

NLWJC - Kagan

DPC - Box 051 - Folder-013

**Tobacco-Settlement: New
Legislation - McCain Bill:
Technicals**

Tob - ser - new legis -
McCain - tech amendments



Cynthia A. Rice

06/16/98 11:20:53 AM

Record Type: Record

To: See the distribution list at the bottom of this message
cc:
bcc:
Subject: I'm sending this file to Commerce now



amend615.wp The only change from the version you saw yesterday is a parenthetical in the description of Snowe #1, which now reads:

Directs portion of funds from lookback surcharges to cessation instead of entire public health account
(With proposed technical amendment, lookback funds in underlying bill would be earmarked for the public health account.)

Cynthia A. Rice



Cynthia A. Rice

06/15/98 04:20:30 PM

Record Type: Record

To: See the distribution list at the bottom of this message
cc:
Subject: List I plan to send to Commerce based on our amendment conversation Friday



amend615.wp Please let me know by 6:00 if you think any revision is required.

One issue I should flag for you: I have listed Snowe #1 as oppose. Our policy is that we want the lookback surcharges to go into public health -- the entire account (22% of total). The bill as currently written -- if it incorporates a technical amendment that is in Commerce's technical amendments package -- does this. The Snowe amendment is thus a narrowing amendment, which would put 20 percent of the funds into cessation only.

Currently, the section 451(b)(1) of the bill says that two types of funds go into the public health account: 1) 22 percent of the overall trust fund and 2) all the funds credited under section 401(b)(3), which in turn -- and here's where we need the technical fix -- cites section 202 of the bill.

Section 202 of the bill originally and now with the Durbin amendment, is the "purposes" section of the lookback subtitle. Commerce Committee's planned technicals would change it to section 204, which would have worked under the pre-Durbin language; now it should be 205, or I think to be safe, subtitle A of Title II, i.e., the entire lookback subtitle.

**Technical Comments on the 5/18/98
Version of McCain Bill
(May 28, 1998)**

OMB

1. **Sec. 204 -- Lookback Assessments:** As currently written, paragraph (f)(5)(A), which determines the target reduction levels for existing manufacturers is incorrect. Multiplying the current percentage reduction by the base incidence percentage would not yield the target reduction level. Revise the language as follows:

“(5) Target reduction levels._

(A) Existing manufacturers._ For purposes of this section, the target reduction level for each type of tobacco product for a year for a manufacturer is *determined by reducing the product of the required percentage reduction for a type of tobacco product for a year and the manufacturers base incidence percentage for such tobacco product: by the required percentage reduction for a type of tobacco product for a year.*”

2. **Sec. 261, Sec. 1991D (f) -- NIH Funding Trigger:** at the end of subsection (f) after the words, “prior fiscal year”, add “, exclusive of funds from the National Tobacco Trust Fund.”

“(f) Trigger . No expenditure shall be made under subsection (a) during any fiscal year in which the annual amount appropriated for the National Institutes of Health is less than the amount so appropriated for the prior fiscal year: , *exclusive of funds from the National Tobacco Trust Fund.*”

3. **Sec. 261 (1991D(a)) -- NIH Authorization of Appropriations:** this section still duplicates the authorization for appropriations in section 451(c) and therefore should be removed.

“SEC. 1991D. RESEARCH ACTIVITIES OF THE NATIONAL INSTITUTES OF HEALTH. “(a) ~~Funding . There are authorized to be appropriated, from amounts in the National Tobacco Settlement Trust Fund established by section 401 of the National Tobacco Policy and Youth Smoking Reduction Act.~~”

4. **Sec. 261 (1991D (b)) -- Medicaid Coverage of Outpatient Smoking Cessation:** Replace the reference to the Public Health Service Act with the Social Security Act. It is not clear why this Medicaid language is included in the section authorizing research activities at NIH.

“(b) Medicaid Coverage of Outpatient Smoking Cessation Agents._ Paragraph (2) of section 1927(d) of the ~~Public Health Service~~ *Social Security Act* (42 U.S.C. 1396r-8(d)) is amended_

5. **Sec. 401 (c) (2) -- Net Revenues in the Tobacco Trust Fund:** insert at the end of the subsection the phrase, "and other offsets".

"(c) Net Revenues._ For purposes of subsection (b), the term "net revenues" means the amount estimated by the Secretary of the Treasury based on the excess of_

(1) the amounts received in the Treasury under subsection (b), over

(2) the decrease in the taxes imposed by chapter 1 and chapter 52 of the Internal Revenue Code of 1986, ~~and other offsets~~, resulting from the amounts received under subsection (b): *and other offsets.*"

6. **Sec. 401 (d) -- Trust Fund Expenditures Technical Change:** would allow spending from the Trust Fund to be both mandatory and discretionary, by replacing "in appropriation acts" with "under this Title". In the second sentence, insert after "net revenues," as follows: "to the authorized allocation accounts under this Title," This would clarify the intent of the language.

"(d) Expenditures from the Trust Fund._ Amounts in the Trust Fund shall be available in each fiscal year, as provided ~~in appropriation Acts~~ *under this Title*. The authority to allocate net revenues as provided *to the allocation accounts under this Title* ~~in this title~~ and to obligate any amounts so allocated is contingent upon actual receipt of net revenues."

