The final regulations promulgated by the Secretary in the rule dated August 28, 1996 (61 Fed. Reg. 44615-18) and codified at part 897 of title

21, Code of Federal Regulations, are hereby deemed to be lawful and to have been lawfully promulgated by the Secretary under chapter IX and section 701 of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, and not under chapter V of the Federal Food, Drug, and Cosmetic Act. The provisions of part 897 that are not in effect on the date of enactment of this Act shall take effect as in such part or upon such later date as determined by the Secretary by order. The Secretary shall amend the designation of authority in such regulations in accordance with this subsection.

(b) LIMITATION ON ADVISORY OPINIONS.—As of the date of enactment of this Act, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents" (60 Fed. Reg. 41314-41372 (August 11, 1995)).

(2) The document entitled "Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act;; (60 Fed. Reg. 41453-41787 (August 11, 1995)).

(3) The preamble to the final rule in the document entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" (61 Fed. Reg. 44396-44615 (August 28, 1996)).

(4) The document entitled "Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination;; (61 Fed. Reg. 44619-45318 (August 28, 1996)).

(c) EFFECT.—The provisions of the final regulations promulgated by the Secretary in the rule dated August 28, 1996 (61 Fed. Reg. 44615-18) shall be given effect as follows:

(1)(A) The regulations codified in sections 897.1, 897.2, 897.3, 897.10, 897.12, 897.14, and 897.16(b) through (d) of title 21, Code of Federal Regulations, shall be deemed to have been promulgated by the Secretary pursuant to chapter IX of

the Federal Food, Drug and Cosmetic Act (as added by section 103 of this Act).

(B) The Secretary shall promulgate a regulation under section 701(a) of the Federal Food, Drug and Cosmetic Act to—

(i) transfer the regulations referred to in subparagraph (A) to the appropriate part of the Code of Federal Regulations; and

(ii) make such other amendments to such regulations if the Secretary determines that such amendments are necessary to conform such regulations to the provisions of this Act.

(2) Any portion or provision of the final regulations not specifically referred to in paragraph (1) shall be considered null and void.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting the Secretary from promulgating regulations to modify the rules and regulations referred to in this section.

SEC. 403. NO EFFECT ON NON-TOBACCO PRODUCTS; INTERPRETATION.

(a) IN GENERAL.—Nothing in this Act, the amendments made to the Federal Food, Drug and Cosmetic Act, or any policy or regulation promulgated pursuant to this Act or amendments, shall be construed to affect the regu-

lation, interpretation, or enforcement of any regulation of, or any policy on, any product that is not a tobacco product under the Federal Food, Drug and Cosmetic Act.

(b) RULE OF CONSTRUCTION.—In administering chapter IX of the Federal Food, Drug and Cosmetic Act (as added by section 104), the Secretary shall ensure that any term in such chapter relating to tobacco products that is the same as or substantially similar to a term in such Act relating to drugs or devices, is interpreted in a manner similar to the interpretation (including judicial interpretation) of such term as it relates to drugs or devices.

SEC. 404. HEALTH AND SAFETY REGULATORY REQUIREMENTS.

The Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX as chapter X;

(2) by redesignating sections 901, 902, 903, 904, and 905 as sections 1001, 1002, 1003, 1004, and 1005, respectively; and

(3) by adding after chapter VIII the following new chapter:

"CHAPTER IX—HEALTH AND SAFETY REGULATORY REQUIREMENTS RELATING TO TOBACCO PRODUCTS

"SEC. 900. STATEMENT OF GENERAL DUTIES; DEFINITIONS.

"(a) GENERAL DUTIES.—As part of the comprehensive health promotion and disease prevention program established under this chapter and the PROTECT Act (and the amendments made by such Act) relating to diseases and conditions associated with the use of tobacco products, and that places a special emphasis on discouraging the use of such products by young Americans, the Secretary shall—

"(1) enforce the provisions relating to adulteration and misbranding of tobacco products under section 901;

"(2) receive, assess, and provide appropriate confidentiality regarding information submitted to the Secretary under section 902;

"(3) develop and implement health risk reduction standards for tobacco products under section 903;

"(4) develop and enforce good manufacturing practice standards for tobacco products under section 904;

"(5) enforce, and as appropriate, revise tobacco product labeling, warning, and packaging standards under section 905;

"(6) enforce tobacco product restriction on marketing and advertising under section 906;

"(7) develop and implement standards that encourage the development and use of reduced risk tobacco products under section 907 and designate as 'Reduced Risk Tobacco Products' those products that meet the standards under such section;

"(8) establish and oversee a tobacco products scientific advisory committee under section 908 to provide advice on the establishment of health risk reduction standards, good manufacturing practice regulations, tobacco product labeling, warning and packaging standards, and standards for the review of reduced risk tobacco products under sections 903, 904, 905, and 907;

"(9) submit reports to Congress evaluating the effectiveness of this chapter and the PROTECT Act as described in section 909;

"(10) assess and collect fees under section 911;

"(11) waive requirements of this chapter upon application of a State or local government as provided for under section 912; and

"(12) recall certain tobacco products or notify consumers of certain products as provided for under section 913.

"(b) DEFINITIONS.—In this chapter:

"(1) CIGARETTE.—The term 'cigarette' means any product which contains nicotine, is intended to be burned or heated under ordinary conditions of use, and consists of—

"(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

"(B) any roll of tobacco wrapped in any substance containing tobacco 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).

"(2) CIGARETTE TOBACCO.—The term 'cigarette tobacco' means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by persons in a cigarette. Unless otherwise stated, the requirements of this title pertaining to cigarettes shall also apply to cigarette tobacco.

"(3) NICOTINE.—The term 'nicotine' means the chemical substance named 3-(1-Methyl-2-

pyrrolidinyl)pyridine or $C_{10}H_{14}N_2$, including any salt or complex of nicotine.

"(4) SMOKELESS TOBACCO.—The term 'smokeless tobacco' means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral or nasal cavity.

"(5) TAR.—The term 'tar' means mainstream total particulate matter minus nicotine and water.

"(6) TOBACCO ADDITIVE.—The term 'tobacco additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in the substance becoming a component of, or otherwise affecting the characteristics of, any tobacco product, including any substance that may have been removed from the tobacco product and then readded in the substance's original or modified form.

"(7) TOBACCO PRODUCT.—

"(A) IN GENERAL.—The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufac-

turing a component, part, or accessory of a tobacco product).

"(B) LIMITATION.—Tobacco leaf that is not in the possession of a tobacco product manufacturer shall not be considered to be a tobacco product within the meaning of subparagraph (A). The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of the manufacturer, or to the producers of tobacco leaf, including tobacco growers and tobacco grower cooperatives. Notwithstanding any other provision of this subparagraph, if a producer of tobacco leaf is also a tobacco plant manufacturer, such producer shall be subject to this chapter in the producers' capacity as a manufacturer. The Secretary shall consult with the Secretary of Agriculture or the Administrator of the Environmental Protection Agency with respect to any matter that involves tobacco leaf or a producer thereof.

"Subchapter A—Tobacco Product Regulation

"SEC. 901. ADULTERATION AND MISBRANDING.

"(a) ADULTERATION.—A tobacco product shall be deemed to be adulterated—

"(1) if it consists in whole or in part of any filthy, putrid, or decomposed substance;

"(2) if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health in a manner beyond the normal risks associated with such products;

"(3) if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or holding are not in conformity with applicable current good manufacturing practice requirements under this section;

"(4) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

"(5) if it is a tobacco product which is subject to a standard established under section 903, unless such product is in all respects in conformity with such standard; or

"(6) if it is not in compliance with the requirements under subsection (g), (h), or (i) of section 906.

"(b) MISBRANDING.—A tobacco product shall be deemed to be misbranded—

"(1) if its labeling is false or misleading in any particular;

"(2) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not placed thereon in conformance with such requirement;

"(3) if its labeling is not in conformance with the requirements of this section or any other applicable requirement of this chapter;

"(4) 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 except to the extent such labeling or claim is authorized under section 907;

"(5) if it is subject to a standard under section 903, unless it bears such labeling as may be prescribed in such standard;

"(6) if it was manufactured in an establishment not duly registered under section 904(a)(2);

"(7) if there was a failure or refusal to comply with any requirement under section 902(a), 902(b), 902(c), 903(d)(3), or 906(b)(1) with respect to such tobacco product;

"(8) if, in the case of any tobacco product distributed or offered for sale in any State—

"(A) its advertising is false or misleading in any particular; or

"(B) it is sold, distributed, or used in violation of regulations prescribed under section 906(a); or

"(9) if it is a Reduced Risk Tobacco Product under section 907, and it is not in compliance with a requirement under section 907(a)(3).

"SEC. 902. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

"(a) REQUIREMENT.—Not later than 6 months after the date of enactment of this chapter, each manufacturer or importer of tobacco products, or agents thereof, shall submit to the Secretary the following information:

"(1) A listing of all tobacco ingredients, substances and compounds that are, on such date, added by the manufacturer to the tobacco, paper, filter or other component of each tobacco product by brand and by quantity in each brand and subbrand.

"(2) A description of the nicotine content of each tobacco product measured in milligrams of nicotine.

"(3) All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health or physiologic effects of tobacco products, their constituents, ingredients, and components, and tobacco additives, described in paragraph (1).

"(4) All documents (including underlying scientific information), whether or not subject to notification under section 907(e), relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

"(5) All documents (including underlying scientific information) relating to marketing research involving the use of tobacco products.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a manufacturer under this subsection.

"(b) ANNUAL SUBMISSION.—A manufacturer or importer that is required to submit information under subsection (a) shall update such information on an annual basis pursuant to a schedule determined by the Secretary.

"(c) TIME FOR SUBMISSION.—

"(1) NEW PRODUCTS.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of this chapter, the manufacturer of such product shall provide the information required under subsection (a) and such product shall be subject to the annual submission under subsection (b).

"(2) MODIFICATION OF EXISTING PRODUCTS.—If at any time a manufacturer adds to its tobacco products a new tobacco additive, increases or decreases the quantity of an existing tobacco additive or the nicotine level, or eliminates a tobacco additive from any tobacco product, the manufacturer shall within 60 days of such action so advise the Secretary in writing and reference such modification in submissions made under subsection (b).

"(d) CONFIDENTIALITY.—Any information obtained by the Secretary under this section that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed.

"SEC. 903. TOBACCO PRODUCT HEALTH RISK REDUCTION STANDARDS.

"(a) AUTHORITY.—

"(1) IN GENERAL.—Not later than 24 months after the date of enactment of this chapter, the Secretary shall by regulation (promulgated under the authority of section 701(a) and consistent with the procedures described in section 553 of title 5, United States Code) establish tobacco product health risk reduction standards that are designed to maximize the net benefits to the public health.

"(2) CONSULTATION.—In developing and promulgating regulations under this chapter, the Secretary shall consult (as the Secretary determines appropriate) with—

"(A) Federal public health and safety officials; and

"(B) other public health and safety experts, including State and local public health and safety officials, and other interested members of the public and affected parties.

"(b) PROCEDURES FOR THE ESTABLISHMENT OF STANDARDS.—

"(1) PUBLICATION OF NOTICE.—

"(A) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of pro-

posed rulemaking for the establishment, amendment, or revocation of any health risk reduction standard for a tobacco product under this section.

"(B) CONTENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a health risk reduction standard for a tobacco product shall be accompanied by a justification of the proposed action and shall—

"(i) invite interested persons to submit to the Secretary, within 120 days of the publication of the notice, requests for changes in the standard based on new information relevant to the standard; and

"(ii) invite interested persons to submit an existing health risk reduction standard for the tobacco product, including a draft or proposed health risk reduction standard, for consideration by the Secretary.

"(C) NOTICE OF REVOCATION.—A notice of proposed rulemaking for the revocation of a health risk reduction standard shall set forth a finding with supporting justification that the

health risk reduction standard is no longer necessary with respect to the tobacco product.

"(D) COMMENTS.—The Secretary shall provide for a comment period, other than for requests made under subparagraph (B)(i), of not less than 120 days after the date on which a notice has been published under this paragraph.

"(2) REQUEST FOR CHANGE.—If, after the publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the health risk reduction standard for a tobacco product, the Secretary shall, within 60 days of the publication of the notice, either deny the request and provide a written response explaining the reasons for the denial, or give notice of an intent to initiate such a change.

"(3) REGULATION FOR ESTABLISHMENT.—

"(A) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) with respect to a health risk reduction standard, and after consideration of such comments and any report from the tobacco products advisory committee under section 908, the Secretary shall—

"(i) promulgate a regulation establishing a health risk reduction standard and publish in the Federal Register findings and considerations on the matters referred to in subsection (c); or

"(ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

"(B) CONTENTS.—A regulation establishing a health risk reduction standard under subparagraph (A) shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before the expiration of the 1-year period beginning on the date of its publication and such date or dates shall be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade, unless the Secretary determines that an earlier effective date is necessary to maximize the net benefits to the public health.

"(4) AMENDING OR REVOKING OF STANDARDS.—

"(A) IN GENERAL.—The Secretary, upon the initiative of the Secretary or upon petition of an interested person, may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3), amend or revoke a health risk reduction standard for a tobacco product.

"(B) EFFECTIVENESS OF AMENDMENT.—The Secretary may declare a proposed amendment of a health risk reduction standard under this section to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest. A proposed amendment of a health risk reduction standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a tobacco product which conforms to such standard without the change or changes provided by such proposed amendment.

"(c) REGULATION OF THE COMPOSITION OF TOBACCO PRODUCTS.—

"(1) IN GENERAL.—The Secretary may adopt a health risk reduction standard under this section that requires the modification of a tobacco product in a manner that involves—

"(A) the gradual modification of nicotine yields of the product;

"(B) the reduction or elimination of other harmful constituents, ingredients (including tobacco additives), substances, compounds and properties of the product in accordance with subsection (d)(4)(B), including the establishment of levels of nicotine and other components, ingredients (including tobacco additives), and constituents of the product, or smoke emitted by such products; or

"(C) other changes to reduce the likelihood of cigarette induced fires;

"(2) OBJECTIVE.—Tobacco product health risk reduction standards established under this section shall—

"(A) be designed to maximize the net benefits to the public health through reducing the overall health risks to the public, including the reduction in risk to the consumers of such products, to individuals who reduce or cease the use

of such products, and to individuals who do not initiate the use of such products;

"(B) where necessary to meet the objectives in subparagraph (A), include requirements—

"(i) with respect to the construction, components, constituents, ingredients (including tobacco additives), and properties of the product, including the establishment of levels of nicotine and other components, ingredients (including tobacco additives), and constituents of the product, or smoke emitted by such products taking into account the technological feasibility of such requirements;

"(ii) specifying the procedures for the testing of such products, including devising procedures to be used by tobacco product manufacturers, the Secretary, or other appropriate entities, to measure relevant health-related characteristics of such products;

"(iii) for the testing of such products, including devising procedures to be used by manufacturers, the Secretary, or other ap-

propriate entities to measure the relevant health related characteristics of such products to assess the conformity of such products with the applicable health risk reduction standards; and

"(iv) to limit the sale and distribution of tobacco products to the extent authorized by this chapter;

"(C) as required under section 905, prescribe certain conditions pertaining to the labeling and advertising of tobacco products; and

"(D) comply with regulations promulgated by the Secretary that specify the health risk assessment procedures for the testing of tobacco and nontobacco constituents contained in tobacco products and determinations concerning such products under subsection (d).

"(3) CONSIDERATIONS.—In determining whether to require a modification or prohibition described in paragraph (1), the Secretary shall identify, make available for public comment, and consider relevant factors including whether the modification or prohibition—

"(A) will result in a significant reduction in the health risks associated with the use of

the tobacco product, constituent, or component involved;

"(B) will result in a significant increase in the number of individuals seeking tobacco product cessation or withdrawal treatments, including an assessment of the effectiveness, availability, and accessibility of such treatments;

"(C) will result in any possible countervailing effects on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant demand for, and supply of, contraband products specifically including increased consumption of other tobacco products that do not meet the requirements of this chapter;

"(D) is technologically feasible for commercial manufacturing; and

"(E) is likely to be accepted by and affordable to adult consumers of tobacco products.

Nothing in this paragraph shall be construed as requiring the Secretary to make a finding on each of the individual considerations described in this paragraph binding with respect to determinations of the Secretary under paragraph (1). The issuance of risk reduction standards under this section requires the

balancing of many considerations and other factors, and risk reduction standards shall not be invalidated solely on the basis of the Secretary's evaluation of any of the individual considerations described in this paragraph.

