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Tobacco-Settlement: New Legislation-Conrad Bill [3]

Tob-acc - new initiative - Conrad bill

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United States Senate

WASHINGTON, DC 20510-3403

October 29, 1997

The Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Ave SW
Washington, DC 20201-0004

Bruce Reed
Assistant to the President for Domestic Policy
The White House
Washington, DC 20500

Dear Secretary Shalala and Mr. Reed:

I am writing to thank you for briefing the Senate Democratic Task Force on Tobacco during the course of the Administration's review of the proposed tobacco settlement, and to seek your further assistance as the task force moves forward to draft comprehensive tobacco legislation.

As I have said, I believe the President was right to focus on youth smoking. If we are to be reasonably confident that comprehensive tobacco legislation will result in significant declines in youth smoking rates, it is essential that the task force better understand the effects of price increases and penalties on youth smoking, and the overall economic effects of such changes. The task force has heard a great deal of sometimes conflicting information on these points. In order to help clarify this set of issues, it would be most helpful if you could provide me with your analysis on the following issues:

1. The President has called for an increase in tobacco prices of $1.50 in a combination of price increases and penalties. The tobacco industry argues that a number of exogenous factors, including inflation, should be counted in determining the size of the price increase. However, most economists believe that only real price increases, not nominal price increases, should be included in this calculation. As the Administration analyzes the effects of price increases on tobacco consumption, the incidence of smoking, and the profitability of the tobacco industry and other industries in the tobacco supply chain, which price increases are relevant to the analysis? In particular, should inflation or exogenous price increases (for example, the ongoing trend of increased state and local sales and excise taxes) be taken into account, or should only those price increases directly attributable to the proposed settlement or comprehensive legislation be considered?

2. What are the implications of different levels of price increases on tobacco consumption, adult smoking rates, youth smoking rates, tobacco industry profitability and share prices, tobacco

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farmer profitability, tobacco wholesalers and retailers, and state and local tax revenues? For example, what would be the effects of the proposed settlement? What would be the effects of a 75 cent per pack increase? $1.00 per pack? $1.25 per pack? $1.50 per pack? $1.75 per pack? $2.00 per pack? $3.00 per pack?

3. Some analysts suggest that sudden, dramatic price increases have a greater effect on smoking rates than a series of smaller price increases. How is the above analysis affected by the timing of the price increases?

4. The proposed settlement envisions companies paying per pack amounts into a settlement fund, and covering these payments through an increase in the price of tobacco products. The settlement contains an anti-trust exemption, in part to ensure that companies raise prices in concert. Others have suggested that the price increase should be effectuated through an increase in the Federal excise tax or through a public health user fee imposed on a per pack basis. What are the pros and cons of these three approaches?

5. If price were the only factor affecting smoking rates, how big a price increase would be required to achieve the youth smoking targets called for in the settlement? How much "credit" should be given for the non-price policy changes proposed in the settlement?

6. How big a price increase would be required to offset the costs of smoking-related illnesses to the Federal government (including Medicare, Medicaid, veterans benefits, CHAMPUS and FEHBP) over the next 25 years?

7. The President called for a $1.50 per pack increase in cigarette prices in a combination of price increases and penalties for missing the youth smoking targets. What are the implications for cigarette consumption, smoking rates, industry profitability, farmers, retailers and wholesalers of different combinations of price increases and penalties? For example, how do the effects of a $1.00 price increase and a 50 cent penalty differ from the effects of a 50 cent price increase and a $1.00 penalty? What about 75 cents each? Or a $1.25 price increase and 25 cent penalties?

8. Look-back penalties for missing the youth smoking targets could be structured in several different ways. The following questions would help the task force understand the implications of some potential options for look-back penalties:

A. What are the pros and cons of imposing penalties on an industry-wide, company specific, or brand specific basis? Would some combination of these approaches make more sense, and why? If the penalties are imposed on a company or brand specific basis, is there justification for a de minimis exemption? Does this create a potential loophole?

B. What are the implications of collecting this penalty as a tax increase collected on each pack sold in the year following a year in which the youth smoking target was missed versus a one-time payment in the following year assessed on the basis of a per pack charge for each pack sold during the year in which the target was missed? If the former option were adopted, would there

be administrative difficulties with assessing different per pack taxes on different brands or computing the size of the tax in time to impose the tax at the beginning of a calendar year?