7. **Sec. 401 (e) -- Budgetary Treatment of Tobacco Trust Fund:** the budget treatment section should be revised as follows to allow receipts to be used on the discretionary side of the ledger.

(e) Budgetary Treatment._ The amount of net ~~receipts~~ *revenues* in excess of that amount which is required to offset the direct spending in this Act under section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 902) shall *not be included in any estimates of changes in direct spending and receipts under section 252 of that Act for any fiscal year. In each fiscal year, such excess amount, reduced by any amounts credited under section 451 (e) of this Act, shall be treated as offsetting collections for purposes of section 251 of that Act (2 U.S.C. 901) and shall* be available exclusively ~~to offset the~~ *for* appropriations required to fund the authorizations of appropriations in this Act (including the amendments made by this Act). ~~and the amount of such appropriations shall not be included in the estimates required under section 251 of that Act (2 U.S.C. 901).~~

8. **Sec. 401 (f) -- Interest on the Trust Fund:** Internal Revenue Code section 9602 (b) (3) should not apply here and the reference to miscellaneous receipts is inaccurate.

"(f) Administrative Provisions._ Section 9602 of the Internal Revenue Code of 1986 shall apply to the trust fund to the same extent as if it were established by subchapter A of

chapter 98 of such Code, except that, ~~for purposes of section 9602(b)(3) shall not apply. any interest or proceeds shall be covered into the Treasury as miscellaneous receipts.~~

9. **Sec. 402 (a) -- Industry Payment Date:** the language should be revised to make clear when industry payments are due:

“(3) Payment date; interest. Each tobacco product manufacturer required to make a payment under paragraph (1) of this subsection shall make such payment within 30 days after ~~the date of compliance with this Act becoming a participating manufacturer under section 1402 (a)(1) of this Act~~ and shall owe interest on such payment at the prime rate plus 10 percent per annum, as published in the Wall Street Journal on the latest publication date on or before the date of enactment of this Act, for payments made after the required payment date.”

10. **Sec. 402 (b) and (c) -- Payments by Industry:** revise the section to move the inflation adjustment into annual payments in section 402 and tighten up the estimated payments. The installments are specified as “reasonably” estimated and no less than one-third of the previous year’s liability.

“(b) Annual *Base* Payments. Each calendar year beginning after the required payment date under subsection (a)(3) the tobacco product manufacturers shall make total payments into the Fund for each calendar year in the following applicable base amounts, subject to adjustment as provided in section 403:

- (1) year 1_ \$14,400,000,000.
- (2) year 2_ \$15,400,000,000.
- (3) year 3_ \$17,700,000,000.
- (4) year 4_ \$21,400,000,000.
- (5) year 5_ \$23,600,000,000.
- (6) year 6 and thereafter_ ~~the adjusted applicable base amount under section 403~~ *amount of the annual base payment for the preceding year, prior to any adjustment as provided in section 403, increased by the greater of 3 percent or the percentage increase in the CPI from the previous year. For purposes of this subparagraph, the CPI for any calendar year is the average for the twelve months of the calendar year of the Consumer Price Index for all-urban consumers published by the Department of Labor. If any increase determined under this subparagraph is not a multiple of \$1,000, the increase shall be rounded to the nearest multiple of \$1,000.*

(c) Payment Schedule; Reconciliation._

(1) Estimated payments. Deposits toward the annual payment liability for each calendar year under subsection (d)(2) shall be made in 3 equal installments due on March 1st, on June 1st, and on August 1st of each year. Each installment shall be equal to one-third of

the *reasonably* estimated annual payment liability for that calendar year. *The minimum estimated liability shall be at least equal to the liability in the previous year.* Deposits of installments paid after the due date shall accrue interest at the prime rate plus 10 percent per annum, as published in the Wall Street Journal on the latest publication date on or before the payment date.”

11. **Sec. 402 (d) (3) (A) -- Definition of Tobacco Units:** to avoid possible gaming of the tobacco definitions and perhaps increase the size of cigarettes, we would propose weight limits. Otherwise a firm could market 15 inch long cigarettes.

“(3) Calculation of tobacco product manufacturer's share of annual payment. _ The share of the annual payment apportioned to a tobacco product manufacturer shall be equal to that manufacturer's share of adjusted units, taking into account the manufacturer's total production of such units sold in the domestic market. A tobacco product manufacturer's share of adjusted units shall be determined as follows:

(A) Units. _ A tobacco product manufacturer's number of units shall be determined by counting each _

(i) pack of 20 cigarettes, *weighing no more than three pounds per 1000*, as 1 adjusted unit;

(ii) *pack of 20 cigarettes, weighing three or more pounds per 1000, as 2 adjusted units;*

(iii) 1.2 ounces of moist snuff as 0.75 adjusted unit; and

(iii) (iv) 3 ounces of other smokeless tobacco product as 0.35 adjusted units.”