"(4) PROCEDURE FOR GENERAL PROHIBITION OF TOBACCO PRODUCTS AND ELIMINATION OF NICOTINE.—

"(A) NONDELEGATION.—The Secretary may not delegate the authority provided under this section to promulgate a regulation that results in a general prohibition of cigarettes or smokeless tobacco or the reduction of nicotine yields of a tobacco product to zero.

"(B) CONGRESSIONAL REVIEW.—In accordance with section 801 of title 5, United States Code, Congress shall review, and may disapprove, any rule of the Secretary establishing, amending, or revoking a tobacco product health risk reduction standard, except that with respect to a standard that results in a general prohibition of cigarettes or smokeless tobacco or the reduction of nicotine yields of a tobacco product to zero, such standard shall only take effect following the date of enactment of a joint

resolution of approval of such standard. The provisions of section 802 of title 5, United States Code, relating to certain disapproval resolutions shall apply to the consideration of any joint resolution of approval under this subsection.

"(d) TOBACCO PRODUCTS RISK ASSESSMENT STANDARDS.—

"(1) TOBACCO INGREDIENTS, COMPOUNDS, ADDITIVES, AND CONSTITUENTS.—The health risk reduction standards promulgated under subsection (c)(2)(D) with respect to the testing of tobacco products shall include provisions relating to the assessment of the health risks posed by the components of tobacco, including but not limited to nicotine and tar, and by tobacco use including carbon-monoxide.

"(2) NONTOBACCO INGREDIENTS, COMPOUNDS, ADDITIVES, AND CONSTITUENTS.—

"(A) IN GENERAL.—The health risk reduction regulations under subsection (c)(2)(D) with respect to the testing of nontobacco ingredients used in tobacco products—

"(i) during the 5-year period beginning on the date of enactment of this chapter, shall apply to new ingredients (those

ingredients that were not previously used in such products on such date of enactment) used in such products and to ingredients in use prior to such date of enactment as the Secretary may require; and

"(ii) after the expiration of the 5-year period described in clause (i), shall apply to all ingredients used in such products.

"(B) IMPLEMENTATION.—In carrying out this section, all requirements with respect to nontobacco ingredients, substances, and compounds shall be implemented in accordance with subparagraph (A).

"(3) HEALTH RISK ASSESSMENTS.—

"(A) REQUIREMENT.—In compliance with paragraphs (1) and (2), and in no case later than 5 years after the date of enactment of this chapter, and annually thereafter, each manufacturer shall submit to the Secretary a health risk assessment for each ingredient, substance, or compound that is listed under section 902(a)(1) with respect to each brand and subbrand of tobacco product manufactured by each such manufacturer.

"(B) AVAILABILITY OF NEW INFORMATION.—The Secretary may include in the regulations promulgated under this section, provisions that permit or, as appropriate, require manufacturers to, in subsequent years, promptly revise information that was submitted under subparagraph (A) in previous years if new data becomes available to that manufacturer. Such regulations may require that a manufacturer submit a notification to the Secretary where the manufacturer determines that no new data has become available during the previous year.

"(C) JOINT SUBMISSION.—At the discretion of the Secretary, the health risk assessments under this paragraph may be conducted by a qualified third party organization on behalf of more than 1 manufacturer for 1 or more product, ingredient, substance or compound if a joint submission is consistent with the public health. Such joint submissions shall be subject to the brand specific requirements of subparagraph (A).

"(D) BASIS OF ASSESSMENT.—The health risk assessment of an ingredient, substance, or

compound described in subparagraph (A) shall—

"(i) be based on the best scientific evidence available at the time of the submission of the assessment; and

"(ii) ascertain whether there is a reasonable certainty among experts qualified by scientific training and experience that the ingredient, substance, or compound is not harmful in the quantities used under the intended conditions of use.

"(4) REGULATORY ACTION.—

"(A) ABSENCE OF A RISK ASSESSMENT.—Not later than 12 months after the date of enactment of this chapter and subject to the requirements of paragraphs (1), (2) and (3)(A), the Secretary shall promulgate regulations to prohibit the use of any ingredient, substance, or compound in the tobacco product of a manufacturer if no health risk assessment has been submitted as required under this subsection by the manufacturer for the ingredient, substance, or compound.

"(B) REVIEW OF HEALTH RISK ASSESSMENTS.—

"(i) APPROVAL, CONDITIONAL APPROVAL, OR DISAPPROVAL.—The Secretary shall approve or disapprove of, or condition, the use of the ingredient, substance, or compound that was the subject of the assessment under this subsection within 180 days of the date on which the health risk assessment is received and provide notice of such approval, conditional approval, or disapproval to the manufacturer. The manufacturer may continue to use ingredients, substances, or compounds that are the subject of such an assessment until the Secretary disapproves or conditions such ingredient, substance, or compound. The Secretary shall establish a procedure to allow manufacturers adequate time to comply with any such condition or disapproval.

"(ii) NEW INGREDIENTS, SUBSTANCES, COMPOUNDS, AND ADDITIVES.—Notwithstanding clause (i), a new ingredient, substance, compound, or additive shall not be introduced into commerce during the 30-day period beginning on the date on which a health risk assessment has been

submitted to the Secretary for such new ingredient, substance, compound, or additive. The Secretary may by order prohibit the use of such new ingredient, substance, compound, or additive until the Secretary completes a review of the assessment involved.

"(iii) GENERAL APPLICABILITY.—At the discretion of the Secretary, the approval, conditional approval, or disapproval of a particular ingredient, substance, or compound under clause (i) may by regulation be made generally applicable to tobacco product manufacturers or a subgroup of such manufacturers. In the case of a conditional approval, the Secretary shall develop a procedure to enable manufacturers to certify that the condition will be complied with.

"(iv) INACTION BY SECRETARY.—If the Secretary fails to act with respect to an assessment during the period referred to in clause (i), the manufacturer submitting the assessment may continue to use the ingredient, substance, or compound in-

volved until such time as the Secretary makes a final decision, or the succeeding annual risk assessment is submitted by the manufacturer and the ingredient, substance, or compound is subsequently disapproved or conditioned. The Secretary shall establish a procedure to allow manufacturers adequate time to comply with any such condition or disapproval.

"(e) COMPLIANCE.—

"(1) IN GENERAL.—Health risk reduction standards under this section shall apply to all tobacco products to which such standards are relevant.

"(2) LIMITATION.—During the period in which a regulation promulgated under this section establishing a health risk reduction standard is in effect, a tobacco product shall not be considered to be in violation of section 301 if such product is in compliance with such regulation, and the requirements of sections 904 and 905.

"(f) EVALUATION.—The Secretary shall periodically evaluate tobacco product health risk reduction standards to determine whether such standards should be amended to reflect new medical, scientific, or technological information.

"SEC. 904. GOOD MANUFACTURING PRACTICE STANDARDS.

"(a) AUTHORITY.—

"(1) IN GENERAL.—The Secretary shall, in accordance with subsections (a) and (b) of section 903, prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of a tobacco product conform to current good manufacturing practice, as prescribed in such regulations, to ensure that such products will be in compliance with this chapter.

"(2) REGISTRATION.—The regulations promulgated under paragraph (1) shall require that all tobacco product manufacturers register with the Secretary.

"(3) SPECIAL CONSULTATION PROCEDURES.—In developing and promulgating any regulation under paragraph (1) the Secretary shall afford the Tobacco Products Scientific Advisory Committee established under section 908 an opportunity (with a reasonable time period) to submit recommendations in response to the notice of proposed rulemaking.

"(4) LIMITATION.—Good manufacturing practice regulations described in paragraph (1) shall be appropriate for the manufacture of a product de-

rived from a raw agricultural commodity for which no therapeutic claim is made.

"(b) PESTICIDE RESIDUES.—The regulations promulgated under subsection (a) shall at a minimum require, after consultation with the Administrator of the Environmental Protection Agency, the development and adherence to applicable tolerances with respect to pesticide chemical residues in finished tobacco products, except that such tolerances shall only apply if the Administrator determines that such tolerances are necessary to prevent such residues from being injurious to health when used in tobacco products.

"(c) PETITIONS FOR EXEMPTIONS AND VARIANCES.—

"(1) IN GENERAL.—Any person subject to any requirement prescribed by regulations under subsection (a) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall by regulation prescribe and shall—

"(A) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to en-

sure that the tobacco product is in compliance with section 903;

"(B) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the product in lieu of the methods, facilities, and controls prescribed by the requirement; and

"(C) contain such other information as the Secretary shall prescribe.

"(2) TOBACCO PRODUCT REQUIREMENTS WAIVER BOARD.—

"(A) AUTHORITY.—The Secretary shall establish a Tobacco Product Requirements Waiver Board (referred to in this paragraph as the 'Waiver Board') to provide advice and make recommendations to the Secretary with respect to the approval or disapproval of petitions submitted under paragraph (1).

"(B) MEMBERSHIP.—The Waiver Board shall be composed of 9 members to be appointed by the Secretary, of which—

"(i) 3 members shall be appointed from among individuals who are officers or

employees of the Federal Government or a State or local government;

"(ii) 2 members shall be appointed from among individuals who are representatives of the interests of the cigarette and smokeless tobacco industries;

"(iii) 2 members shall be appointed from among individuals who are representatives of the interests of physicians and other health professionals; and

"(iv) 2 members shall be appointed from among individuals who are representatives of the interests of the general public.

"(C) CHAIRPERSON.—The Secretary shall designate 1 of the members of the Waiver Board to serve as the Chairperson.

"(D) COMPENSATION AND EXPENSES.—

"(i) COMPENSATION.—Members of the Waiver Board who are not officers or employees of the United States, while attending conferences or meetings of the Waiver Board or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not ex-

ceed the daily equivalent of the rate of pay for level 4 of the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including traveltime) they are so engaged.

"(ii) EXPENSES.—While conducting the business of the Waiver Board away from their homes or regular places of business, each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently.

"(3) ACTION ON PETITION.—

"(A) IN GENERAL.—Not later than 120 days of the date on which the Secretary receives the recommendations of the Waiver Board, the Secretary shall issue an order approving or denying a petition submitted under paragraph (1). The Secretary may approve—

"(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure

that the product will comply with this section and is otherwise consistent with the public health; and

"(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the product in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to ensure that the product will comply with this section and is otherwise in compliance with the public health.

"(B) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to ensure that the product will comply with this section.

"(4) INFORMAL HEARING.—After the issuance of an order under paragraph (3) respecting a peti-

tion, the petitioner shall have an opportunity for an informal hearing on such order.

"(d) RECORDKEEPING AND REPORTING.—

"(1) IN GENERAL.—The regulations promulgated under subsection (a) shall require that manufacturers maintain such files and records as the Secretary may reasonably require relating to tobacco product safety. Such regulations may require manufacturers to report serious adverse events that are not well-known or well-documented by the scientific community (including events related to contamination or a change in any ingredient or any major change in manufacturing processes).

"(2) REPORTING.—A report shall be submitted under paragraph (1) concerning a tobacco product for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process.

"(e) EFFECTIVE DATE OF CERTAIN REGULATIONS.—Regulations promulgated under this section shall be implemented over a 2-year period in consultation with manufacturers of tobacco products and tobacco producers.

"SEC. 905. TOBACCO PRODUCT LABELING, WARNING, AND PACKAGING STANDARDS.

"(a) CIGARETTES.—

"(1) IN GENERAL.—

"(A) PACKAGING.—It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this subsection, one of the following statements:

"WARNING: Cigarettes Are Addictive.

"WARNING: Tobacco Smoke Can Harm Your Children.

"WARNING: Cigarettes Cause Fatal Lung Disease.

"WARNING: Cigarettes Cause Cancer.

"WARNING: Cigarettes Cause Strokes And Heart Disease.

"WARNING: Smoking During Pregnancy Can Harm Your Baby.

"WARNING: Smoking Can Kill You.

"WARNING: Tobacco Smoke Causes Fatal Lung Disease In Nonsmokers.

"WARNING: Quitting Smoking Now Greatly Reduces Serious Risks To Your Health.

"(B) ADVERTISING.—It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless the advertising bears, in accordance with the requirements of this subsection, one of the following statements:

"WARNING: Cigarettes Are Addictive.

"WARNING: Tobacco Smoke Can Harm Your Children.

"WARNING: Cigarettes Cause Fatal Lung Disease.

"WARNING: Cigarettes Cause Cancer.

"WARNING: Cigarettes Cause Strokes And Heart Disease.

"WARNING: Smoking During Pregnancy Can Harm Your Baby.

"WARNING: Smoking Can Kill You.

"WARNING: Tobacco Smoke Causes Fatal Lung Disease In Nonsmokers.

"WARNING: Quitting Smoking Now Greatly Reduces Serious Risks To Your Health.

"(2) REQUIREMENTS FOR LABEL STATEMENTS.—

"(A) LOCATION.—Each label statement required by subparagraph (A) of paragraph (1) shall be located on the upper portion of the front panel of the cigarette package (or carton) and occupy not less than 25 percent of such front panel.

"(B) TYPE AND COLOR.—With respect to each label statement required by subparagraph (A) of paragraph (1), the phrase 'WARNING' shall appear in capital letters and the label statement shall be printed in 17 point type with adjustments as determined appropriate by the Secretary to reflect the length of the required statement. All the letters in the label statement shall appear in conspicuous and legible type, in contrast by typography, layout, or color with all other printed material on the package, and be printed in an alternating black-on-white and white-on-black format as determined appropriate by the Secretary.

"(C) EXCEPTION.—The provisions of subparagraph (A) shall not apply in the case of a flip-top cigarette package (offered for sale on April 1, 1997) where the front portion of the flip-top does not comprise at least 25 percent of

the front panel. In the case of such a package, the label statement required by subparagraph (A) of paragraph (1) shall occupy the entire front portion of the flip top.

"(3) REQUIREMENTS FOR ADVERTISING.—

"(A) LOCATION.—Each label statement required by subparagraph (B) of paragraph (1) shall occupy not less than 20 percent of the area of the advertisement involved.

"(B) TYPE AND COLOR.—

"(i) TYPE.—With respect to each label statement required by subparagraph (B) of paragraph (1), the phrase 'WARNING' shall appear in capital letters and the label statement shall be printed in the following types:

"(I) With respect to whole page advertisements on broadsheet newspaper—45 point type.

"(II) With respect to half page advertisements on broadsheet newspaper—39 point type.

"(III) With respect to whole page advertisements on tabloid newspaper—39 point type.

"(IV) With respect to half page advertisements on tabloid newspaper—27 point type.

"(V) With respect to DPS magazine advertisements—31.5 point type.

"(VI) With respect to whole page magazine advertisements—31.5 point type.

"(VII) With respect to 28cm x 3 column advertisements—22.5 point type.

"(VIII) With respect to 20cm x 2 column advertisements—15 point type.

The Secretary may revise the required type sizes as the Secretary determines appropriate within the 20 percent requirement.

"(ii) COLOR.—All the letters in the label statement under this subparagraph shall appear in conspicuous and legible type, in contrast by typography, layout, or color with all other printed material in the advertisement, and be printed in an alternating black-on-white and white-on-black

format as determined appropriate by the Secretary.

"(4) ROTATION OF LABEL STATEMENTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the label statements specified in subparagraphs (A) and (B) of paragraph (1) shall be rotated by each manufacturer or importer of cigarettes quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Secretary. The Secretary shall approve a plan submitted by a manufacturer or importer of cigarettes which will provide the rotation required by this paragraph and which assures that all of the label statements required by subparagraphs (A) and (B) will be displayed by the manufacturer or importer at the same time.

"(B) APPLICATION OF OTHER ROTATION REQUIREMENTS.—

"(i) IN GENERAL.—A manufacturer or importer of cigarettes may apply to the

Secretary to have the rotation schedule described in clause (iii) apply with respect to a brand style of cigarettes manufactured or imported by such manufacturer or importer if—

"(I) the number of cigarettes of such brand style sold in the fiscal year of the manufacturer or importer preceding the submission of the application is less than ¼ of 1 percent of all the cigarettes sold in the United States in such year; and

"(II) more than ½ of the cigarettes manufactured or imported by such manufacturer or importer for sale in the United States are packaged into brand styles which meet the requirements of subclause (I).

If an application is approved by the Secretary, the rotation schedule described in clause (iii) shall apply with respect to the applicant during the 1-year period beginning on the date of the application approval.

"(ii) PLAN.—An applicant under clause (i) shall include in its application a plan under which the label statements specified in subparagraph (A) of paragraph (1) will be rotated by the applicant manufacturer or importer in accordance with the label rotation described in clause (iii).