C. Penalties could be assessed as a flat fee or per pack charge that does not vary no matter how much the youth smoking target is missed, or it could be structured to ramp up steeply as the distance from the target increases. What are the pros and cons of different ways of graduating the penalty depending on the amount by which the target is missed?

Your input on these important economic questions will be most helpful to the task force.

In addition, it would be helpful if you could expand on the President's statement with respect to documents. Many members of our task force believe that the tobacco industry has abused the attorney client privilege to shield documents relating to public health, marketing to children, and the manipulation of nicotine levels. In their view, the document disclosure provisions in the proposed settlement are inadequate. However, many members of the task force are also concerned that removing this privilege might set a dangerous precedent for other situations where the attorney client privilege has been used appropriately. Do you have any suggestions for a system of disclosing important public health documents in the possession of the tobacco industry without undermining the attorney client privilege more generally?

Again, thank you for your helpful input into the task force process. I look forward to working closely with you as the task force proceeds with drafting comprehensive tobacco legislation.

Sincerely,

KENT CONRAD
United States Senate

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 Tob-ser - new legislation - Conrad bill

TITLE II—FDA JURISDICTION OVER TOBACCO PRODUCTS

SEC. 201. REFERENCE.

Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 202. NO EFFECT ON NON-TOBACCO PRODUCTS.

Nothing in this Act, the amendments made to the Federal Food, Drug and Cosmetic Act, or any regulation issued pursuant to this Act or amendments, shall be construed to affect the regulation, interpretation, or enforcement of any regulation of any product that is not a tobacco product by the Secretary under the Federal Food, Drug and Cosmetic Act.

SEC. 203. STATEMENT OF GENERAL AUTHORITY.

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

SEC. 204. TREATMENT OF TOBACCO PRODUCTS AS DRUGS AND DEVICES.

(a) DEFINITIONS.—

(1) DRUG.—Section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended by striking "; and (D)" and inserting "; (D) nicotine in tobacco products; and (E)".

(2) DEVICES.—Section 201(h) (21 U.S.C. 321(h)) is amended—

(A) in paragraph (2), by striking "or" at the end;

(B) in paragraph (3), by striking "and" at the end and inserting "or"; and

(C) by inserting after paragraph (3), the following:

"(4) a delivery component of a tobacco product; and".

(3) OTHER DEFINITIONS.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

"(kk) The term 'tobacco product' means any product made or derived from tobacco leaf made for human consumption including, but not limited to, cigarettes, cigarillos, cigarette tobacco, cigars, little cigars, pipe tobacco, and smokeless tobacco, and roll-your-own tobacco.".

(b) REGULATORY AUTHORITY.—Section 503(g) (21 U.S.C. 353(g)) is amended by adding at the end the following:

"(5) The Secretary may regulate any tobacco product as a drug, device, or both, and may designate the office of the Administration that shall be responsible for regulating such products.".

(c) DEVICES.—Section 520(e)(1) (21 U.S.C. 360j(e)(1)) is amended by striking "or use—" and inserting "or use, including restrictions on the access to, and the advertising and promotion of, tobacco products—".

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

"(u) In the case of a tobacco product, it is sold, distributed, advertised, or labeled in violation of this Act or the regulations promulgated under this Act.

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

the reduced probability that existing users of tobacco products will quit.".

(e) ENFORCEMENT.—Section 301 (42 U.S.C. 331) is amended by adding at the end the following:

"(aa) The failure to comply with the requirements of section 581.

"(bb) The failure or refusal to comply with any of the requirements of subsections (a), (b) or (e) of section 908.".

(f) STATE AND LOCAL REQUIREMENTS.—Section 521 (21 U.S.C. 360k) is amended—

(1) in subsection (a), by striking "subsection (b)" and inserting "subsections (b) and (c)"; and

(2) by adding at the end the following:

"(c) This section shall not apply to devices that are tobacco products.".

SEC. 205. RECALL AUTHORITY.

Section 518(e)(1) (21 U.S.C. 360h(e)(1)) is amended by inserting after "adverse health consequences or death," the following: "and for tobacco products that the best public health result would be achieved,".