12. **Sec. 403 -- Volume Adjustment:** this is a conforming change that removes the inflation adjustment from Sec. 403 into Sec. 402. (See item #10 above)

~~ADJUSTMENTS~~ **VOLUME ADJUSTMENT:**

~~The applicable base amount under section 402(b) for a given calendar year shall be adjusted as follows in determining the annual payment for that year:~~

~~(1) Inflation adjustment. _~~

~~(A) In general. _ Beginning with the sixth calendar year after the date of enactment of this Act, the adjusted applicable base amount under section 402(b)(6) is the amount of the annual payment made for the preceding year increased by the greater of 3 percent or the annual increase in the CPI, adjusted (for calendar year 2002 and later years) by the volume adjustment under paragraph (2).~~

~~(B) CPI. For purposes of subparagraph (A), the CPI for any calendar year is the average of the Consumer Price Index for all-urban consumers published by the Department of Labor.~~

~~Ⓒ Rounding. If any increase determined under subparagraph (A) is not a multiple of \$1,000, the increase shall be rounded to the nearest multiple of \$1,000.~~

~~(2) Volume adjustment. Beginning with calendar year 2002, the applicable base amount (as adjusted for inflation under paragraph (1)) shall be adjusted for changes in volume of domestic sales by multiplying the applicable base amount by the ratio of the actual volume for the calendar year to the base volume. For purposes of this paragraph, the term "base volume" means 80 percent of the number of units of taxable domestic removals and taxed imports of cigarettes in calendar year 1997, as reported to the Secretary of the Treasury. For purposes of this subsection, the term "actual volume" means the number of adjusted units as defined in section 402(d)(3)(A).~~

13. Sec. 451 (a)(1) -- State Litigation Settlement Account: To improve clarity, revise the last sentence of the subparagraph (1) to read as follows:

"If after 10 years, the estimated 25-year total amount projected to be received in this account is estimated to be other than ~~will be different than amount than~~ \$196,500,000,000 then ~~beginning with the eleventh year~~ the 40 percent share will be adjusted, ~~as necessary beginning the eleventh year,~~ to a percentage not in excess of 50 percent and not less than 30 percent, **estimated at that time** to achieve the 25-year total amount."

14. Sec. 451 (a) (4) -- State Use of Funds: The current language indicates that the States "may use amounts under this subsection as the State determines appropriate, consistent with other provisions in this Act." Please strike "as the State determines appropriate," since specified uses of State funds (including unrestricted funds) are listed elsewhere in the bill.

~~"(4) Use of funds . A State may use amounts received under this subsection as the State determines appropriate, consistent with the other provisions of this Act."~~

15. Sec. 451 (b)(2) and 451 (c)(2) -- Cancer Clinical Trials: confirms that spending within the Public Health and Research accounts for Cancer Clinical Trials is mandatory, consistent with the FY 1999 Budget.

~~"(b) Public Health Allocation Account.~~

~~(1) In general. There is established within the trust fund a separate account, to be known as the Public Health Account. Twenty-two percent of the net revenues credited to~~

the trust fund under section 401(b)(1) and all the net revenues credited to the trust fund under section 401(b)(3) shall be allocated to this account.

(2) Authorization of appropriations. _ Amounts in the Public Health Account, *with the exception of spending for section 455 which is available without further appropriation*, shall be available to the extent and only in the amounts provided in advance in appropriations Acts, to remain available until expended, only for the purposes of:"

“(c) Health and Health-related Research Allocation Account. _

(1) In general. _ There is established within the trust fund a separate account, to be known as the Health and Health-Related Research Account. Of the net revenues credited to the trust fund under section 401(b)(1), 22 percent shall be allocated to this account.

(2) Authorization of appropriations. _ Amounts in the Health and Health-Related Research Account, *with the exception of spending for section 455 which is available without further appropriation*, shall be available to the extent and in the amounts provided in advance in appropriations acts, to remain available until expended, only for the following purposes:”

16. Sec. 451 (b) (2) (C) (iv) -- International Activities: Clarifies that international tobacco prevention activities in Title XI, Subtitle A, are funded from within the Public Health Allocation Account.

(C) Education and prevention. _ Of the total amounts allocated to this account, not less than 50 percent, but not more than 65 percent are to be used to carry out_.....

(iv) international activities under ~~section 432~~ *Title XI, Subtitle A.*

17. Sec. 451 (b)(2)(D)(ii) &(iii) -- Anti-Smuggling Activities: Clarifies that ATF/Customs can be supported through appropriations and fees.

“(I) Food and Drug Administration activities.

(I) The Food and Drug Administration shall receive not less than 15 percent of the funds provided in subparagraph (D) in the first fiscal year beginning after the date of enactment of this Act, 35 percent of such funds in the second year beginning after the date of enactment, and 50 percent of such funds for each fiscal year beginning after the date of enactment, as reimbursements for the costs incurred by the Food and Drug Administration in implementing and enforcing requirements relating to tobacco products.

(II) No expenditures shall be made under subparagraph (D) during any fiscal year in which the annual amount appropriated for the Food and Drug Administration is less than the amount so appropriated for the prior fiscal year.

(ii) State retail licensing activities under section *231 and section 232* ~~251~~.

(iii) Anti-Smuggling activities under *Title XI, Subtitle B, in addition to any other amounts made available under section 1139* ~~section 1141~~.

18. **Sec. 451 (b) (2) (E), and 451(c)(2)(E) -- Funding for Cancer Clinical Trials:** Add new section (b)(2)(E) and revise language at (c)(2)(E) as follows: [text for both sections is identical]:

“Cancer Clinical Trials under section 455. Of the total amounts allocated to this account, ~~\$750,000,000~~ *\$375,000,000* shall be used *over* for the first 3 fiscal years for this purpose.