"(iii) OTHER ROTATION REQUIREMENTS.—Under the rotation schedule which the manufacturer or importer with an approved application may put into effect, each of the label statements specified in subparagraph (A) of paragraph (1) shall appear on the packages of each brand style of cigarettes with respect to which the application was approved an equal number of times within the 12-month period beginning on the date of the approval by the Secretary of the application.

"(5) APPLICATION OF REQUIREMENT.—Paragraph (1) does not apply to a distributor or retailer of cigarettes who does not manufacture, package, or import cigarettes for sale or distribution within the United States.

"(6) TELEVISION AND RADIO ADVERTISING.—It shall be unlawful to advertise cigarettes and little cigars on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

"(b) SMOKELESS TOBACCO.—

"(1) IN GENERAL.—

"(A) PACKAGING.—It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco the package of which fails to bear, in accordance with the requirements of this subsection, one of the following statements:

WARNING: This Product May Cause Mouth Cancer.

WARNING: This Product May Cause Gum Disease And Tooth Loss.

WARNING: This Product Is Not A Safe Alternative To Cigarettes.

WARNING: Smokeless Tobacco Is Addictive.

"(B) ADVERTISING.—It shall be unlawful for any manufacturer or importer of smokeless tobacco to advertise or cause to be advertised

within the United States any smokeless tobacco unless the advertising bears, in accordance with the requirements of this subsection, one of the following statements:

WARNING: This Product May Cause Mouth Cancer.

WARNING: This Product May Cause Gum Disease And Tooth Loss.

WARNING: This Product Is Not A Safe Alternative To Cigarettes.

WARNING: Smokeless Tobacco Is Addictive.

"(2) REQUIREMENTS FOR LABEL STATEMENTS.—

"(A) LOCATION.—Each label statement required by subparagraph (A) of paragraph (1) shall be located on the principal display panel of the product and occupy not less than 25 percent of such panel.

"(B) TYPE AND COLOR.—With respect to each label statement required by subparagraph (A) of paragraph (1), the phrase 'WARNING' shall appear in capital letters and the label statement shall be printed in 17 point type with adjustments as determined appropriate by the

Secretary to reflect the length of the required statement. All the letters in the label statement shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package and be printed in an alternating black on white and white on black format as determined appropriate by the Secretary.

"(3) ADVERTISING AND ROTATION.—The provisions of paragraphs (3) and (4)(A) of subsection (a) shall apply to advertisements for smokeless tobacco and the rotation of the statements required under paragraph (1)(A) on such products.

"(4) APPLICATION OF REQUIREMENT.—Paragraph (1) does not apply to a distributor or retailer of smokeless tobacco who does not manufacture, package, or import such products for sale or distribution within the United States.

"(5) TELEVISION AND RADIO ADVERTISING.—It shall be unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

"(c) ADDITIONAL TOBACCO PRODUCT STATEMENTS.—

"(1) REQUIREMENT.—Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated advertising concerning, tobacco products otherwise permitted under this chapter shall include, in a type size and format as the Secretary may prescribe in a regulation promulgated under subsection (d), the product name and a statement of the general use of the product as provided for in paragraph (2).

"(2) GENERAL USE STATEMENTS.—

"(A) CIGARETTES.—A statement of general use for cigarettes or cigarette tobacco is as follows (whichever is appropriate):

'Cigarettes—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Cigarette Tobacco—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

"(B) SMOKELESS TOBACCO.—A statement of general use for a smokeless tobacco is as follows (whichever is appropriate):

'Loose Leaf Chewing Tobacco—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Plug Chewing Tobacco—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Twist Chewing Tobacco—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Moist Snuff—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Dry Snuff—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

"(d) REGULATIONS.—

"(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this title, the Secretary shall promulgate such regulations as may be necessary to implement subsections (a), (b), and (c).

"(2) AUTHORITY TO REVISE TOBACCO PRODUCT LABELING STATEMENTS.—

"(A) IN GENERAL.—The Secretary may by informal notice and comment rulemaking change the text of any of the statements required under subsections (a) and (b). The Secretary may require that the label of a tobacco product include a listing of particular ingredients if is has been determined, through notice

and comment rulemaking, that such ingredient labeling will protect or advance the public health. A rule promulgated under this subparagraph shall not become effective prior to the expiration of the 1-year period beginning on the date on which the final rule is published in the Federal Register.

"(B) LIMITATION.—The Secretary may not promulgate any rule under subparagraph (A) during the 5-year period beginning on the effective date of the PROTECT Act unless the Secretary determines through notice and comment rulemaking that important new information about the health risks associated with tobacco use requires additional warning statements.

"(C) ASSESSMENTS.—The Secretary, in consultation with the Tobacco Products Scientific Advisory Committee and other relevant experts, shall, as scientific data regarding the effectiveness of warning labels in deterring youth smoking becomes available, periodically (but not more frequently that once every 3 years) assess the efficacy of current labels and

the public health benefits of revising such labels.

"(3) COMMON OR USUAL NAMES.—The Secretary, in accordance with the procedures set forth in section 903, shall promulgate regulations requiring the disclosure to the public of the common or usual name of each ingredient (other than tobacco, water, or reconstituted tobacco sheet made wholly from tobacco) contained in a tobacco product in descending order of predominance by weight, except that such regulations—

"(A) may provide for the disclosure of spices, flavorings, and colorings but shall not name each spice, flavoring, or coloring; and

"(B) may exempt from disclosure incidental additives, including processing aids and chemical preservatives, that are present in a tobacco product at insignificant levels that the Secretary determines do not have any functional effect or health risk.

"(e) EXPORTS.—Packages of cigarettes or smokeless tobacco manufactured, imported, or packaged—

"(1) for export from the United States; or

"(2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the United States;

shall be exempt from the requirements of this chapter, but such exemptions shall not apply to cigarettes or smokeless tobacco manufactured, imported, or packaged for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

"SEC. 906. TOBACCO PRODUCTS MARKETING AND ADVERTISING REGULATORY AUTHORITY.

"The Secretary may by informal notice and comment rulemaking under section 701(a), in appropriate consultation with the Federal Trade Commission, impose additional restrictions on the marketing and advertising of tobacco products, including restrictions on marketing consistent with the provisions described in section 402, if the Secretary determines that such marketing and advertising has significantly contributed to the use of tobacco products by individuals under 18 years of age. The Federal Trade Commission and the Secretary shall set forth their respective duties in a memorandum of understanding to be submitted to the Committee on Commerce of the House of Representatives, the Committee on Commerce of the Senate and the Committee on Labor and Human Resources of the Senate.

"SEC. 907. REDUCED RISK TOBACCO PRODUCTS.

"(a) REQUIREMENTS.—

"(1) IN GENERAL.—For purposes of this chapter, the term 'Reduced Risk Tobacco Product' means a tobacco product that delivers nicotine to the human body while simultaneously delivering 1 or more other toxic substances to the human body, and which the Secretary designates as a Reduced Risk Tobacco product under paragraph (2).

"(2) DESIGNATION.—A product shall be designated by the Secretary as a Reduced Risk Tobacco Product if—

"(A) the Secretary finds that the product has the potential to reduce harm to individuals and overall public health caused by a tobacco product, based on an application submitted by the manufacturer of the product (or other responsible person) that—

"(i) demonstrates, on the basis of chemical analysis, that use of such product results in ingestion or inhalation of a substantially lower yield of toxic substances than use of conventional tobacco products in the same category as the proposed reduced risk product; and

"(ii) demonstrates, through appropriate testing on animals and humans, that use of the product presents substantially less risk to human health than use of conventional tobacco products; and

"(B) the manufacturer (or other person) agrees to conduct studies of the long-term health effects of such product (in accordance with 1 or more protocols agreed upon between the manufacturer of the product and the Secretary) and submit the results of such study, together with underlying data, to the Secretary.

"(3) MARKETING REQUIREMENTS.—A tobacco product may be marketed as a Reduced Risk Tobacco Product only if such product—

"(A) bears a label, prescribed by the Secretary, stating that the product contains toxic substances other than nicotine, that such product should only be used by persons who use tobacco products, and other relevant information;

"(B) bears a label, as prescribed by the Secretary, concerning the product's contribution to reducing harm to health; and

"(C) complies with requirements prescribed by the Secretary relating to marketing and advertising

of the product, and other provisions of this chapter as prescribed by the Secretary.

"(b) REVOCATION OF DESIGNATION.—At any time after the date on which a tobacco product is designated as a Reduced Risk Tobacco Product under this section the Secretary may, after providing an opportunity for an informal hearing, revoke such designation if the Secretary determines, based on information not available at the time of the designation, that—

"(1) the finding made under subsection (a)(2)(A) is no longer valid; or

"(2) the studies required under subsection (a)(2)(B) are not conducted on a timely basis.

"(c) STUDIES.—The Secretary, in consultation with the Tobacco Products Scientific Advisory Committee, shall conduct and support, through grants and contracts, studies of the role of smoking cessation products and reduced risk tobacco products in reducing the burden of illness and death in the United States resulting from the use of tobacco products.

"(d) REGULATION AS A NEW DRUG.—Any tobacco product accompanied by a claim to diagnose, cure, mitigate, treat, or prevent a disease, not including statements that the Secretary may permit for reduced risk tobacco

products under this section, will be subject to regulation as a new drug under section 505.

"(e) DEVELOPMENT OF REDUCED RISK TOBACCO PRODUCT TECHNOLOGY.—

"(1) NOTIFICATION OF SECRETARY.—The manufacturer of a tobacco product shall provide written notice to the Secretary upon the development or acquisition by the manufacturer of any technology that would reduce the risk of such products to the health of the user for which the manufacturer is not seeking designation as a 'Reduced Risk Tobacco Product' under subsections (a) and (b).

"(2) DETERMINATION.—Within 6 months of the date on which a notice is received by the Secretary under paragraph (1), the Secretary shall determine whether the technology described in such notice is likely to result in tobacco products that are less hazardous to the health of users.

"(3) CONFIDENTIALITY.—The Secretary shall, not later than 180 days after the date of enactment of this chapter, promulgate regulations to provide a manufacturer with appropriate confidentiality protections with respect to technology that is the subject of a determination under paragraph (2), but in no case will require the disclosure to the public of

any trade secret or confidential commercial information.

"(4) LICENSING.—

"(A) IN GENERAL.—With respect to any technology for which a notification has been provided under paragraph (1), the manufacturer shall be encouraged to permit the licensure and use of such technology by other manufacturers of tobacco products to which this chapter applies.

"(B) FEES.—The Secretary of Commerce shall, not later than 180 days after the date of enactment of this chapter, promulgate regulations that encourage the payment of a commercially reasonable fees by each manufacturer that uses the technology described under subparagraph (A) to the manufacturer that submits the notice under paragraph (1) for such technology. Such regulations shall contain procedures for the resolution of fee disputes between manufacturers under this subparagraph through the use of expert arbitrators.

"(f) REQUIREMENT OF MANUFACTURE AND MARKETING.—

"(1) PURPOSE.—It is the purpose of this subsection to provide for a mechanism to create incentives that help ensure that tobacco products that are designed to be less hazardous to the health of users are developed, tested, and made available to consumers.

"(2) DETERMINATION.—Upon a determination by the Secretary that the manufacture of a tobacco product that is less hazardous to the health of users is technologically and commercially feasible, the Secretary may, in accordance with this subsection and through the issuance or amendment of a health risk reduction standard under section 903—

"(A) require the disclosure of the existence of such technology;

"(B) prohibit the use of technology that is superseded by such new technology; and

"(C) require that manufacturers cease manufacturing and marketing tobacco products that do not incorporate such technology.

"(g) BASIS FOR DETERMINATION.—For purposes of subsections (e)(2) and (f)(2), the determination as to whether a tobacco product may be less hazardous to the health of users shall take into account the reduced risk

to the health of the user, its contribution to reducing addiction to tobacco products, and the overall public health.

"SEC. 908. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this chapter, the Secretary shall establish an advisory committee, to be known as the 'Tobacco Products Scientific Advisory Committee', to assist the Secretary in establishing, amending, or revoking a regulation promulgated under section 903, 904, 905, 906, or 907.

"(b) MEMBERSHIP.—

"(1) IN GENERAL.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee—

"(A) individuals with expertise in the medicine, science, or technology involving the manufacture and use of tobacco products, who are of appropriately diversified professional backgrounds;

"(B) individuals with expertise in law or ethics;

"(C) a representative of tobacco product manufacturers;

"(D) a representative of the general public selected from public health organizations; and

"(E) a representative of the general public selected from organizations representing manufacturers and users of tobacco products.

"(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Federal Government. The Secretary may appoint Federal officials as ex-officio members.

"(3) CHAIRPERSON.—The Secretary shall designate 1 of the members of advisory committee to serve as chairperson of the Advisory Committee.

"(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information and recommendations to the Secretary—

"(1) in establishing, amending, or revoking regulations under section 903, 904, 905, 906, or 907;

"(2) on the effects of the alteration of the nicotine yield levels in tobacco products;

"(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved, and, if so, determine what that level is; and

"(4) as requested, review other safety, dependence or health issues relating to tobacco products as requested by the Secretary.

"SEC. 909. REPORTS.

"Not later than 18 months after the date of enactment of this chapter, and biennially thereafter, the Secretary shall prepare and submit to Congress a report containing—

"(1) a description of the current sales, advertising, and marketing practices associated with tobacco products;

"(2) a description of the use patterns of tobacco products, including a report on use by individuals under 18 years of age;

"(3) a description of the effects of health promotion and disease prevention efforts related to the use of tobacco products;

"(4) an evaluation of the health promotion and disease prevention efforts relating to tobacco products and the identification of areas appropriate for further research; and

"(5) such recommendations for legislation and administrative action relating to tobacco products as the Secretary considers appropriate.

"SEC. 910. JUDICIAL REVIEW.

"(a) APPLICATION OF SECTION.—

"(1) IN GENERAL.—Not later than 60 days after the effective date of any regulation under this chapter establishing, amending, or revoking a health risk reduction standard for a tobacco product, any person adversely affected by such regulation may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has its principal place of business for judicial review of such regulation. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose.

"(2) RECORD OF PROCEEDING.—The Secretary shall file in the court under paragraph (1) the record of the proceedings on which the Secretary based the regulation involved as provided for in section 2112 of title 28, United States Code.

"(3) DEFINITION.—For purposes of this section, the term 'record' means all notices and other matter published in the Federal Register with respect to the regulation reviewed, all information submitted to the Secretary with respect to such regulation, proceedings of any panel or advisory committee with respect to such regulation, any hearing held

with respect to such regulation, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation, as being relevant to such regulation.

"(b) ADDITIONAL DATA, VIEWS, AND ARGUMENTS.—If the petitioner applies to the court under this section for leave to adduce additional data, views, or arguments respecting the regulation being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify such findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

"(c) STANDARD FOR REVIEW.—Upon the filing of the petition under subsection (a) judicial review of a regulation, the court shall have jurisdiction to review the regula-

tion in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation promulgated under this chapter shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

"(d) FINALITY OF JUDGMENTS.—The judgment of the court affirming or setting aside, in whole or in part, any regulation under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided for in section 1254 of title 28, United States Code.

"(e) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided for by law.

"(f) STATEMENT OF REASONS.—To facilitate judicial review under this section or under any other provision of law of a regulation issued under this chapter, each such regulation shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

"SEC. 911. AUTHORITY TO ASSESS AND USE FEES.

"(a) IN GENERAL.—The Secretary shall, not later than 60 days after the date of enactment of this chapter, annually assess and collect fees for submissions made

under sections 902, 903, and 907 in accordance with this section to be used as the sole source of funding with respect to the regulation and control of tobacco products under this chapter.

"(b) TOBACCO PRODUCT FEE.—The Secretary shall set the amount of the fees under subsection (a) for the first fiscal year in which this section is applies in an amount to equal $100,000,000, of which not less than $13,000,000 for each fiscal year shall be used to assist in meeting the increased enforcement needs of the Food and Drug Administration as a result of the enactment of this chapter and any increased enforcement activities necessary to reduce contraband products, and may adjust the level of such fees and set-aside in subsequent fiscal years.

"(c) PAYMENT SCHEDULE.—The Secretary shall promulgate regulations to implement procedures for the assessment and collection of fees under this section.

"(d) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (b) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

"(e) APPORTIONMENT OF FEES.—The Secretary shall, not later than 60 days after the enactment of this

chapter, issue regulations apportioning fees under subsection (a) among submissions required under sections 902, 903, and 907.

"SEC. 912. PRESERVATION OF STATE AND LOCAL AUTHORITY.