SEC. 206. GENERAL HEALTH AND SAFETY REGULATION OF TOBACCO PRODUCTS.

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

(1) by redesignating chapter IX as chapter X;

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

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

"CHAPTER IX—TOBACCO PRODUCTS

"SEC. 901. PROMULGATION OF REGULATIONS.

"(a) IN GENERAL.—Any regulations necessary to implement this chapter shall be promulgated not later than 12 months after the date of enactment of this chapter using notice and comment rulemaking (in accordance with chapter 5 of title 5, United States Code). Such regulations may be revised thereafter as determined necessary by the Secretary.

"(b) BLACK MARKETS.—[To be supplied]

"SEC. 902. SCIENTIFIC ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this chapter, the Secretary shall establish an advisory committee, to be known as the 'Scientific Advisory Committee', to assist the Secretary.

"(b) MEMBERSHIP.—

"(1) IN GENERAL.—The Secretary shall appoint as members of the Scientific Advisory Committee any individuals with expertise in the medical, sci-

entific, or other technological data involving the manufacture and use of tobacco products, and of appropriately diversified professional backgrounds.

"(2) LIMITATIONS.—Notwithstanding section 5(b) of the Federal Advisory Committee Act (5 U.S.C. App. 3), the Secretary may not appoint to the Committee any individual who—

"(A) is in the regular full-time employ of the Federal Government;

"(B) is, or is in the employ of, a manufacturer, distributor, or retailer of a tobacco product, or organization substantially funded by manufacturers, distributors, or retailers of tobacco products;

"(C) is, or is in the employ of, an attorney representing an entity described in subparagraph (B); or

"(D) is, or is in the employ of, a consultant employed by or under retainer to an entity described in subparagraph (B).

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

"(c) COMPENSATION AND EXPENSES.—Members of the Scientific Advisory Committee shall be entitled to the

same compensation and expenses as the compensation and expenses provided to members of the advisory committees established under section 514(b)(5)(B).

"(d) DUTIES.—The Scientific Advisory Committee shall—

"(1) provide assistance to the Secretary;

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

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

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

"SEC. 903. PERFORMANCE STANDARDS AND SAFETY AND EFFICACY.

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

"(1) the reduction or elimination of nicotine yields of the product;

"(2) the reduction or elimination of other constituents or harmful components of the product; or

"(3) standards relating to any other requirement pursuant to section 512(a)(2).

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

"(c) SAFETY AND EFFICACY.—

"(1) IN GENERAL.—With respect to a device that is a tobacco product, the assurance in the 1st sentence of section 513(a)(1)(B) need not be found if the Secretary finds that special controls achieve the best public health result.

"(2) APPLICATION OF STANDARD TO TOBACCO PRODUCTS.—For purposes of section 513(a)(1)(B), subsections (c)(2)(C), (d)(2)(B), (e)(2)(A), (f)(3)(B)(i), and (f)(3)(C)(i) of section 513, and sections 514, 519(a), 520(e), and 520(f), the safety and effectiveness of a device that is a tobacco product need not be found if the Secretary finds that the action to be taken under any such provision would achieve the best public health result by reducing the overall risks to human health. The finding as to

whether the best public health result has been achieved shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

"(A) the increased or decreased likelihood that existing consumers of tobacco products will stop using such products; and

"(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

"(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed as in any way limiting or altering the safety and efficacy standard in effect under section 513 on the date of enactment of this chapter as such standard relates to drugs and devices that are not tobacco products.

"SEC. 904. DISCLOSURE AND REPORTING OF TOBACCO AND NONTOBACCO INGREDIENTS AND CONSTITUENTS.

"(a) DISCLOSURE OF ALL INGREDIENTS.—

"(1) IMMEDIATE AND ANNUAL DISCLOSURE.—Not later than 30 days after the date of enactment of this chapter, and annually thereafter, each manufacturer of a tobacco product shall submit to the

Secretary an ingredient list for each brand of tobacco product it manufactures that contains the information described in paragraph (2).