19. **Sec. 451(c)(2)(B) -- NIH Authorization:** Revise the funding allocation ranges as shown below:

“(B) National Institutes of Health Research under section 1991D of the Public Health Service Act, as added by this Act. Of the total amounts allocated to this account, not less than ~~75~~ *79* percent, but not more than ~~87~~ *87* percent shall be used for this purpose.”

20. **Sec. 451 (c)(2)(C) -- Small Cleanup Change:** delete the phrase, “authorized under sections 2803 of that Act, as so added.”

“(C) Centers for Disease Control under section 1991C of the Public Health Service Act, as added by this Act, and Agency for Health Care Policy and Research under section 1991E of the Public Health Service Act, as added by this Act. ~~authorized under sections 2803 of that Act, as so added.~~ Of the total amounts allocated to this account, not less than 12 percent, but not more than 18 percent shall be used for this purpose.”

21. **Sec. 451 (c)(2)(D) -- Delete Floor on NSF Research:** revise paragraph (D) as follows:

“(D) National Science Foundation Research under section 454. ~~Of the total amounts allocated to this account, not less than 1 percent, but not more than 1 percent shall be used for this purpose.~~”

22. **Sec. 455 (c)(1) and (c)(2) -- Clinical Trial Program:** insert word changes to clarify these sub-sections.

“(c) Approved Clinical Trial Program. _

(1) In general. _ For purposes of this section, the term “approved clinical trial program” means a clinical trial program which is *sponsored by* _ *(in order of coverage by funding)*

~~(A)~~(C) the National Institutes of Health;

(B) a National Institutes of Health *supported* cooperative group or a National Institutes of Health *supported* center; ~~and or~~

⊙ (A) the National Cancer Institute,

with respect to programs that oversee and coordinate extramural clinical cancer research, trials sponsored by such Institute and conducted at designated cancer centers, clinical trials, and Institute grants that support clinical investigators.

(2) Modifications in approved trials. _ Beginning 1 year after the date of enactment of this Act, the Secretary, in consultation with the *National* Cancer Policy Board of the Institute of Medicine, may modify or add to the requirements of paragraph (1) with respect to an approved clinical trial program.”

23. **Sec. 1139 -- Anti-Smuggling Fees:** revise to ensure that collection and spending of these fees are subject to appropriations.

“SEC. 1139. FUNDING.

(a) License Fees. _ The Secretary may, in the Secretary's sole discretion, set the fees for licenses required by this chapter, in such amounts as are necessary to recover the costs of administering the provisions of this chapter, including preventing trafficking in contraband tobacco products.

(b) Disposition of Fees. _ Fees collected by the Secretary under this chapter shall be deposited in an account with the Treasury of the United States that is specially designated for paying the costs associated with the administration or enforcement of this chapter or any other Federal law relating to the unlawful trafficking of tobacco products. *To the extent provided in advance in appropriations acts*, the Secretary is authorized and directed to pay out of any funds available in such account any expenses incurred by the Federal Government in administering and enforcing this chapter or any other Federal law relating to the unlawful trafficking in tobacco products (including expenses incurred for the salaries and expenses of individuals employed to provide such services). None of the funds deposited into such account shall be available for any purpose other than making payments authorized under the preceding sentence.”

(c) Collection and Spending Subject to Appropriations: To the extent and in the amounts provided in advance in appropriations acts, the fees authorized by this chapter shall be collected in each fiscal year and shall be available for purposes of this chapter.

24. **Sec. 1162 (b) -- Tobacco Vending Machines:** these changes clarify the discretionary nature of this authorization.

“Sec. 1162 (b) Compensation for Banned Vending Machines . _

(1) In general . _ The owners and operators of tobacco vending machines *are authorized to shall* be reimbursed, subject to the availability of appropriations under subsection (d), for the fair market value of their tobacco vending machines.”

“(b) (4) Compensation Fund . _

(A) Rules for disbursement of funds . _

(I) Payments to owners and operators . *Any funds appropriated to the corporation under subsection (d) may be disbursed by the corporation* ~~The Corporation shall disburse funds~~ to compensate the owners and operators of tobacco vending machines in accordance with the following:”

“(b) (4) © Return of account funds not distributed to vendors . _ The Corporation shall be dissolved on the date that is 4 years after the date of enactment of this Act. ~~Any funds not dispersed or allocated to claims pending as of that date shall be transferred to a public anti-smoking trust, or used for such other purposes as Congress may designate.~~”

25. Sec. 1161 (a) and 1162 (d) -- Child Care and Vending Machine Authorization of Appropriations: authorizations for appropriations from the Trust Fund should be removed because they can be funded through the appropriations process, but the appropriations should not come from the Trust Fund.

“SEC. 1161. IMPROVING CHILD CARE AND EARLY CHILDHOOD DEVELOPMENT.

(a) In General. _ There are authorized to be appropriated ~~to the Secretary from the National Tobacco Trust Fund~~ such sums as may be necessary for each fiscal year to be used by the Secretary for the following purposes:”

Section 1162 - -

“(d) Authorization of Appropriations. _ There are authorized to be appropriated to the Corporation from funds not otherwise obligated in the Treasury ~~or out of the National Tobacco Trust Fund~~, such sums as may be necessary to carry out this section.”