"(a) ADDITIONAL REQUIREMENTS.—

"(1) IN GENERAL.—Except as provided in paragraph (3), nothing in this Act shall be construed as prohibiting a State or political subdivision thereof from adopting or enforcing a requirement applicable to a tobacco product that is in addition to, or more stringent than, requirements established under this chapter.

"(2) APPLICATION OF STATE LAW.—In the case of a requirement of a State or political subdivision thereof that is more stringent than a requirement established under this chapter, the requirement of the State or political subdivision shall apply.

"(3) PREEMPTION OF STATE AND LOCAL REQUIREMENTS.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product or manufacturer thereof any requirement that relates to, and is different from or in addition to, any requirement applicable under sections 902, 903, 904, 905, and 907.

"(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"(c) WAIVERS.—Upon the application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and an opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a tobacco product if—

"(1) the requirement is more stringent than a requirement applicable under the provisions described in subsection (a)(3) which would be applicable to the tobacco product if an exemption were not in effect under this subsection; or

"(2) the requirement—

"(A) is required by compelling local conditions; and

"(B) compliance with the requirement would not cause the tobacco product to be in violation of any applicable requirement of this chapter.

"SEC. 913. NOTIFICATION AND RECALL AUTHORITY.

"(a) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product has been distributed in violation of this chapter in a manner that would pose a greater threat to public health than the threat normally posed to public health by similar tobacco products, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the product) to immediately cease distribution of such product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require notification to the consumers of such products or a recall of such product. Such notification shall be in a manner that the Secretary determines is most efficient to communicate the health risks to consumers and potential consumers of such products. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(b) AMENDMENT TO ORDER.—

"(1) IN GENERAL.—If, after providing an opportunity for an informal hearing under subsection

(a), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in paragraphs (2) and (3), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

"(2) LIMITATIONS.—An amended order under paragraph (1)—

"(A) shall not include recall of a tobacco product from individuals; and

"(B) shall provide for notice to individuals subject to the risks associated with the use of such product.

"SEC. 914. SEVERABILITY.

"If any provision of this chapter or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect the other provisions of this chapter and the application of such provision to other persons or circumstances shall not be affected thereby.".

SEC. 405. TECHNICAL PROVISIONS.

(a) APPLICATION OF FEDERAL CIGARETTE LABELING AND ADVERTISING ACT.—The provisions of the Fed-

eral Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.) that apply to cigarettes shall be superseded by the provisions of this title (and the amendments made by this title).

(b) REPEAL.—The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq.) is repealed.

(c) PRESERVATION OF FEDERAL TRADE COMMISSION AUTHORITY.—Nothing in this title, or an amendment made by this title, shall be construed to limit the authority of the Federal Trade Commission to regulate the advertising and marketing of tobacco products pursuant to its authority under sections 5 and 12 of the Federal Trade Commission Act.

SEC. 406. FEDERAL LICENSING OF MILITARY AND OTHER ENTITIES.

(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Defense, Secretary of State, and other appropriate Federal officials, shall establish and implement a Federal tobacco licensing program to be applied to entities that sell or distribute tobacco products—

(1) on any military installation (as defined in section 2801(c)(2) of title X, United States Code);

(2) in any United States embassy;

(3) in any facility owned and operated by the Federal Government either in the United States or in a foreign country;

(4) in any duty-free shop located within the United States; or

(5) through any other Federal entity or on any other Federal property as determined appropriate by the Secretary.

(b) REQUIREMENTS OF PROGRAM.—The program established under subsection (a) shall apply requirements (including those for penalties, suspensions, and revocations) similar to those required to be implemented by States under this title (and the amendments made by this title).

(c) INDIAN TRIBES AND TRIBAL LANDS.—For purposes of applying and enforcing the provisions of this title (and the amendments made by this title) to entities that sell or otherwise distribute tobacco products on Indian reservations (as defined in section 403(9) of the Indian Child Protection and Family Violence Prevention Act (25 U.S.C. 3202(9))), an Indian tribe or tribal organization shall be treated as a State.

Tob - pct - new leg -
Hatch-Feinstein

THE WHITE HOUSE
WASHINGTON

June 26, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
Elena Kagan

SUBJECT: Analysis of Hatch-Feinstein Tobacco Bill

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.

Although few Democrats believe that the Hatch bill could pass the Senate as written, a fair number remain open to the possibility of negotiating with Hatch to try to produce a strengthened bill. As usual, the major hurdle in any negotiation of this kind would be the issue of liability protection. This memo, after providing a more detailed analysis of the Hatch bill, discusses briefly whether -- and, if so, how -- we should engage in such discussions.

I. Summary of Hatch-Feinstein

A. Overall Cost and Price Per Pack

The charts Hatch distributed earlier this week dramatically exaggerated the cost of the McCain bill -- and to a lesser extent exaggerated the cost of his own. Hatch's analysis erred in

not taking into account either bill's volume adjustment, using nominal rather than real numbers in calculating the base payments in the McCain bill, and assuming that companies would pay maximum lookback charges under both bills. OMB and Treasury have done estimates that correct these problems by taking into account the volume adjustment in both bills, measuring both in real rather than nominal dollars, and making more realistic assumptions on lookbacks. The chart below presents these estimates, along with a corresponding set of estimates for the June 20th settlement.

	AG's Agreement (25-yr cost in 99$)	Hatch-Feinstein (25-yr cost in 99$)	McCain Mgrs Amdt (25-yr cost in 99$)
Base Payment	$267 billion	$291 billion	$408 billion
Est. Lookbacks[1]	$14 billion	$80 billion	$59 billion
Total	$281 billion	$371 billion	$467 billion
Per-Pack Increase in 2008			
Base payment	$0.64	$0.69	$1.10
Lookback[2]	$0.05	$0.25	$0.19
Total	$0.69	$0.94	$1.29
Youth Smoking Reduction by 2008	36%	40%	46%

B. Spending

The attached OMB chart compares the available revenue and spending priorities in the McCain and Hatch bills and the settlement. McCain raises $59 billion over 5 years; Hatch raises $46 billion; and the settlement raises $40 billion. The Hatch bill divides the money in almost exactly the same way as the McCain manager's amendment (i.e., before the Senate approved tax cut and drug amendments). Under the McCain manager's amendment, 40% goes to states, 22% to public health, 22% to health research, and 16% to farmers; under the Hatch bill, 42% goes to states, 21% to public health, 20% to health research, and 17% to farmers. The major potential difference is that the Hatch bill includes an offset for liability payments that could reduce the available revenue for each of these purposes by up to 36% (depending on the number and size of verdicts rendered against the tobacco companies).

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[1] Estimates for settlement and Hatch-Feinstein assume no abatement -- see below.

[2] For comparative purposes, we assume here and below (in our discussion of lookbacks) that not only industry-wide, but also company-specific lookbacks would be passed on to price.

In addition, the Hatch bill imposes different requirements for the use of state funds. The McCain manager's amendment required that 50% of state monies be used for seven specified activities: the Child Care and Development Block Grant, the Maternal and Child Health Services Block Grant, child welfare and abuse programs, Substance Abuse and Mental Health Services Administration (SAMHSA) programs, the Safe and Drug Free Schools Program, the Eisenhower Professional Development Program, and (to a limited extent) the Children's Health Insurance Program (CHIP). (The Kerry amendment, which the Senate passed by a large margin, further provided that half of these restricted monies -- i.e., 50% of the 50% -- be put into the Child Care Block Grant alone.) By contrast, the Hatch bill provides that 60% of state funds be used for "anti-smoking or tobacco-related purposes," pursuant to a plan that must be approved by the Secretaries of HHS and the Treasury and the Attorney General; the bill further provides that these anti-tobacco activities may be conducted "in conjunction with and under" a wide variety of programs, including state education reform programs (for purposes such as establishing standards and reducing class size), child care programs, Head Start, the school lunch program, CHIP, the Maternal and Child Health Block Grant, Indian Health Service programs, and the community health center program.

C. Lookback Surcharges

The Hatch bill includes industry-wide lookback surcharges that are dramatically larger than those in the settlement and somewhat larger than those in the McCain bill. The settlement assessed charges (which were deductible) at $80 million for each percentage point missed, with an annual cap of $2 billion. The McCain manager's amendment assessed charges (which were nondeductible) at between $80 and $240 million per point (depending on the magnitude of the miss), with a cap of $4 billion -- equivalent to about $6 billion adjusted for taxes. (The Durbin amendment cut both the per-point assessments and the cap in half in exchange for higher company-specific penalties.) Hatch assesses charges (which are, as in the settlement, deductible) at between $100 and $300 million per point for the first five years, with a cap of $5 billion, and between $250 and $500 million per point thereafter, with a cap of $10 billion. Whereas maximum industry-wide penalties under the McCain manager's amendment would have been about 39 cents per pack (with maximum company-specific penalties equaling another 38 cents per pack, if passed on to price), maximum industry-wide penalties under the Hatch bill (in year six and onward) could reach 60 cents per pack.

A comparison of actual lookback payments under the two bills is somewhat trickier. Hatch provides for a double-counting adjustment to keep from penalizing companies more than once for the same teenage smoker, which reduces actual penalties dramatically and prevents them (even in the very worst case) from ever reaching the caps. The effect of this adjustment, however, is partially offset by Hatch's use of a lower baseline from which to calculate youth smoking reductions -- a ten-year (1986-96) historical average, rather than the 1998 level. Taking both these factors -- as well as our forecasts of youth smoking reduction -- into account, Treasury and OMB estimate that the Hatch surcharges would generate about $80 billion in industry-wide payments over 25 years, with a per-pack increase of about 25 cents in 2008. By

comparison, the McCain manager's amendment would generate about $40 billion in industry-wide payments plus another $19 billion in company-specific penalties over 25 years, with a per-pack increase in 2008 of about 19 cents (13 cents from industry payments and 6 cents from company payments, assuming these are passed on).[3]

The Hatch bill, however, also contains a provision -- derived, like the double-counting adjustment, from the June 20th settlement -- that could bring lookback payments down to zero. Under the bill, each company could petition the Secretary of HHS to abate all or part of its share of the industry-wide penalty, and appeal a denial of that petition to the D.C. Circuit. The decision to abate would depend on whether the manufacturer had (1) complied with the Act, (2) "pursued all reasonably available measures to attain the reductions," (3) directly or indirectly undermined the achievement of the reductions or any other provisions of the Act, and (4) taken (or failed to take) any other action determined appropriate by the Secretary. The manufacturer would carry the burden of proof in this abatement proceeding, and a court could reverse the Secretary's decision only if it were arbitrary or capricious. The public health community is nonetheless likely to object strenuously to this provision, much as it did to the abatement scheme in the June 20th settlement agreement.

Even more important to the public health community and Congressional Democrats is the failure of the Hatch bill to provide for company-specific charges. As you know, this matter has taken on near-religious import among many Democrats and public health advocates. Because of their views on this question, we insisted that the McCain manager's amendment charge individual companies $1,000 per youth smoker above the targets, a figure representing two times foregone profits. The Durbin amendment, which the Senate passed by a quite large margin, increased these charges to between $80 and $240 million per percentage point missed -- between 2.5 and 7.5 times foregone profits -- up to a cap of $5 billion. The Hatch bill no doubt reflects a considered judgment that a substantial company-specific surcharge will prevent the companies from returning to the bargaining table, but the absence of such a surcharge will greatly dismay many Democrats and the anti-tobacco lobby.

D. FDA Regulation

On preliminary review (we are still awaiting full feedback from the agency), the Hatch bill's FDA provisions appear highly problematic. As you recall, we agreed with Sens. McCain and Frist to create a separate title in the Food Drug and Cosmetic Act (FDCA) for the regulation of tobacco products so long as the authority granted in that title was equivalent to the authority granted in the Act's drug and device title. (FDA issued its rule under the drug and device title,

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[3] As amended by Durbin, the McCain bill would raise $94 billion over 25 years, mostly in company-specific penalties. The per-pack price increase in 2008 (assuming, once again, that company-specific penalties are passed on to price) would equal about 33 cents -- 11 cents from the industry-wide surcharges and 22 cents from the company-specific surcharges.

on the theory that cigarettes are a drug delivery device.) Although we agreed to a few provisions in the McCain manager's amendment that further restricted the FDA's authority (one provision, for example, limited the ability of the FDA to restrict sales of tobacco products in certain kinds of retail outlets, even though the FDA has this authority under the drug and device title), the principle of equivalency is very important both to the FDA and to the public health community. In several respects, the Hatch bill appears to violate that principle.

The FDA's authority over the manufacture of tobacco products would be more limited under the Hatch bill than under the current drug and device title. Under Hatch, the FDA would lack "premarket approval authority" -- the authority it uses to prevent a new or unconventional product (e.g., a smokeless cigarette) from going onto the market, or to attach conditions to the product's sale. The FDA also would confront several limitations on its ability to require manufacturers to modify their current products to make them safer. The FDA would have authority only over ingredients, and not over the filter, paper, or construction of a tobacco product. Further, the FDA might lose its ability to require changes in product ingredients after 24 months from the date of the bill's enactment (although this provision is ambiguous). Finally, the FDA could not prohibit a tobacco product or eliminate nicotine in a tobacco product without a joint resolution of Congress affirming the FDA's decision. Although the likelihood of the FDA's taking action of this kind may seem slight (especially if the FDA must act within 24 months!), this issue has taken on symbolic importance in the public health community.

Equally important, the FDA's ability to regulate on matters involving advertising and access would be more limited under the Hatch bill than under the drug and device title. Whereas the FDA has interpreted current drug and device law to give it authority over all tobacco product advertising -- and the McCain bill would make an explicit grant of this authority to the FDA -- the Hatch bill would authorize the FDA to regulate only advertising that "has significantly contributed to the use of tobacco products" by minors. Further, the Hatch bill would repeal all of the advertising restrictions in the current FDA rule. Although the bill would include these provisions (plus even more sweeping restrictions) in the protocols signed by participating manufacturers, this repeal would prevent the restrictions from applying to non-participating manufacturers or to distributors and retailers (though their activities could be regulated indirectly through contracts with participating manufacturers); further, the repeal would leave no advertising restrictions at all in place if the protocols were invalidated. Finally, the Hatch bill, although codifying the FDA rule's provisions on youth access, would give authority to the CDC, rather than the FDA, to issue any further regulations on this subject.

E. Liability Provisions

The liability provisions of the Hatch bill are strikingly similar to those of the June 20th settlement. The bill would: (1) settle the state suits and the Castano addiction claims; (2) ban any class actions against the tobacco companies in the future; (3) prohibit any punitive damages for past misconduct of the tobacco companies; and (4) impose an annual liability cap of $5.5 billion, with 80% of all monies paid under this cap to be offset against the companies' payments to the

government. The only liability provision included in the June 20th settlement that is not contained in the Hatch bill is a prohibition on forms of case consolidation other than class actions. The Hatch bill also retains the settlement's provision on attorneys' fees, which punts determination of these fees to a panel of arbitrators.

F. Farmers

The Hatch bill essentially adopts the Lugar approach to protecting tobacco farmers. Like Lugar, Hatch would buy out all tobacco quota holders and end the tobacco program immediately. Hatch would compensate producers over seven years, rather than Lugar's three, to make room for other spending; for this reason, his bill will be less attractive than Lugar's to the tobacco farming community. Hatch includes some of Ford's economic development provisions in his bill, but otherwise makes little effort to develop a compromise proposal. Some people who are working closely with Hatch, however, say that he will move in the direction of the LEAF Act to gain more support for his bill.

G. Other provisions -- ETS and antitrust

The Hatch bill incorporates a strong environmental tobacco smoke standard (the same standard contained in both the settlement and the McCain manager's amendment), but leaves all enforcement of that standard to the states. The public health community probably will attack this enforcement provision, pointing out that both the settlement and the McCain manager's amendment provided for predominantly federal enforcement. (Under the manager's amendment, OSHA could grant enforcement authority to a state, but only upon finding that the state's enforcement scheme was equally or more effective.)

The Hatch bill also includes a very limited antitrust exemption. This exemption would allow the companies (1) to furnish the Secretary of HHS with information on distributors or retailers not complying with the Act, (2) to obtain a list of non-complying distributors and retailers compiled by the Secretary, and (3) to refuse to deal with distributors and retailers on that list because of their non-compliance. The Justice Department has no serious objection to this provision, but the presence of any antitrust exemption -- however limited and however beneficial its purpose -- might provoke some slight criticism from liberal Democrats.