"(2) REQUIREMENTS.—The list described in paragraph (1) shall, with respect to each brand or variety of tobacco product of a manufacturer, include—

"(A) a list of all ingredients, constituents, substances, and compounds that are found in or added to the tobacco or tobacco product (including the paper, filter, or packaging of the product if applicable) in the manufacture of the tobacco product, for each brand or variety of tobacco product so manufactured, including, if determined necessary by the Secretary, any material added to the tobacco used in the product prior to harvesting;

"(B) the quantity of the ingredients, constituents, substances, and compounds that are listed under subparagraph (A) in each brand or variety of tobacco product;

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

"(D) for each brand or variety of cigarettes—

"(i) the filter ventilation percentage (the level of air dilution in the cigarette as provided by the ventilation holes in the filter, described as a percentage);

"(ii) the pH level of the smoke of the cigarette; and

"(iii) the tar, nicotine, and carbon monoxide delivery level under Federal Trade Commission parameters and any other smoking conditions established by the Secretary, reported in milligrams of tar, nicotine, and carbon monoxide per cigarette;

"(E) for each brand or variety of smokeless tobacco products—

"(i) the pH level of the tobacco;

"(ii) the moisture content of the tobacco expressed as a percentage of the weight of the tobacco; and

"(iii) the nicotine content—

"(I) for each gram of the product, measured in milligrams of nicotine;

"(II) expressed as a percentage of the dry weight of the tobacco; and

"(III) with respect to unionized (free) nicotine, expressed as a percentage per gram of the tobacco and expressed in milligrams per gram of the tobacco; and

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

"(3) METHODS.—The Secretary shall have the authority to promulgate regulations to establish the methods to be used by manufacturers in making the determinations required under paragraph (2).

"(b) SAFETY ASSESSMENTS.—

"(1) APPLICATION TO NEW INGREDIENTS.—

"(A) IN GENERAL.—Not later than 1 year after the date of enactment of this chapter, and annually thereafter, each manufacturer shall submit to the Secretary a safety assessment for each new ingredient, constituent, substance, or compound that such manufacturer desires to make a part of a tobacco product. Such new ingredient, constituent, substance, or compound shall not be included in a tobacco product prior to approval by the Secretary of such a safety assessment.

"(B) METHOD OF FILING.—A safety assessment submitted under subparagraph (A) shall be signed by an officer of the manufacturer who is acting on behalf of the manufacturer and who has the authority to bind the manufacturer, and contain a statement that ensures that the information contained in the assessment is true, complete and accurate.

"(C) DEFINITION OF NEW INGREDIENT.—For purposes of subparagraph (A), the term 'new ingredient, constituent, substance, or compound' means an ingredient, constituent substance, or compound listed under subsection (a)(1) that was not used in the brand or variety of tobacco product involved prior to January 1, 1998.

"(2) APPLICATION TO OTHER INGREDIENTS.—With respect to the application of this section to ingredients, constituents substances, or compounds listed under subsection (a) to which paragraph (1) does not apply, all such ingredients, constituents, substances, or compounds shall be reviewed through the safety assessment process within the 5-year period beginning on the date of enactment of this chapter. The Secretary shall develop a procedure for

the submission of safety assessments of such ingredients, constituents, substances, or compounds that staggers such safety assessments within the 5-year period.

"(3) BASIS OF ASSESSMENT.—The safety assessment of an ingredient, constituents, substance, or compound described in paragraphs (1) and (2) shall—

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

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

"(c) PROHIBITION.—

"(1) REGULATIONS.—Not later than 12 months after the date of enactment of this chapter, the Secretary shall promulgate regulations to prohibit the use of any ingredient, constituent, substance, or compound in the tobacco product of a manufacturer—

"(A) if no safety assessment has been submitted by the manufacturer for the ingredient, constituent, substance, or compound as otherwise required under this section; or

"(B) if the Secretary finds that the manufacturer has failed to demonstrate the safety of the ingredient, constituent, substance, or compound that was the subject of the assessment under paragraph (2).

"(2) REVIEW OF ASSESSMENTS.—

"(A) GENERAL REVIEW.—Not later than 180 days after the receipt of a safety assessment under subsection (b), the Secretary shall review the findings contained in such assessment and approve or disapprove of the safety of the ingredient, constituents, substance, or compound that was the subject of the assessment. The Secretary may, for good cause, extend the period for such review. The Secretary shall provide notice to the manufacturer of an action under this subparagraph.