26. Sec. 1163 (c) -- Required Coverage for Minimum Hospital Stay: end subsection (c) after the words, “Such notice shall be in writing”. This change is needed since the particular form of notice is best determined by the DOL regulation that this new legislation mandates.

~~“(c) Notice . _A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan shall provide notice to each participant and beneficiary under such plan regarding the coverage required by this section in accordance with regulations promulgated by the Secretary. Such notice shall be in writing. and prominently positioned in any literature or correspondence made available or distributed by the plan or issuer and shall be transmitted_~~

~~“(1) in the next mailing made by the plan or issuer to the participant or beneficiary;~~

~~“(2) as part of any yearly informational packet sent to the participant or beneficiary; or~~

~~“(3) not later than January 1, 1998;~~

~~whichever is earlier.~~

27. Other Minor Fixes:

(A) Minor edits are also included in the following sections. The sections affected are: 261 (1981A(c)(2)), 406, 452 (a), 452 (e)(1), and 1163 (b)(3).

- Section 261 (1981A(c)(2))--

~~“(2) Federal grantees . _From amounts available under section 1981(b)(2), the Secretary may make grants, or supplement existing grants, to entities eligible for funds under the programs described in section 1981C(d)(c)(1) and (10) to enable such entities to carry out smoking cessation activities under this subpart, except not less than 25 percent of this amount shall be used for the program described in 1981C(d)(c)(6).” [It appears the intent was to have the section 1981C© cited here.]~~

- Section 406 --

~~“SEC. 406. ENFORCEMENT FOR NONPAYMENT.~~

~~(a) Penalty . _Any tobacco product manufacturer that fails to make any payment required under section 402 or 404 within 60 days after the date on which such fee is due is liable for a civil penalty computed on the unpaid balance at a rate of prime plus 10 percent per annum, as published in the Wall Street Journal on the latest publication date on or before the payment date, during the period the payment remains unmade.~~

~~(b) Noncompliance Period . _For purposes of this section, the term “noncompliance period” means, with respect to any failure to make a payment required under section 402 or 404, the period_”~~

- Section 452 (a) --

“SEC. 452. GRANTS TO STATES.

(a) Amounts. From the amount made available under section ~~402(a)~~ **452(a)** for each fiscal year, each State shall receive a grant on a quarterly basis according to a formula.”

- Sect. 452(d) -- Technical change that would not lock in the 1998 matching requirements over the 25 year period.

“(d) Federal-State Match Rates. ~~Current (1998)~~ Matching requirements, **as provided in the relevant underlying statutes that authorize the programs cited in subsection (b)(2)**, shall apply to each program listed under subsection (b)(2), except for the program described under subsection (b)(2)(B). For the program described under subsection (b)(2)(B), after an individual State has expended resources sufficient to receive its full Federal amount under section 418(a)(2)(B) of the Social Security Act (subject to the matching requirements in section 418(a)(2)(C) of such Act), the Federal share of expenditures shall be 80 percent.”

- Section 452 (e)(1)

“(e) Maintenance of Effort. To receive funds under this subsection, States must demonstrate a maintenance of effort. This maintenance of effort is defined as the sum of

(1) an amount equal to 95 percent of Federal fiscal year 1997 State spending on the programs under subsections (b)(2)(~~B~~)(A), ~~(e)(B)~~, and ~~(e)(C)~~; and”

- Sec. 1163 (b) (3) - -

“(b) Reconstructive Surgery. A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits with respect to a mastectomy shall ensure that, in a case in which a mastectomy patient elects breast reconstruction, coverage is provided for

“(1) all stages of reconstruction of the breast on which the mastectomy has been performed;

“(2) surgery and reconstruction of the other breast to produce a symmetrical appearance; and

“(3) the costs of prostheses and complications of mastectomy including lymphedemas;

in the manner determined by the attending physician and the patient to be *medically* appropriate. Such coverage may be subject to annual deductibles and coinsurance provisions as may be deemed appropriate and as are consistent with those established for other benefits under the plan or coverage. Written notice of the availability of such coverage shall be delivered to the participant upon enrollment as part of the summary plan description of section 102 (b). ~~and annually thereafter.~~

■ Sec. 1163 (g)--

`(g) Preemption, Relation to State Laws . _

``(1) In general . _Nothing in this section shall be construed to preempt any State law in effect on the date of enactment of this section with respect to health insurance coverage that _

``(A) such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a mastectomy performed for treatment of breast cancer and at least a 24-hour hospital length of stay following a lymph node dissection of breast cancer;

``(B) requires coverage of at least the coverage of reconstructive breast surgery otherwise required under this section; or

``(C) requires coverage for breast cancer treatments (including breast reconstruction) in accordance with scientific evidence-based practices or guidelines recommended by established medical associations.”

[Note: In the section dealing with ERISA and the pre-emption of State laws above, there may be a drafting error since “(g)(1)(C)” appears to allow state laws for scientifically-based practice guidelines to prevail. This should be checked. The drafter may have omitted a provision like “(g)(2)(B)” except referring to “(1)(C)” instead of (1)(B)].