II. Legislative Options

Senate Democrats are divided on how to respond to Hatch -- and more generally, on how to move forward on tobacco legislation. Some on the left, led by Sen. Kennedy, want to take the tobacco issue into the fall elections. A very few on the right, led by Sens. Feinstein and Breaux, want to accept the Hatch bill as written. Most Democrats -- including Sens. Daschle, Kerry, and Conrad -- fall between these two camps: they want to pass a bipartisan bill in the Senate and they are willing to talk with Hatch, but they do not like the Hatch bill as written and/or do not think it could pass. Kerry seems to prefer a streamlined McCain bill, still with a $1.10 price increase,

but with fewer titles and a less complicated spending structure; he would leave liability protections out of the bill, but enter into an agreement to try to put some back in conference. Conrad seems to prefer a smaller bill -- perhaps in the 65-cent-per-pack range -- with no liability protections at all (and no agreement to put them in later).

The Republicans who matter (Lott, Stevens, Domenici, etc.) do not seem likely to gravitate toward these alternative Democratic approaches. (McCain will follow Lott's lead; he will not endorse another bill until Lott guarantees him 60 votes for cloture.) Their views could change if Republicans return from the recess feeling more anxious about the tobacco issue. For this reason, the activity of the public health community and the DNC over the next week in states with hotly contested seats is very important. But given the weakness and demoralization of the public health groups, we should not expect them to alter dramatically the political dynamic. The likelihood is that Lott will be after the recess where he was before: in favor of a Hatch-type bill, but uncertain how to pass it and disinclined to expend much further energy on the issue.

In these circumstances, Lott might well decide to support a different approach to ridding the Republicans of their tobacco problem: (1) pass a slimmed-down bill (such as will be offered in the House after recess) that does not accomplish much, but also does not contain anything objectionable and/or (2) include a small tobacco tax hike in a reconciliation bill to help fund a marriage penalty (or other kind of) tax cut. Such an approach would place us in the position of opposing a Republican anti-tobacco measure either because it does not do all it might or because it is a part of a broader tax bill that we view as irresponsible. We might be able to carry this argument, but should not underestimate the difficulty of doing so.

We see a few basic options. First, we could encourage Democrats to unite behind a modified McCain bill, along the lines of what Kerry or Conrad is suggesting, and try to interest the Republicans in that proposal. To make this option as strong as possible, Larry suggests uniting around a bill that essentially suspends all spending and therefore is not subject to a point of order. This approach may help to make the electoral case against Republican Senators in the fall, because the Democrats could say that the Republicans refused to support even a smaller tobacco bill that addressed their tax-and-spend concerns. Taken alone, however, the approach is unlikely to lead to the passage of comprehensive tobacco legislation this year, because the Republicans who matter will not support a bill of this size without liability protections; they instead will adopt one or both of the options mentioned above -- a minimalist bill or a tax increase in a reconciliation bill -- to get them off the hook with the voters.

Second, we could encourage Democrats to negotiate with Hatch, or do so ourselves. (This option, of course, could go hand-in-hand with the first; Democrats could bring a new proposal to Hatch and then strike a further compromise.) Hatch might be willing to make some changes to his bill, including on FDA regulation, lookbacks, farmers, and liability protections. But it is very unclear whether he will make sufficient changes to get Democrats like Kerry and Daschle on board, and even if he does, it is unclear how to get the resulting bill off the Senate floor with the key provisions -- including the liability protections -- intact.

Third, we could try to structure broader negotiations, involving the Administration, Lott and Daschle, McCain and Kerry, Hatch and Feinstein, and perhaps a couple of others, such as Conrad and Domenici. (An even broader negotiation would involve House members, but we do not believe anything coherent is likely to follow from discussions involving the House at this time.) The purpose of these negotiations would be to get broad-ranging agreement on a comprehensive bill that the leaders then could push through the Senate. This bill, presumably, would be a cross between McCain and Hatch -- probably with the money nearer to Hatch but the liability protections closer to the McCain manager's amendment. Larry suggests that the probability of success in these negotiations is low -- and that it could be improved if Democrats first placed pressure on Republicans by offering the kind of streamlined bill discussed in option 1. Time, however, is not on our side, and a high-stakes, high-risk strategy that demonstrates leadership on the issue may be the only way to move comprehensive tobacco legislation forward during this session of Congress.

We look forward to discussing these options further with you when you return.

Comparison of the S. 1415, the AG/Company Proposal, and Hatch-Feinstein

5-year totals in billions nominal $, except where noted

	S.1415		AG/Company Proposal				Hatch/Feinstein			
			Min Civil Judgments		Max Civil Judgments		Min Civil Judgments		Max Civil Judgments	
	%	$	%	$	%	$	%	$	%	$
Estimated Net Receipts		59		40		40		46		46
Uses										
Judgments	0%	0	0%	0	33%	13	0%	0	36%	17
States	40%	24	66%	27	44%	18	42%	19	27%	12
Public Health	22%	13	25%	10	17%	7	21%	10	13%	6
Research/NIH	22%	13	9%	4	6%	2	20%	9	13%	6
Farmers	16%	9	0%	0	0%	0	17%	8	11%	5
Tax Cuts	0%	0	0%	0	0%	0	0%	0	0%	0
	100%	59	100%	40	100%	40	100%	46	100%	46
Gross Payments (Billions 99$, 25 yrs)		408		267		267		291		291
% Change from S. 1415				-35%				-29%		
Add'l Cost/Pack in 2003 (99$)		$1.10		$0.64		$0.64		$0.66		$0.66
% Change from S. 1415				-42%				-40%		

Assumptions

Receipts are based on OMB's estimate of likely CBO/JCT scoring

Judgment payments limited to 1/3 of total and are paid first (AG/Company, Hatch).

S. 1415:

Excludes Gramm, Coverdell, Lugar, and Veterans amendments

Assumes price caps rising to $1.10 per pack

AG/Tobacco Company:

Spending percentage based on Center on B&PP estimates

Hatch/Feinstein:

$46 billion is spending for the first 5 years; the 25-year stream is $408 billion

$5.5 billion liability cap per year with a liability payment credit

Spending for farmers assumes higher payments in the first five years for Lugar.

In the maximum liability case, the amount of the liability credit is included in net revenues, gross payments, and cost per pack.

Tob-acc - Hatch-Feinstein

7:00 Hatch/Feinstein mtg

CA contraband - 20-50 m loss in taxes
8% of mkt

Feinstein - wants to make spending 'more dramatic'

(Most bipart press conf)
↓
Lott will stand w/ him.
Only way - leader w/ us:
no amendments

① Potus show up for it
② 70 or more votes -
→ has to be a lot more dem bipart

Off: Looking for 30

Off - Have to change liab protection -
cap + CA limits?

RT: 10 - 20 new
25 - 35 w/ Potus

Off - need to get Lott + Potus together.
Bryan - Daschle too
RT: Cornyn should be involved.

DF/Tor: Can't get to 35 ^ w/out Cornyn

Off: co specific - no way
has to be same as element -
can't get I can change.

Tob-acc-New legislation-
Hatch-Feinstein

Review of Hatch Analysis

OMB and the Treasury Dept. disagree with the Hatch's analysis as shown in the table below:

	Hatch Estimate (25 year cost, real 1999$)	OMB/Treasury Estimate (25 year cost, real 1999$)
McCain Base Payment	$574 billion	$408 billion
McCain Lookback Surcharges*	$132 billion	$59 billion
Total McCain	$706 billion	$467 billion
Hatch Base Payment	$408 billion	$291 billion
Hatch Lookback Surcharges	$204 billion	$80 billion
Hatch Total	$612 billion	$371 billion

* These figures are for the lookback surcharges before the Durbin amendment. With the Durbin amendment, Hatch thinks the surcharges raise $236 billion and Treasury thinks they raise $94 billion.

The Hatch analysis overstates the gross payments manufacturers will make by:

- Confusing real and nominal payments in their comparisons. For example, the equivalent of the proposed settlement's $368 billion and Hatch's $408 billion is $516 billion for McCain, not $574.

- Ignoring the effects of the volume adjustment and the price cap agreed to by McCain, which would reduce the 25-year payments from $516 billion (in 1999 dollars) to $408 billion.

- Ignoring the fact that net receipts available to the government will be reduced by lost income and excise taxes and other offsets. As a result, it overstates the funds that will be available under the Hatch/Feinstein proposal.

With the volume adjustments, OMB believes that Congressional scorekeepers would estimate the 25-year gross payments as $267 billion for the proposed settlement (64 cents per pack) $291 billion for Hatch (66 cents per pack) and $408 billion for McCain ($1.10 per pack).

There are several problems with Hatch's analysis of lookback surcharges. The most significant is that it assumes that the companies will pay the maximum lookback surcharge and that they will do so every year. Both we and CBO/JCT think that is extremely unlikely.

Also attached is a more detailed financial comparison prepared by OMB staff of the Hatch, McCain, and proposed settlement (excluding lookback surcharges), as well as a side-be-side summarizing the policy provisions of the three proposals.

Comparison of the S. 1415, the AG/Company Proposal, and Hatch-Feinstein

5-year totals in billions nominal $, except where noted

	S.1415		AG/Company Proposal				Hatch/Feinstein			
			Min Civil Judgments		Max Civil Judgments		Min Civil Judgments		Max Civil Judgments	
	%	$	%	$	%	$	%	$	%	$
Estimated Net Receipts		59		40		40		46		46
Uses										
Judgments	0%	0	0%	0	33%	13	0%	0	36%	17
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Public Health	22%	13	25%	10	17%	7	21%	10	13%	6
Research/NIH	22%	13	9%	4	6%	2	20%	9	13%	6
Farmers	16%	9	0%	0	0%	0	17%	8	11%	5
Tax Cuts	0%	0	0%	0	0%	0	0%	0	0%	0
	100%	59	100%	40	100%	40	100%	46	100%	46
Gross Payments (Billions 99$, 25 yrs)		408		267		267		291		291
% Change from S. 1415				-35%				-29%		
Add'l Cost/Pack in 2003 (99$)		$1.10		$0.64		$0.64		$0.66		$0.66
% Change from S. 1415				-42%				-40%		

Assumptions

Receipts are based on OMB's estimate of likely CBO/JCT scoring

Judgment payments limited to 1/3 of total and are paid first (AG/Company, Hatch).

S. 1415:

Excludes Gramm, Coverdell, Lugar, and Veterans amendments

Assumes price caps rising to $1.10 per pack

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Spending percentage based on Center on B&PP estimates

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$46 billion is spending for the first 5 years; the 25-year stream is $408 billion

$5.5 billion liability cap per year with a liability payment credit

Spending for farmers assumes higher payments in the first five years for Lugar.

In the maximum liability case, the amount of the liability credit is included in net revenues, gross payments, and cost per pack.

Comparison of McCain, Hatch and Settlement
June 25, 1998

	McCain	Hatch	Settlement
Total Payments over 25 Years* (real 99$)	$408 billion (after volume adjustment). Payments continue after 25th year.	$291 billion after volume adjustment (Originally reported as $428.5 billion, and $408 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 (excludes Gramm, Coverdell, Lugar and Veterans amendments)	$47 billion	$40 billion
Price Increase*	$1.10 per pack	66 cents per pack	64 cents per pack

* OMB estimate.

	McCain	Hatch	Settlement
Lookback Surcharges: Industry	$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). Surcharges 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. Surcharges 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.

* OMB estimate.

	McCain	Hatch	Settlement
Lookback Surcharges: Company Specific	$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 67% over 10 years.	Reduce youth smoking by 60% over 10 years.	Reduce youth smoking by 60% over 10 years.
Full FDA Authority	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 could not require manufacturers to modify products to make them safer; FDA would not have premarket approval authority for new or unconventional products.	Provides full authority in the device title. (However, FDA could not ban nicotine for 12 years and procedural hurdles such as formal rulemaking requirements would hinder FDA activity to modify tobacco products).

* OMB estimate.

	McCain	Hatch	Settlement
Advertising and Access Provisions	Codifies advertising and access provisions in the FDA rule and adds additional restrictions through a consent protocol.	Repeals advertising restrictions in 1996 Rule, but includes them in the consent protocol along with the additional restrictions contained in the settlement. (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 advertising and access provisions in the FDA rule and adds additional restrictions.
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). 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 $17.35 billion over 7 years ($18.6 over 25 years) to compensate farmers and fund economic development programs.	None.
Public Health	$13B over 5 years (22%) before taking into account Gramm and Coverdell and Vets amendments (even with these amendments, probably funding is probably higher than Hatch, although due to Coverdell, anti-drug uses compete with public health.)	$6-$10B over 5.	$7-10B over 5.

	McCain	Hatch	Settlement
Research	$13B over 5 years (22%) before taking into account Gramm and Coverdell and Vets amendments (even with these amendments, probably funding is probably higher than Hatch). Mostly NIH, but includes CDC/AHCPR.	$6-$9B over 5.	$2-$4B over 5.
State Funds	$24B over 5 before taking into account Gramm and Coverdell and Vets amendments (even with these amendments, probably funding is probably higher than Hatch). 50% restricted to menu of child care and other uses.	$13-$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.
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. Enforcement is by OSHA and civil actions. 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.	Includes provisions to protect against environmental tobacco smoke. Exempts the hospitality industry (e.g., bars, restaurants).
Liability Protections for Industry:			
1. Liability Cap	None (Gregg amendment struck the $8 billion cap).	$5.5 billion per year.	$5 billion per year.
2. Bar on Class Actions	None.	Yes.	Yes.
3. Bar on Punitive Damages	None.	Yes.	Yes.
4. Credit Against Base Payments	No.	Yes. 80% credit (could be 36% of all uses).	Yes. 80% credit.
Antitrust Exemption	No	Yes -- limited.	Yes.

	McCain	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; 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 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.
Tax Cut	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.

Tob-set - new legislative - Hatch-Feinstein

and

Tob-set - lookbacks

Bruce N. Reed
06/29/98 03:19:13 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Estimated total increase in cost/pack

---------- Forwarded by Bruce N. Reed/OPD/EOP on 06/29/98 03:23 PM ----------

JOSHUA
GOTBAUM
06/26/98 02:29:32 PM

Record Type: Non-Record

To: Bruce N. Reed/OPD/EOP

cc: Cynthia A. Rice/OPD/EOP, Richard J. Turman/OMB/EOP
Subject: Estimated total increase in cost/pack

The figures below deal with the "peaks and valleys" problem with the lookback by using the 3-year average whose mid-point is the 10th year.

---------- Forwarded by Joshua Gotbaum/OMB/EOP on 06/26/98 02:15 PM ----------

Comparing Total Additional Cost Per Pack in Hatch & McCain in 2008

	Hatch	McCain
From base payment	.69	1.10
From surcharge*	.25	.19
total, per-pack	.94	1.29

* uses 3-year average for surcharge for both Hatch and McCain (*sans* Durbin).

Tob-rer-new legislative - Hatch-Feinstein and Tob-rer-lookback penalties

JUN 25 1998

Memo To: Bruce Reed
Elena Kagan
Cynthia Rice
Josh Gotbaum

From: Jon Gruber

Re: Hatch-Feinstein Lookback - Revised

Here is a more refined analysis of Hatch-Feinstein lookback, correcting some earlier mistakes, and containing a more detailed comparison to both old and new McCain.

Hatch-Feinstien Lookback Results

Targets: Same as AG settlement and McCain. But, uses daily smoking instead of monthly. Also, since use older Michigan surveys relying on lower teen smoking rate, targets are effectively harder to meet than McCain. That is, daily smoking rate today is 18.2%, but baseline daily smoking rate was 15.2%, so that a 30% reduction from baseline is really a 58% reduction from today's smoking rate.

Penalties: First five years of lookback: $100 million per percentage point for 0-5; $200 million for 6-10; $300 million for 10+. Next five years: $250 million per percentage point for 0-5; $500 million per percentage point thereafter. **But there is a double-counting adjustment, as in AG settlement, that dramatically lowers the effective payments.**

Results:

Table 1 shows our base case estimates of the impact of the lookback provisions, using our youth elasticity model

- The actual reductions in teen smoking are substantially less than under McCain - in the out years, teen smoking falls by 42-43%, whereas with the Durbin lookback mechanism teen smoking was falling by almost 50% (all figures account for "feedback" effects of lookback surcharges themselves on youth smoking).
    - The reductions from "baseline" are very different for Hatch, however, since their baseline is the historical smoking measure. This leads to the lower numbers in the third column.
- The base penalty column presents the penalty payments if there were no adjustments. Note that all figures refer to the year for which the penalty is levied, not the year in which it is actually remitted to the government - this follows the Hatch tables. These are then adjusted in two ways.
- The first is a population change adjustment - the amounts are increased to account for growing teen population.
- The second is the double-counting adjustment - the amounts are decreased to account for teens for whom there was a surcharge in the previous year. It is unclear how to actually carry this out in practice. We approximate the exercise by:
    - Estimating penalty teens by age (13, 14, ..., 17)
    - Industry is always charged for penalty 13 year olds
    - Industry is then charged for net increase in penalty 14-17 year olds
    - Ratio of these "new" penalty teens to total penalty teens is the double-counting adjustment.