ATF

28. Section 1131(b)(5) should read as follows: “The term “retailer” includes any duty free store that sells, offers for sale, or otherwise distributes at retail in any single transaction 30 or less packages *of cigarettes* or ~~it~~ *the* equivalent for other tobacco products *as the Secretary shall by regulation prescribe.*

29. Section 1131(b)(6): replace “its” with “the”.

30. Section 1131(b)(9) should read “...except that such term shall not include a person who manufactures less than 30,000 cigarettes, or ~~its~~ *the* equivalent *for other tobacco products as the Secretary shall by regulation prescribe*, in any twelve month period; ; and the term “licensed manufacturer” means any such person licensed under the provisions of this subtitle. ~~except that such term shall not include a person who produces cigars, cigarettes, smokeless tobacco, or pipe tobacco solely for his own personal consumption or use.~~
31. Section 1134(d)(3)(B): replace “violation” with “violations”.
32. Section 1134(e)(1): replace “chapter” with “subtitle”
33. Section 1134(g)(5): should read: “...any record or report that he is required to *be kept pursuant to this chapter subtitle* or the regulations promulgated thereunder.”
34. Section 1138(a)(2): replace “any” with “sufficient”.
35. Section 1138(a)(5) should read:
- (5) by adding at the end of the following:
- “(6) the term ‘tobacco product’ means cigars, ~~cigarettes~~, smokeless tobacco, roll your own and pipe tobacco (as such terms are defined in section 5701 of the Internal Revenue Code of 1986); and
- “(7) the term ‘contraband tobacco product’ means-
- ~~“(A) a quantity in excess of 30,000 of any tobacco product that is manufactured, sold, shipped, delivered, transferred, or possessed in violation of Federal laws relating to the distribution of tobacco products.~~
- ~~“(B) a quantity of~~
36. Section 1138(a)(5): (7) should read “if the person in possession of the tobacco product is unable to provide *any sufficient* evidence....”
37. Section 1138(b)(2): in (c)(2) strike “knowingly to fail or” and “distribution”.
38. Section 1138(d)(6): in (c)(1)(A) replace “for” with “forth”; replace “persons” with “person’s” both times it appears in paragraph.
39. Section 1138(e)(3): strike existing (d) and replace amendment with: “(d) any proceeds and any property, real or personal, that constitutes or is derived from or is traceable to the unlawful distribution of tobacco shall be subject to seizure and forfeiture under section 981(a)(1)(C) of title 18, United States Code.
40. Section 1139(a) should read: “The Secretary may, in the Secretary’s sole discretion, set the fees for licenses required by this *chapter subtitle*, in such amounts as are necessary to re-

cover the costs *incurred by the Treasury Department* of administering *and enforcing* the provisions of this chapter, including preventing trafficking in contraband tobacco products. *subtitle, or any other Federal law relating to the unlawful trafficking of tobacco products.*

41. Section 1139(b): strike all references to "chapter" and replace with "subtitle"; strike "Federal Government" and replace with "Treasury Department."
42. Section 1140: strike "chapter" and replace with "subtitle".

DOJ

43. Section 6(14) -- Definition of Secretary
The definition should read "Except as in Title XIV . . ." (not Title VII)
44. Section 101
In Section 906(d)(1), substitute "potential" for "potentiality"
45. Section 202
Last line should read "and by providing support . . ."
46. Section 204(b)
8th line should say "for the industry as a whole and for particular manufacturers."
47. Section 204(d)(2)
The last phrase might be less confusing if it said "is such that the 95-percent confidence interval around such point estimates is no more than plus or minus 1 percentage point."
48. Section 204(f)
The references to subsections (b) and © should be revised to make clear that the cited provisions appear in section 203, not 204.
49. Section 261 -- Tobacco Use Prevention and Cessation Incentives
In a number of places, this section refers to the Tobacco Settlement Trust Fund. The name of this Fund was changed to the "National Tobacco Trust Fund." These references are in amended Sections 1981, 1991, and 1991D.
50. Section 261 -- Amended Section 1981©
In amended Section 1981C(b)(1)(H), there is a horrible typo -- "undeserved" should be "underserved."
51. Section 401 -- Establishment of Trust Fund

In Section 401(b)(3), the word "penalties" should be deleted and replaced by "assessments." This is a reference to the lookback surcharges.

52. Section 402(b) -- Annual Payments

As drafted the payment schedule for the annual payment is tied to the date of the upfront payment. Because the latter payment is consensual, this no longer makes sense for non-participating manufacturers. To fix this, the first sentence should be changed to "Each calendar year beginning after the year of enactment of this Act, the tobacco product manufacturers shall"

53. Section 406 -- Enforcement for Non-Payment

Sections (a) and (b) refer to failure to make payments under Sections 402 and 404. Section 404 no longer contains required payments, and thus should be deleted in both subsections.

54. Section 451 -- Allocation Accounts

It was my understanding that it was agreed that the various accounts were not to be referred to as "Litigation Settlement" accounts, and that the payments were not to be referred to as settlement payments. Leaving this vague gives us more flexibility in defending against a constitutional challenge. The following changes are required:

- Delete "Litigation Settlement" in the Title of Section 451(a)
- Delete "Litigation Settlement" in the first sentence of Section 451(a)(1)
- Delete "settlement" in the second sentence of Section 451(a)(1)
- Delete "Litigation Settlement" in the first sentence of Section 451(a)(3)

This problems recurs in Section 603(e)(2)(A)(I) and (ii) and "Litigation Trust" should be deleted from both sections.