- The penalty amounts vary substantially over time with this double-counting adjustment. This is because when the targets "step down" over time, there are a larger number of "new teens" who are hit - that is, the double-counting adjustment knocks out fewer teens, since there are so many teens who weren't penalty teens in the previous year.

- The 25 year total payment under Hatch is almost $80 billion. This is clearly dramatically lower than that reported in their propoganda. This is because they assume that the maximum lookback caps are hit in every year, whereas in fact they are only hit in one year, 2005.

  - Of much more minor consequence, they add in the lookback penalties for smokeless as well. We don't include those for our analysis, of either Hatch or McCain.

Comparison to McCain:

Table 2 provides comparable figures for the McCain bill, including the Durbin-ammended lookback penalty. Note that this table is off by one year from the budget scoring tables I sent around on June 11, since I am following the Hatch table convention of reporting the penalties in the year for which they are levied, not the year in which they are actually paid.

- The total penalties under the ammended McCain bill over 25 years are almost $94 billion, or about 18% higher than Hatch.

- This 25 year total is much lower than the $235 billion figure in the Hatch propoganda.

- On the other hand, the ratio of this total to Hatch's total is very close to the ratio in the Hatch propoganda. Hatch says that his penalties are 86% as large as Durbin's ammendment to McCain; the truth is that his penalties are 85% as large.

Table 3 undertakes a similar exercise for the original McCain managers ammendment.

- The total penalties here are about $59 billion, or about 26% lower than Hatch. Once again, the 25 year total is much lower than in Hatch propoganda

- This total is significantly closer to Hatch's total than in their propoganda. Their propoganda says that Hatch is 54% greater than original McCain. The truth is that Hatch is 36% greater than original McCain.

Adjustments: Two comments on the Hatch adjustments:

- The double-counting adjustment is horrible. It has at least three key disadvantages:

  - It is effectively unworkable. The approximation used here is just that - it doesn't account for the fact that some folks may have quit between ages 13 and 14 and

some new smokers may have taken their place, and that the firms should be charged for those new smokers. While double-counting adjustments sound good in theory, they are unworkable in practice without longitudinal data that follows the same teens over time.

- It leads to a strange pattern of penalties, which vary dramatically from year-year

- It makes the penalties sound a lot more severe than they are. Even in the very worst case, the penalties never hit the caps presented by Hatch-Feinstein.

- On the other hand, the adjustment for teen population change is a good idea if you use $/percentage point (it obviously doesn't matter for $/kid), and we should be trying to incorporate that into our suggested lookback.

TABLE 1: SECOND PASS HATCH ESTIMATES - BASE CASE

year	target reduction	actual reduction from '98	actual reduction from baseline	base penalty	pop change adjusted	dble count adjusted	per pack equivalent
1998							
1999	0	26.4	11.5	0	0	0	0.00
2000	0	32.5	18.8	0	0	0	0.00
2001	0	35.3	22.2	0	0	0	0.00
2002	0	35.1	22.0	0	0	0	0.00
2003	30	36.0	23.1	884	977	977	0.05
2004	30	37.5	24.9	520	585	79	0.00
2005	50	37.6	24.9	6019	6873	5000	0.26
2006	50	39.8	27.7	5317	6124	1310	0.07
2007	50	39.9	27.8	5282	6074	1682	0.09
2008	60	40.5	28.5	14641	16793	8189	0.45
2009	60	41.6	29.8	13834	15731	3722	0.21
2010	60	42.6	31.0	13252	14946	3681	0.21
2011	60	43.4	32.0	12760	14358	3644	0.21
2012	60	41.8	30.0	13755	15444	5046	0.29
2013	60	42.3	30.6	13419	15032	3941	0.23
2014	60	42.5	30.8	13342	14913	4097	0.24
2015	60	42.6	31.1	13226	14749	4019	0.24
2016	60	42.3	30.6	13444	15061	4420	0.26
2017	60	42.5	30.9	13309	14977	4131	0.25
2018	60	42.5	30.9	13282	15013	4216	0.25
2019	60	42.7	31.1	13216	15005	4180	0.25
2020	60	42.6	31.0	13252	15113	4282	0.26
2021	60	42.7	31.1	13194	15212	4309	0.27
2022	60	42.8	31.2	13149	15326	4347	0.27
2023	60	42.9	31.3	13086	15416	4355	0.27
25 year total						79629.34101	

TABLE 2: McCAIN COMPARISON - with Durbin Ammendment

year	Industry	Company	Total	Total, After-Tax
1998				
1999	0	0	0	0
2000	0	0	0	0
2001	0	0	0	0
2002	0	0	0	0
2003	0	0	0	0
2004	0	0	0	0
2005	647	1293	1940	2910
2006	499	998	1498	2246
2007	382	765	1147	1721
2008	1729	3459	5188	7783
2009	1497	2995	4492	6739
2010	1287	2575	3862	5793
2011	1099	2199	3298	4947
2012	1187	2375	3562	5343
2013	1221	2442	3662	5493
2014	1211	2422	3634	5451
2015	1170	2339	3509	5264
2016	1152	2303	3455	5182
2017	1143	2286	3428	5143
2018	1134	2268	3402	5102
2019	1119	2238	3357	5035
2020	1103	2207	3310	4966
2021	1089	2179	3268	4902
2022	1076	2152	3228	4842
2023	1062	2125	3187	4780
				93641.90403

TABLE 3: McCAIN COMPARISON - Managers Ammendment (pre-Durbin)

year	Industry	Company	Total	Total, After-Tax
1998				
1999	0	0	0	0
2000	0	0	0	0
2001	0	0	0	0
2002	0	0	0	0
2003	0	0	0	0
2004	0	0	0	0
2005	341	273	614	921
2006	326	263	589	883
2007	311	251	562	844
2008	2091	880	2971	4457
2009	1851	809	2660	3990
2010	1641	747	2388	3582
2011	1457	697	2154	3232
2012	1530	715	2245	3368
2013	1566	722	2289	3433
2014	1572	722	2294	3441
2015	1553	716	2269	3403
2016	1546	717	2264	3395
2017	1545	720	2265	3398
2018	1544	723	2268	3401
2019	1542	726	2267	3401
2020	1538	728	2266	3399
2021	1535	735	2270	3405
2022	1532	742	2275	3412
2023	1529	750	2279	3419
				58783.02414

Tob-acr-new legislation-
Hatch-Feinstein

CHIEF OF STAFF TO THE PRESIDENT

Please
FAX
answers
to us

Bruce - Elena

POTUS - wants to know ① is the analysis correct ② what we would need to change to do HATCH ③ Connie Mack called last night said he could support HATCH if we did - I say no — EBB

NOTE READS:

" BRUCE - ELENA

POTUS WANTS TO KNOW ① IS THIS ANALYSIS CORRECT ② WHAT WE WOULD NEED TO CHANGE TO DO HATCH ③ CONNIE MACK CALLED LAST NIGHT SAID HE COULD SUPPORT HATCH IF WE DID - I SAY NO — EBB "

" PLEASE FAX ANSWERS TO US. "

6-24-98

Copied Bowles

Hatch-Feinstein Substitute Bill

Cessation and Research

States receiving funds must conduct anti-tobacco programs consistent with smoking cessation guidelines issued by the Agency for Health Care Policy and Research.

State anti-tobacco and cessation programs must be approved by the Attorney General, Secretary of Treasury and Secretary of HHS.

Separate Title of Act includes detailed provisions to restrict minors' access to tobacco products and reduce underage smoking.

National anti-tobacco product consumption and tobacco product cessation program to be established and implemented by Secretary of HHS.

These programs are to be provided in part by state and community action funded by block grants and in part by direct action by HHS through the Agency for Health Care Policy and research.

Settlement of Cases and Liability

Settles as to participating manufacturers all state actions, including political subdivisions, parens patriae actions, punitive damages for past conduct and addiction/dependency claims reserving the right of individuals to pursue individual claims not based on addiction/dependency claims.

Precludes future class actions.

Requires payment by participating manufacturers of $398.3+ billion ($303,337,500,000 as compensatory damages and $95 billion as punitive damages), plus a $10 billion initial payment.

Does not settle liability for future conduct including punitive damages.

Limits payment of tobacco related judgments to $5.5 billion per year; however, payment of any judgments by participating manufacturers shall entitle them to a credit of 80% of such payment against future payments under the Act. Any excess is paid the following year.

Fees

Establishes a 3 member arbitration panel to award attorneys fees and expenses relating to litigation affected by, or legal services that resulted in whole or in part in the Act.

One member appointed by participating tobacco manufacturer, one by private attorneys and Attorneys General who were signatories to the Memorandum of Understanding of June 30, 1997 ("Settlement") and one appointed jointly by participating tobacco manufactures and the aforementioned private attorneys and Attorneys General.

Fees are to be subject to criteria including time and labor, skill required, novelty and difficulty of the issues, preclusion of other work, amount involved and results obtained, undesirability of action and experience and reputation of attorneys involved, which have been approved on numerous occasions in similar situations for the setting of attorneys' fees by the United States Supreme Court, the United States Courts of Appeals, and other courts.

Fees and expenses are to be paid by participating manufacturers outside of any monies payable under the Act.

FDA and Advertising

Provides for full FDA authority over tobacco products, including the authority to promulgate regulations resulting in a general prohibition of cigarettes or smokeless tobacco, or the reduction of nicotine yields of a tobacco product to zero, subject to Congressional approval.

Mandates that the advertising restrictions agreed to in the June 20, 1997 Settlement will be included in the Protocol, thereby going beyond the restrictions contained in the FDA rule and insuring that the tobacco industry will waive any constitutional rights to challenge these restrictions.

Tobacco Farmers

Terminates federal programs that support the production of tobacco. (Sections 831 and 835)

Allocates $18.623 billion ($17.348 billion in the first seven years) to compensate quota owners and tobacco producers and fund related assistance programs. (Section 101 C(2), Section 802)

Quota owners are paid $8 times the average annual quantity of quota owned during the 1997 crop year. [Total payment is spread over seven equal installments 1999-2005.] (Section 812-13)

Producers are paid $4 times the average crop during the last three years. [Total payment is spread over seven equal installments 1999-2005.] (Section 815-16)

Tobacco worker transition program administered by Secretary of Labor with benefits up to $50 million per year similar to programs under the Trade Act of 1974. (Section 816)

Farmer opportunity grants beginning at $42 million and rising to $72 million a year for college training. (Section 817)

Rural economic assistance block grants $200 million per year 1999-2005 go to tobacco growing states. (Section 821)

Cost

Participating manufacturers make licensing payments totaling $408,337,500,000 over 25 years. (Section 102)

Payments are increased by the greater of 3% or the CPI. (Section 102 C)

From year one forward, payments may increase based on total volume, but may only decrease based on reductions in adult volumes, such decrease to be adjusted by 25% of any increase in profits.

Approximately one-half of funds paid shall be paid into a state account and one-half into a federal account, less amounts available for tobacco transition, Native Americans and asbestos-related injuries.

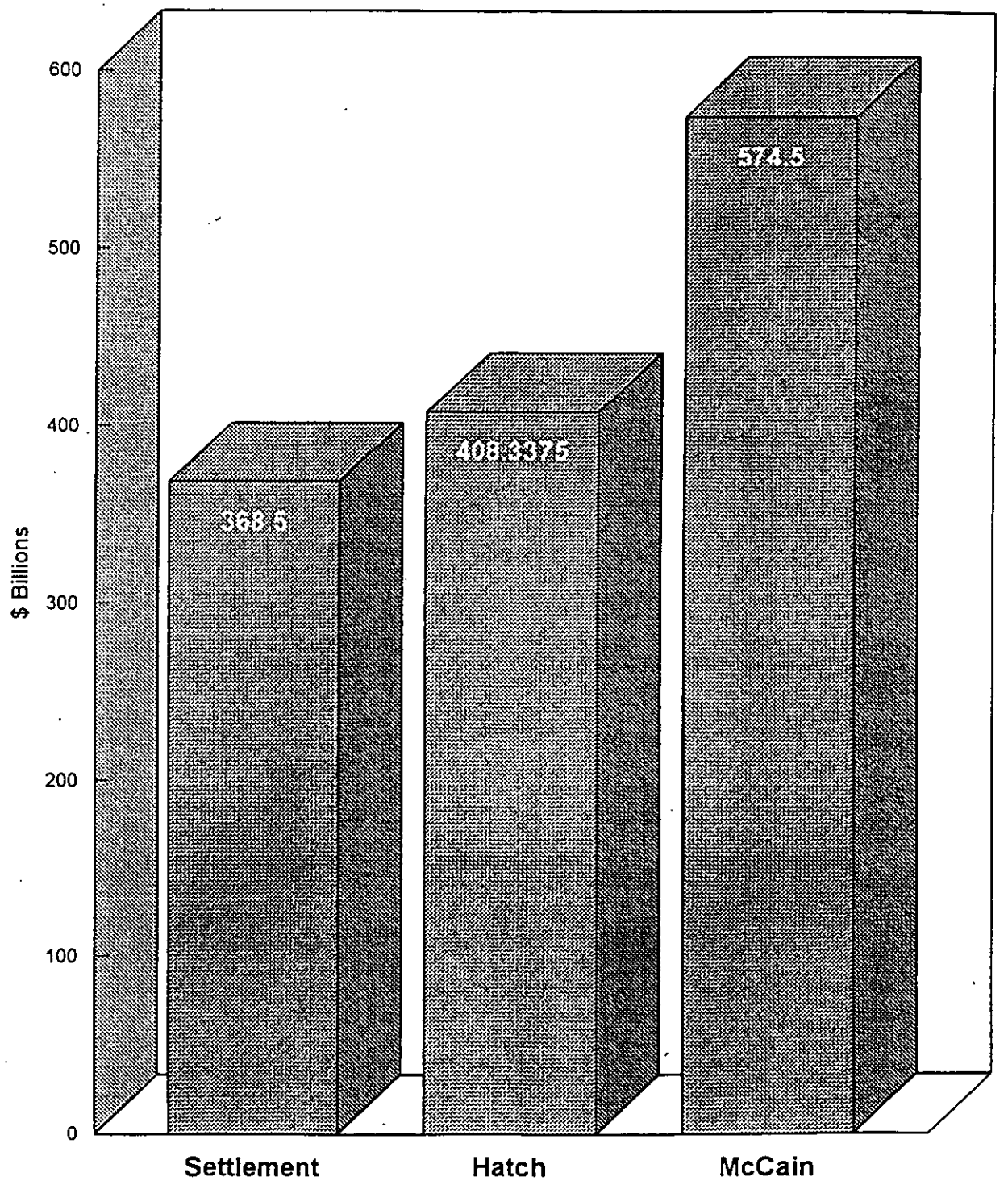
Funds allocated as follows (Section 101):

In billions of dollars

Year	States	Public Health	Research	Asbestos	Agri-culture	Native Ameri-cans	Law En-force-ment
1st	3.97	1.1	2.15	0	2.476	0.2	0.325
2nd	4.47	1.6	2.15	0.2	2.476	0.2	0.325
3rd	5.47	2.2	2.55	0.2	2.476	0.2	0.325
4th	7.72	3.3	3.7	0.2	2.476	0.2	0.325
5th	8.22	3.5	4.0	0.2	2.476	0.2	0.325
6th	8.72	4.0	4.0	0.2	2.484	0.2	0.325
7th	8.72	4.0	4.0	0.2	2.484	0.2	0.325
8th	8.72	4.0	4.0	0.2	0.100	0.2	0.325
9th	8.72	4.0	4.0	0.2	0.100	0.2	0.325
10th	8.72	4.0	4.0	0.2	0.100	0.2	0.325
11th	8.72	4.0	4.0	0.2	0.0575	0.2	0.325
12th	8.72	4.0	4.0	0.2	0.0575	0.2	0.325
13th	8.72	4.0	4.0	0.2	0.0575	0.2	0.325
14th	8.72	4.0	4.0	0.2	0.0575	0.2	0.325
15th	8.72	4.0	4.0	0.2	0.0575	0.2	0.325
16th	8.72	4.0	4.0	0.2	0.065	0.2	0.325
17th	8.72	4.0	4.0	0.2	0.065	0.2	0.325
18th	8.72	4.0	4.0	0.2	0.065	0.2	0.325
19th	8.72	4.0	4.0	0.2	0.065	0.2	0.325
20th	8.72	4.0	4.0	0.2	0.065	0.2	0.325
21st	8.72	4.0	4.0	0.2	0.0725	0.2	0.325
22nd	8.72	4.0	4.0	0.2	0.0725	0.2	0.325
23rd	8.72	4.0	4.0	0.2	0.0725	0.2	0.325
24th	8.72	4.0	4.0	0.2	0.0725	0.2	0.325
25th	8.72	4.0	4.0	0.2	0.0725	0.2	0.325

INDUSTRY BASE PAYMENTS

Constant Business-Expense Dollars, No Volume Reductions



Floor Amendments do not change industry base payments

Chart 1

INDUSTRY BASE PAYMENTS ($ billions)

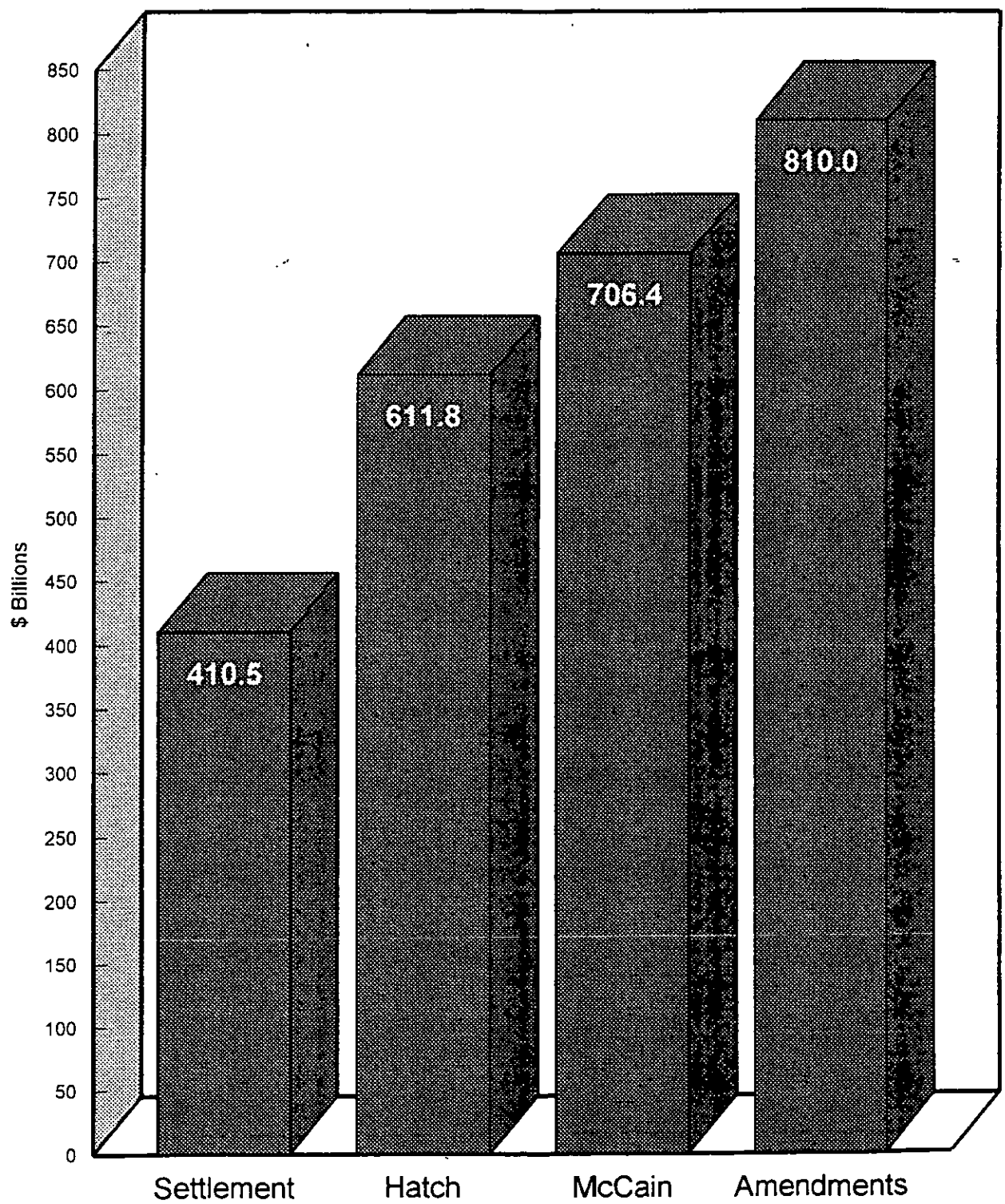
A	B	C	D
Year	Settlement	McCain	Hatch
1998	10	10	10
1999	8.5	14.4	9.7925
2000	9.5	15.4	12.9925
2001	11.5	17.7	16.0925
2002	14	21.4	14.4925
2003	15	23.6	15.4925
2004	15	23.6	16.5
2005	15	23.6	16.5
2006	15	23.6	16.5
2007	15	23.6	16.5
2008	15	23.6	16.5
2009	15	23.6	16.4575
2010	15	23.6	16.4575
2011	15	23.6	16.4575
2012	15	23.6	16.4575
2013	15	23.6	16.4575
2014	15	23.6	16.465
2015	15	23.6	16.465
2016	15	23.6	16.465
2017	15	23.6	16.465
2018	15	23.6	16.465
2019	15	23.6	16.4725
2020	15	23.6	16.4725
2021	15	23.6	16.4725
2022	15	23.6	16.4725
2023	15	23.6	16.4725

368.5	574.5	408.3375

Spreadsheet 1

BASE PAYMENTS + LOOK-BACK PENALTIES

Constant Business-Expense Dollars. No Volume Reductions



S1415 Look-Back Penalties are Not Tax Deductible

Chart 2

BASE PAYMENTS + LOOK-BACK PENALTIES ($ billions)

	A	B	C	D	E	F	G	H	I	J	K	L
	June 20 Agreement			McCain			With Floor Amendments			Hatch Feinstein		
Year	Base Payment	Look-Back	Total	Base Payment	Look-Back (Tax Adjusted)	Total	Base Payment	Look-Back (Tax Adjusted)	Total	Base Payment	Look-Back (Tax Adjusted)	Total
1998	10.0		10.0	10.0		10.0	10.0		10.0	10		10.0
1999	8.5		8.5	14.4		14.4	14.4		14.4	9.7925		9.8
2000	9.5		9.5	15.4		15.4	15.4		15.4	12.9925		13.0
2001	11.5		11.5	17.7	3.6	21.3	17.7	8.6	26.3	16.0925		16.1
2002	14.0		14.0	21.4	3.6	25.0	21.4	8.6	30.0	14.4925		14.5
2003	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	15.4925	5.5	21.0
2004	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.5	5.5	22.0
2005	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.5	5.5	22.0
2006	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.5	5.5	22.0
2007	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.5	5.5	22.0
2008	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.5	11.0	27.5
2009	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4575	11.0	27.5
2010	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4575	11.0	27.5
2011	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4575	11.0	27.5
2012	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4575	11.0	27.5
2013	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4575	11.0	27.5
2014	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.465	11.0	27.5
2015	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.465	11.0	27.5
2016	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.465	11.0	27.5
2017	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.465	11.0	27.5
2018	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.465	11.0	27.5
2019	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4725	11.0	27.5
2020	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4725	11.0	27.5
2021	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4725	11.0	27.5
2022	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4725	11.0	27.5
2023	15.0	2.0	17.0	23.6	5.9	29.5	23.6	10.4	34.0	16.4725	11.0	27.5
	368.5	42.0	410.5	574.5	131.9	706.4	574.5	235.5	810.0	408.3	203.5	611.8

Spreadsheet 2

Bruce is Right!

BASE PAYMENTS + LOOK-BACK + JUDGMENTS

Constant Business-Expense Dollars. No Volume Reductions

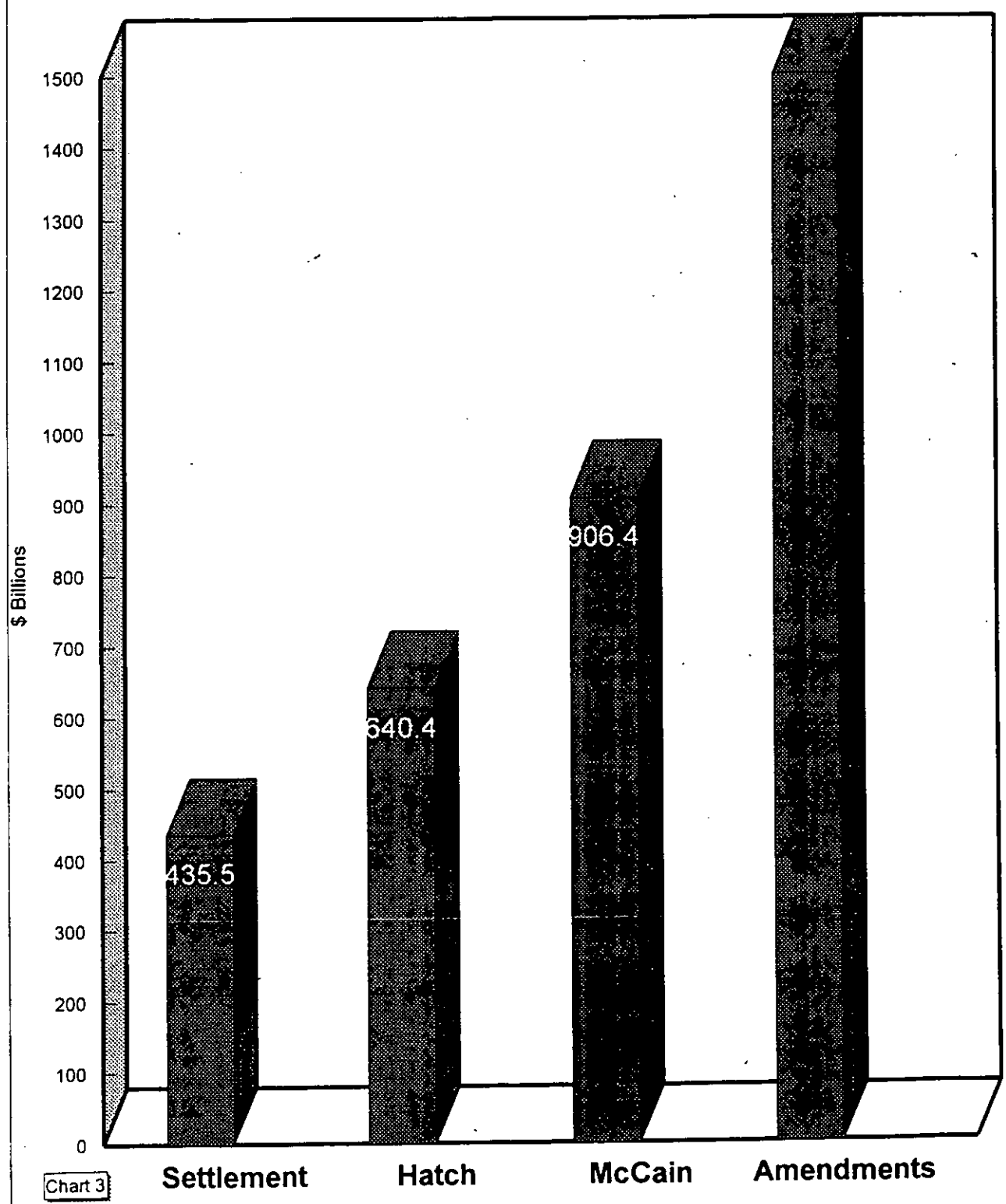


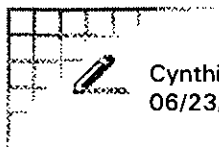
Chart 3

BASE PAYMENTS + LOOK-BACK + JUDGMENTS ($ billions)

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
	June 20 Agreement				Manager's Amendment				With Floor Amendments				Hatch Feinstein			
Year	Base Payment	Look-Back	Additional Tort Payments	Total	Base Payment	Look-Back (Tax Adjusted)	Additional Tort Payments	Total	Base Payment	Look-Back (Tax Adjusted)	Additional Tort Payments	Total	Base Payment	Look-Back (Tax Adjusted)	Additional Tort Payments	Total
1998	10.0			10.0	10.0			10.0	10.0		27.0	37.0	10		1.1	11.1
1999	8.5		1.0	9.5	14.4		8.0	22.4	14.4		27.0	41.4	9.7925		1.1	10.9
2000	9.5		1.0	10.5	15.4		8.0	23.4	15.4		27.0	42.4	12.9925		1.1	14.1
2001	11.5		1.0	12.5	17.7	3.6	8.0	29.3	17.7	8.6	27.0	53.3	16.0925		1.1	17.2
2002	14.0		1.0	15.0	21.4	3.6	8.0	33.0	21.4	8.6	27.0	57.0	14.4925		1.1	15.6
2003	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	15.4925	5.5	1.1	22.1
2004	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.5	5.5	1.1	23.1
2005	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.5	5.5	1.1	23.1
2006	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.5	5.5	1.1	23.1
2007	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.5	5.5	1.1	23.1
2008	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.5	11.0	1.1	28.6
2009	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4575	11.0	1.1	28.6
2010	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4575	11.0	1.1	28.6
2011	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4575	11.0	1.1	28.6
2012	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4575	11.0	1.1	28.6
2013	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4575	11.0	1.1	28.6
2014	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.465	11.0	1.1	28.6
2015	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.465	11.0	1.1	28.6
2016	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.465	11.0	1.1	28.6
2017	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.465	11.0	1.1	28.6
2018	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.465	11.0	1.1	28.6
2019	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4725	11.0	1.1	28.6
2020	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4725	11.0	1.1	28.6
2021	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4725	11.0	1.1	28.6
2022	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4725	11.0	1.1	28.6
2023	15.0	2.0	1.0	18.0	23.6	5.9	8.0	37.5	23.6	10.4	27.0	61.0	16.4725	11.0	1.1	28.6
	368.5	42.0	25.0	435.5	574.5	131.9	200.0	906.4	574.5	235.5	702.0	1512.0	408.3	203.5	28.6	640.4

Spreadsheet 3

Tob-ncr-new legis -
Hatch-Feinstein



Cynthia Dailard
06/23/98 06:20:56 PM

Record Type: Record

To: Cynthia A. Rice/OPD/EOP, Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:
Subject: You may have already seen this...

---------- Forwarded by Cynthia Dailard/OPD/EOP on 06/23/98 06:24 PM ----------

SHIMABUKUR_L @ A1
06/23/98 06:16:00 PM

Record Type: Record

To: Cynthia Dailard

cc:
Subject: You may have already seen this...

Date: 06/23/98 Time: 18:01
THatch, Feinstein want tobacco bill similar to states' agreement

WASHINGTON (AP) Two senators added their bill to a growing tobacco policy revival effort Tuesday, saying Congress should not waste election-year momentum by ignoring legislation that would support anti-smoking research.

``I think we'd be stupid not to grab that'' opportunity, said Judiciary Committee Chairman Orrin Hatch of Utah, who is cosponsoring the legislation with Sen. Dianne Feinstein, D-Calif.

``If this fails, then both sides deserve the blame,'' Hatch said.

The proposal was instantly panned from opposite sides of the political spectrum.

Sen. Don Nickles, R-Okla., said the bill's price tag is still too high to comport with the GOP's promise to lower taxes and shrink government.

``I don't see the Senate getting bogged down in any bill that spends hundreds of billions of dollars,'' he told reporters.

Sen. Edward Kennedy, D-Mass, one of Congress' foremost anti-smoking activists, said the bill didn't do enough to discourage kids from smoking.

``It's totally and completely inadequate,'' he said.

Feinstein acknowledged the difficulties the bill faces.

``I think there's a lot of involvement of people's egos in the issue and some don't want to see anybody else come along with any

kind of a solution," Feinstein said.

Hatch and Feinstein have not formally introduced the bill, and neither congressional leaders nor the White House have endorsed it. Still, it draws more attention to the pile of suggestions for how to revive the anti-smoking legislation that was shelved by the Senate last week.

Senate Democrats have promised to offer the rejected bill a sweeping measure sponsored by Sen. John McCain, R-Ariz. as an amendment to virtually every measure that comes to the Senate floor. A group of conservative Senate leaders are crafting a more narrow approach that would address teen smoking and drug use.

House leaders are expected this week to roll out their own bill, a measure that would fund an anti-smoking advertising campaign, limit vending machine placement and address teen drug abuse.

Hatch and Feinstein, meanwhile, said the only model that would significantly reduce teen smoking and crack down on tobacco companies is their bill, modeled on the $368 billion settlement struck last June between the industry and the dozens of states suing them.

Under the measure they described, the bill would charge tobacco companies $428 billion over 25 years, about $88 billion less than the price tag of McCain's bill.