55. Section 603(e)(1)(A) -- Eligibility of Tribes for Grants

As drafted, the bill prohibits public health grants to tribes that are not participating tobacco product manufacturers. This means that a tribe that does not manufacturer tobacco products cannot receive public health grants. I would recommend deleting this clause in its entirety or changing the first sentence to read "For each fiscal year . . . funds, except for a tribe that is a tobacco product manufacturer, but not a participating tobacco product manufacturer pursuant to Title XIV of this Act, for the same" Because some tribes use tobacco for ceremonial use or have very small tobacco operations, I believe that the former option is far superior.

56. Section 702 -- Application/Preemption

Typo -- "an" should be "a"

57. Section 703(a) -- Rules Governing Tobacco Claims
The bill as drafted states that all issues other than the evidentiary presumptions are governed "by the law of the State or Tribe in which the tobacco claim was brought." This should read "the Federal, State, or Tribal law otherwise governing the tobacco claim." This makes clear that federal law or another state's law may control in a given case.
58. Section 801(b) -- Tobacco Company Plan
The reference to "Section 201" should be to "Section 203."
59. Section 903(b)(2)(C) -- Public Inspection of Documents
This section in advertently refers to the Depository, which is not responsible for determinations of privilege. This section should read:

The log shall not contain privileged material, attorney work product, or trade secrets and shall be made available for public inspection and review.

60. Section 903(b)(3) -- Declaration of Compliance
Delete "Depository"; insert "panel"
61. Section 903(c)(6) -- Document Categories
In subsection (6), delete "or submitted to the Depository"
62. Section 903(c)(8) -- Declaration of Compliance
Delete "into the depository"
63. Section 903(d) -- Future Documents
This section got confused in the final draft. Here is my proposed rewrite:

(d) Future Documents

(1) Disclosure Requirements. -- With respect to documents created after the date of enactment of this Act, the tobacco product manufacturers and their trade associations shall provide the documents described in subsection © as follows:

(A) One copy of all such documents (except for documents containing attorney-client privileged material, attorney work product, or trade secrets) to the Depository established under Title XIV, if such a Depository exists;

(B) One copy of the documents (except for documents containing attorney-client privileged material and attorney work product) to the Food and Drug Administration.

The numbering of the rest of the section needs to be changed to accommodate this clarification.

64. Section 904 -- Document Review
Typo -- "An" should be "Any"
65. Section 906(a)
The appellate review provision would allow "any person" to appeal from a decision by a three-judge panel upholding a claim of privilege. This probably should be changed to specify that "any person who petitioned the panel to review a claim of privilege may obtain appellate review" The current version appears to allow substitution of an entirely new party on one side of the litigation.
66. Section 906(b) -- Appeal of Panel Decision
Typo -- Delete "the" in first line
67. Section 906(e) -- Effect of Non-disclosure
Substitute "under this Title" for "by the Depository"
68. Section 1162 -- Ban on Sale Through Vending Machines
Typo in Section 1162(b)(2)(A) -- "Reimburment" should be "Reimbursement"
69. Section 1402 -- Participating Tobacco Product Manufacturer
Typo in Section 1402(a)(2) -- "products" should be "product"
70. 1402(b)(1)(A) -- add a new subsection (v): "(v) violating, or aiding and abetting the violation of, any of the prohibitions specified in Title XI of this Act."
71. Section 1403 -- Protocol
Section 1403(b)(7) attempts to ensure that participating manufacturers will comply with both industry-wide and manufacturer-specific lookback assessments; it is, however, a little ambiguous. The phrase "that require manufacturers to make look-back assessments" should be replaced with "that require payment of look-back assessments."
72. Section 1403 -- Protocol
Section 1403(b)(8)(C) refers to "trade secret exclusions." It should be "trade secret protection."
73. Proposed Bankruptcy Language for Title II and IV or for Title XI:
Any obligation, interest, or debt of a tobacco product manufacturer arising under [this Title] [under this Act] shall be given priority and shall not be rejected, avoided discharged, or otherwise modified or diminished in a proceeding, under Title 11, United States Code, or any liquidation, reorganization, receivership, or other insolvency

proceeding under State law. A trustee or receiver in any proceeding under Title 11, United States Code, or any liquidation, reorganization, receivership, or other insolvency proceeding under State law, may avoid any transfer of an interest of the tobacco product manufacturer, or any obligation incurred by such manufacturer, that was made or incurred on or within 2 years before the date of the filing of a bankruptcy petition, if such manufacturer made such transfer or incurred such obligation to hinder or defeat in any fashion the payment of any obligation, interest, or debt of the manufacturer arising [under this Title] [under this Act}. Any property vesting in the manufacturer following such a proceeding shall be subject to all claims and interest of creditors arising [under this Title] [under this Act].

CDC

74. Section 204(f)(7):

This de minimis rule ignores the definition in 204(f)(4). 204(f)(7) should read: "...as the usual products smoked or used for such year *in the annual survey* is less than ~~1~~ percent *or equal to the de minimis level as defined in subsection 204(f)(4)*."