Also unlike McCain's bill, the measure would not require tobacco companies to raise cigarette prices, mandating only that the industry make their payments on time, regardless of how the money is raised. Hatch acknowledged, however, that the industry likely would pass on that burden by raising pack prices by as much as $1.00 a pack over 10 years.

The Hatch-Feinstein bill would ban class action lawsuits against the tobacco industry and cap the damages companies could be forced to pay at $5.5 billion a year and $1 million a year per plaintiff.

Like McCain's bill, Hatch and Feinstein's measure would fund anti-smoking research, settle state lawsuits and approve new authority for the Food and Drug Administration.

The funding would provide:

-$100 billion biomedical research into addiction and smoking-related diseases, funds that could not be diverted for other purposes.

-$92 billion for public health programs such as smoking cessation and public education.

-$18.7 billion for tobacco farmers, also phasing out the price support system.

-$9.4 billion to beef up law enforcement.

-$204 billion to states to settle their lawsuits against the industry.

In addition, the tobacco companies would be fined up to $10 billion if teen smoking rates do not sufficiently drop. The bill also would establish a three-member panel to decide attorneys' fees, which tobacco companies would pay in addition to the money required by the bill.

``That's not peanuts,'' Hatch said.

APNP-06-23-98 1804EDT

Tob - sec - new legislation -
Hatch - Feinstein

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

June 25, 1998

To: **Bruce Reed, Elena Kagan**

c: Jack Lew, Sylvia Mathews, Jon Gruber

From: Joshua Gotbaum

Re: **Problems with the Hatch/Feinstein Comparison to McCain**

You asked whether Hatch's analysis comparing his bill to S. 1415 is correct. It is not.

In general, it sharply **overstates the differences between the McCain bill as amended and the Hatch proposal.**

It overstates the gross payments that manufacturers will make:

- **Ignores the effects of the volume adjustment** and the price cap agreed to by McCain, which would reduce the 25-year real payments from $516B (99$) to $408B.

- Even before taking volume adjustments into account, **they confuse real and nominal** base payment levels in their comparison "spreadsheet 1". The equivalent to $368 for AG's and $408 for Hatch is not $574, it's $516.

- With volume adjustments, we believe that CBO/JCT would estimate (if asked) 25-year real gross payments at $267 (AG), $291 (Hatch) and $408 for McCain with the manager's amendment. An effect of the volume adjustment is also to reduce the effective cost per pack. Rather than $1.10 (real 99$), we think it's closer to **66 cents per pack by 2003**.

On lookback surcharges, there are several problems with the analysis. The most significant is that it **assumes that the companies will pay the maximum lookback surcharge and that they will do so every year. We think this is extremely unlikely**. Neither we nor Joint Tax estimates that the maximum surcharge will be imposed.

It also completely ignores the fact that net receipts available to the government will be reduced by lost income and excise taxes and other offsets. As a result, it **overstates the funds that will be available under the Hatch/Feinstein proposal.**

There are literally dozens of problems with the bill as drafted (as there were with the initial versions of S. 1415). Nonetheless, it still might be worth negotiating to see if you can pick up 3 more votes.

The attached table summarizes our view of an "apples to apples" comparison between the three bills.

Comparison of the S. 1415, the AG/Company Proposal, and Hatch-Feinstein

5-year totals in billions nominal $, except where noted

	S.1415		AG/Company Proposal				Hatch/Feinstein			
			Min Civil Judgments		Max Civil Judgments		Min Civil Judgments		Max Civil Judgments	
	%	$	%	$	%	$	%	$	%	$
Estimated Net Receipts		59		40		40		46		46
Uses										
Judgments	0%	0	0%	0	33%	13	0%	0	36%	17
States	40%	24	66%	27	44%	18	42%	19	27%	12
Public Health	22%	13	25%	10	17%	7	21%	10	13%	6
Research/NIH	22%	13	9%	4	6%	2	20%	9	13%	6
Farmers	16%	9	0%	0	0%	0	17%	8	11%	5
Tax Cuts	0%	0	0%	0	0%	0	0%	0	0%	0
	100%	59	100%	40	100%	40	100%	46	100%	46
Gross Payments (Billions 99$, 25 yrs)		408		267		267		291		291
% Change from S. 1415				-35%				-29%		
Add'l Cost/Pack in 2003 (99$)		$1.10		$0.64		$0.64		$0.66		$0.66
% Change from S. 1415				-42%				-40%		

Assumptions

Receipts are based on OMB's estimate of likely CBO/JCT scoring

Judgment payments limited to 1/3 of total and are paid first (AG/Company, Hatch).

S. 1415:

Excludes Gramm, Coverdell, Lugar, and Veterans amendments

Assumes price caps rising to $1.10 per pack

AG/Tobacco Company:

Spending percentage based on Center on B&PP estimates

Hatch/Feinstein:

$46 billion is spending for the first 5 years; the 25-year stream is $408 billion

$5.5 billion liability cap per year with a liability payment credit

Spending for farmers assumes higher payments in the first five years for Lugar.

In the maximum liability case, the amount of the liability credit is included in net revenues, gross payments, and cost per pack.

INDUSTRY BASE PAYMENTS ($ billions)

A	B	C	D
Year	Settlement	McCain	Hatch
1998	10	10	10
1999	8.5	14.4	9.7925
2000	9.5	15.4	12.9925
2001	11.5	17.7	16.0925
2002	14	21.4	14.4925
2003	15	23.6	15.4925
2004	15	23.6	16.5
2005	15	23.6	16.5
2006	15	23.6	16.5
2007	15	23.6	16.5
2008	15	23.6	16.5
2009	15	23.6	16.4575
2010	15	23.6	16.4575
2011	15	23.6	16.4575
2012	15	23.6	16.4575
2013	15	23.6	16.4575
2014	15	23.6	16.465
2015	15	23.6	16.465
2016	15	23.6	16.465
2017	15	23.6	16.465
2018	15	23.6	16.465
2019	15	23.6	16.4725
2020	15	23.6	16.4725
2021	15	23.6	16.4725
2022	15	23.6	16.4725
2023	15	23.6	16.4725
	368.5	574.5	408.3375

Spreadsheet 1

516

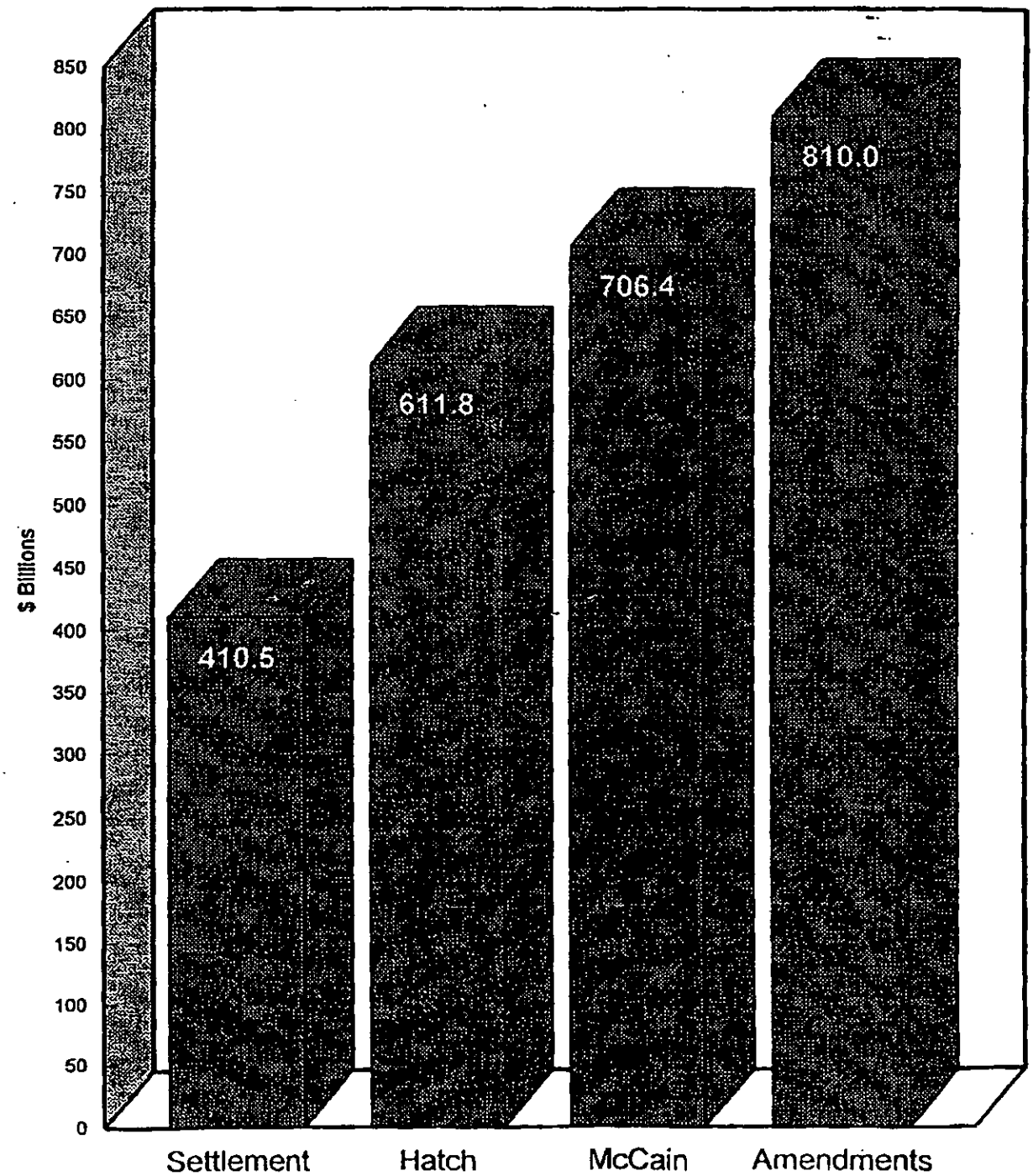
Mixes real & nominal $.

Ignores volume adjustment

Assumes maximum youth smoking charge.

BASE PAYMENTS + LOOK-BACK PENALTIES

Constant Business-Expense Dollars. No Volume Reductions



S1415 Look-Back Penalties are Not Tax Deductible
Chart 2

Tob - acr - new legislation -
Hatch-Feinstein bill

Elena Kagan
06/22/98 07:31:53 PM

Record Type: Record

To: Laura Emmett/WHO/EOP

cc:
Subject: Comparisons between S. 1415, AG's and Hatch/Feinstein

please print
---------- Forwarded by Elena Kagan/OPD/EOP on 06/22/98 07:45 PM ----------

JOSHUA
GOTBAUM
06/22/98 06:40:33 PM

Record Type: Non-Record

To: Cynthia A. Rice/OPD/EOP

cc: See the distribution list at the bottom of this message
Subject: Comparisons between S. 1415, AG's and Hatch/Feinstein

We're faxing you a table (also attached) summarizing what we now know about the financial differences.

Please note that **we really don't know what's in Hatch/Feinstein** (e.g., whether there is or is not a credit for tort fund and whether it is limited to 1/3, what the year-by-year amounts are and what the relative spending priorities are, just to name a few).

For S. 1415/AG's/Hatch, the table shows 25 year gross real payments of $408B, $267B & $303B, respectively.

The cost/pack ranges from $1.10 real to $0.64 to $0.69.

5 Yr nominal net receipts go from $59B to $40B to $47B, using our guestimated CBO scoring.

hatchtoo.xl

PRELIMINARY DRAFT

not most recent

Comparison of the S. 1415, the AG/Company Proposal, and Hatch-Feinstein

5-year totals in billions nominal $, except where noted

	S.1415		AG/Company Proposal				Hatch/Feinstein (NO DETAIL YET)			
			Min Civil Judgments		Max Civil Judgments		Min Civil Judgments		Max Civil Judgments	
	%	$	%	$	%	$	%	$	%	$
Estimated Net Receipts		59		40		40		47		47
Uses										
Judgments	0%	0	0%	0	33%	13	0%	0	33%	16
States	40%	24	66%	27	44%	18	42%	20	28%	13
Public Health	22%	13	25%	10	17%	7	19%	9	12%	6
Research/NIH	22%	13	9%	4	6%	2	20%	9	13%	6
Farmers	16%	9	0%	0	0%	0	20%	9	13%	6
Tax Cuts	0%	0	0%	0	0%	0	0%	0	0%	0
	100%	59	100%	40	100%	40	100%	47	100%	47
Gross Payments (Billions 99$, 25 yrs)		408		267		267		303		303
% Change from S. 1415				-35%		—		-26%		
Add'l Cost/Pack in 2003 (99$)		$1.10		$0.64		$0.64		$0.69		$0.69
% Change from S. 1415				-42%				-37%		

Assumptions

Receipts are based on OMB's estimate of likely CBO/JCT scoring

Judgment payments limited to 1/3 of total and are paid first (AG/Company, Hatch).

S. 1415:

Excludes Gramm, Coverdell, Lugar, and Veterans amendments

Assumes price caps rising to $1.10 per pack

AG/Tobacco Company:

Spending percentage based on Center on B&PP estimates

Hatch/Feinstein:

$47.4 billion over 5 years is based on distributing $428 billion (over 25 years) consistent with the $408 billion (over 25 years) under Hatch's original bill.

$5.5 billion liability cap per year; may or may not include a liability payment credit

Spending percentages are based on specified dollar figures in Hatch proposal materials.

Spending for farmers assumes higher payments in the first five years for Lugar.

Tob - scr - new legislation -
Hatch-Feinstein

Bruce N. Reed
06/26/98 03:56:40 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Estimated total increase in cost/pack

So Hatch is 94 cents and McCain is $1.29.

---------- Forwarded by Bruce N. Reed/OPD/EOP on 06/26/98 04:00 PM ----------

JOSHUA
GOTBAUM
06/26/98 02:29:32 PM

Record Type: Non-Record

To: Bruce N. Reed/OPD/EOP

cc: Cynthia A. Rice/OPD/EOP, Richard J. Turman/OMB/EOP
Subject: Estimated total increase in cost/pack

The figures below deal with the "peaks and valleys" problem with the lookback by using the 3-year average whose mid-point is the 10th year.

---------- Forwarded by Joshua Gotbaum/OMB/EOP on 06/26/98 02:15 PM ----------

Comparing Total Additional Cost Per Pack in Hatch & McCain in 2008

	Hatch	McCain
From base payment	.69	1.10
From surcharge*	.25	.19
total, per-pack	.94	1.29

* uses 3-year average for surcharge for both Hatch and McCain (*sans* Durbin).

Tob - scr - new Lyn —
Hatch - Feinstein bill

Cynthia A. Rice 06/21/98 02:02:19 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Laura Emmett/WHO/EOP, Cynthia Dailard/OPD/EOP

cc:

Subject: Gruber info on Hatch lookbacks

Gruber ran into one of Hatch's staffers this weekend, and got some general info on their lookback surcharges:

They have no company specific, only industry-wide, but the industry wide are fairly large (starting at $100 m per point, then $200 m, then $300 m with a cap of $5 billion in early years rising to $10 billion later). But they are all abateable, i.e., the burden of proof is on the Secretary, which they think is necessary to avoid constitutional problems.

Today, Sen. Feinstein said on CNN that they plan to release their bill next week. Bruce, did you get any more detail on their bill at your meeting?

I'll get DOJ ready to say why surcharges don't need to be abateable to be constitutional and get those revised numbers from OMB.

Tob-acc-talking points

Tobacco Q&A's
June 16, 1998

Q. What is your position on the Reed amendment to the tobacco legislation? While the amendment was adopted yesterday, I understand Senator McCain offered a motion to reconsider the amendment.

A. We do not expect another vote on this amendment. We understand that those opposed to the amendment do not believe they have the votes to defeat it. We did not take a position on it, but we view the amendment as an acceptable addition to the bill.

Q. What is your position on the Gorton amendment on attorneys fees?

A. The President's overriding priority is ensuring that tobacco legislation promotes the public health. He does not view the issue of legal fees as central to this effort, and he has not made a specific proposal on how the legislation should handle legal fees. In general, he believes that the lawyers who brought the tobacco suits should be fairly compensated, but that they should not be paid out of proportion to the work they actually did and the risks they actually undertook.

Q. What is your opinion on the Kennedy-Ashcroft amendment?

A. The Kennedy-Ashcroft amendment would make the tobacco company payments under the legislation non-deductible. As a matter of tax policy, we have real reservations about this amendment. Existing tax law allows such payments to be treated as a normal business expenses, and it violates normal tax policy principles to single out one industry, or one kind of normal business expense, for special treatment.