75. Title II, Sec. 1981A

Allotment (c)(2) [It begins "It is difficult to determine..."] contains references that do not exist. Suggested change: The paragraph should read--

"(2) Federal grantees. From amounts available under section 1981(b)(2), the Secretary may make grants, or supplement existing grants, to entities eligible for funds under the programs described in section 1981C(c)(1) through (10) to enable such entities to carry out smoking cessation activities under this subpart, except not less than 25 percent of this amount shall be used for the program described in 1981C(c)(6)."

76. Title II, Sec. 204(f)(6)(C)

The bill's reference to an "actual percentage" could be read to suggest the necessity of undertaking an extensive, census-like survey rather than using representative samples in determining brand-specific youth smoking prevalence. This reading would provide an impediment to implementing the lookback provisions of the bill. Suggested changes: Clarify this section by striking "actual percentage" and inserting "percent" before "prevalence" and inserting "in such statistically representative survey" following "percent prevalence of young individuals."

77. Title II, Sec. 221, Part D

Section 1981C9(d)(2) of the bill describes an appropriate goal (as a standard for funding); but as drafted it may be unattainable or infeasible. Suggested changes: amend to read: "(2) fund educational, recreational, or health activities not, *to the maximum extent practicable, based on scientific evidence of efficacy.*"

78. Title II, Section 1982
The paragraph describing the Secretary's authority to award grants (1982(b)(5)) has been inadvertently placed in the wrong subsection. Suggested changes: Move 1982(b)(5) to subsection 1982(c).
79. Title II, Section 1982(g)(1)
Reference to subsection (h) is erroneous (correct reference not apparent). Furthermore, subsection (h) may be unnecessary, as it appears to duplicate the broader and appropriately-drafted trigger that appears in Sec. 1991(2).
80. Title II, Section 1982(c)(1)(B)(I)(II) and (III)
This section of the bill is ambiguously drafted and may not achieve its intent to properly describe the universe of qualified grantees. Suggested changes: Clarify entities eligible to receive funding by changing language to read: "(II) has a demonstrated record of working effectively to reduce tobacco product use; and (III) has a demonstrated record of expertise in conducting national multi-media communications campaigns in other areas of public health which require behavior change. Also, for clarity, place the prohibition on funding entities doing tobacco industry related work in separate clause.
81. Title IV, Sec. 401 Location of the penalty provisions--replace "202" with "204"
82. Title V, Sec. 451 Location of prevention activities--replace "223" with "1981C."
83. Title XI, Subtitle A, Sec. 1107(a)(3)
Typo. Insert the word "tobacco" as follows: "...appropriate governmental *tobacco* control activities.."

NIH

84. Section 251, 1991D: - *Research Activities of the National Institutes of Health*

"(c) Guaranteed Minimum"

As amended, it no longer makes sense for this paragraph to continue to be entitled "guaranteed minimum." The paragraph does not include a minimum amount that must be spent on behavioral research. Suggested change: Make the title "(c) Behavioral and Other Research"

FDA

85. Section 903: There appears to have been a technical problem that jumbled the subsections. The following changes should be made:

- current (d)(1) and (d)(2) should be moved to page 130 and inserted after current (c)(7) as (c)(8) and (c)(9) respectively.
- current (c)(8),(9),(10) should be renumbered as (c)(10), (11), (12).
- current (c)(10) should be renumbered as (c)(12): strike “title” insert “Act”.
- (d)(1): strike “and”.
- (d)(2): insert “;” at the end.
- current (d)(3), (4) are encompassed within © and can be deleted.
- (d)(5) should be renumbered as (3) and “provide” should be inserted at the beginning; strike the period at the end and insert “; and”.
- (d)(6) should be renumbered as (4) and “provide” should be inserted at the beginning.

Tob-set -
 new legislation -
 McCain. -
 technicals

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

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

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

PRESERVATION PHOTOCOPY

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

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

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

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

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

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

PRESERVATION PHOTOCOPY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

| Type of Change | Bill Title | Section Number | Page Number | Description of Issue | Proposed Change | Agency |
|----------------|------------|----------------|-------------|--|---|--------------|
| Technical | II | 202 | 104-105 | Requires use of University of Michigan "Monitoring the Future" survey (or survey with same methodology) to measure underage tobacco use. | <p>Strike 202(a) and insert: "Determination of Underage Use. – The Secretary shall conduct an annual performance survey of underage tobacco use; such survey shall comply with the following requirements:</p> <ul style="list-style-type: none"> ▶ be based on a nationally representative sample of at least 20,000 completed interviews of young individuals to assure sufficient survey precision. ▶ be a household-based, in person survey. ▶ measure use of each type of tobacco product within the past 30 days. ▶ identify usual brand of each type of tobacco product used within the past 30 days. ▶ permit the calculation of the actual percentage reductions in underage use of a type of tobacco product (or, in the case of the manufacturer-specific surcharge, the use of a type of tobacco product of a manufacturer) based on the point estimates of the percentage of young individuals reporting use of a type of tobacco product (or, in the case of the manufacturer-specific surcharge, the use of a type of tobacco product of a manufacturer) from the annual | ASPE/ HHS |

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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