"(B) INACTION BY SECRETARY.—If the Secretary fails to act with respect to an assessment of an existing ingredient, constituent, substance, or additive during the period referred to

in subparagraph (A), the manufacturer of the tobacco product involved may continue to use the ingredient, constituents, substance, or compound involved until such time as the Secretary makes a determination with respect to the assessment.

"(d) RIGHT TO KNOW; FULL DISCLOSURE OF INGREDIENTS TO THE PUBLIC.—

"(1) IN GENERAL.—Except as provided in paragraph (3), a package of a tobacco product shall disclose all ingredients, constituents, substances, or compounds contained in the product in accordance with regulations promulgated under section 701(a) by the Secretary.

"(2) DISCLOSURE OF PERCENTAGE OF DOMESTIC AND FOREIGN TOBACCO.—The regulations referred to in paragraph (1) shall require that the package of a tobacco product disclose, with respect to the tobacco contained in the product—

"(A) the percentage that is domestic tobacco; and

"(B) the percentage that is foreign tobacco.

"(3) HEALTH DISCLOSURE.—Notwithstanding section 301(j), the Secretary may require the public

disclosure of any ingredient, constituent, substance, or compound contained in a tobacco product that relates to a trade secret or other matter referred to in section 1905 of title 18, United States Code, if the Secretary determines that such disclosure will promote the public health.

"SEC. 905. TOBACCO PRODUCT WARNINGS, LABELING AND PACKAGING.

"(a) CIGARETTE WARNINGS.—

"(1) IN GENERAL.—

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

"WARNING: Cigarettes Are Addictive.

"WARNING: Tobacco Smoke Can Harm Your Children.

"WARNING: Cigarettes Cause Fatal Lung Disease.

"WARNING: Cigarettes Cause Cancer.

"WARNING: Cigarettes Cause Strokes And Heart Disease.

"WARNING: Smoking During Pregnancy Can Harm Your Baby.

"WARNING: Smoking Can Kill You.

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

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

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

"WARNING: Cigarettes Are Addictive.

"WARNING: Tobacco Smoke Can Harm Your Children.

"WARNING: Cigarettes Cause Fatal Lung Disease.

"WARNING: Cigarettes Cause Cancer.

"WARNING: Cigarettes Cause Strokes And Heart Disease.

"WARNING: Smoking During Pregnancy Can Harm Your Baby.

"WARNING: Smoking Can Kill You.

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

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

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

"(2) REQUIREMENTS FOR LABELING.—

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

"(B) TYPE AND COLOR.—With respect to each label statement required by subparagraph (A) of paragraph (1), the phrase 'WARNING' shall appear in capital letters and the label

statement shall be printed in 17 point type with adjustments as determined appropriate by the Secretary to reflect the length of the required statement. All the letters in the label shall appear in conspicuous and legible type, in contrast by typography, layout, or color with all other printed material on the package, and be printed in an alternating black-on-white and white-on-black format as determined appropriate by the Secretary.

"(C) EXCEPTION.—With respect to cigarettes manufactured and distributed prior to January 1, 2000, the provisions of subparagraph (A) shall not apply with respect to the front panel in the case of a flip-top cigarette package (offered for sale on June 1, 1997) where the front portion of the flip-top does not comprise at least 25 percent of the front panel. In the case of such a package, the label statement required by subparagraph (A) of paragraph (1) shall occupy the entire front portion of the flip-top.

"(3) REQUIREMENTS FOR ADVERTISING.—

"(A) LOCATION.—Each label statement required by subparagraph (B) of paragraph (1)

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

"(B) TYPE, COLOR AND FORMAT.—

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

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

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

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

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

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

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

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

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

Within the 20 percent requirement described in subparagraph (A), the Secretary may revise the required type sizes if the Secretary determines that such revisions will enhance public health protections.

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

"(iii) FORMAT.—The label statements under subparagraph (B) of paragraph (1) shall be black when the background is white and white when the background is black, and shall be in the point size required under this subparagraph. The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first down stroke of the capital 'W' of the word 'WARNING' in the label statements.

"(C) LANGUAGE REQUIREMENT.—The label statements required under paragraph (1)(B) shall be in English, except that—

"(i) in the case of an advertisement that appears in a newspaper, magazine, periodical or other publication that is not in English, such statements shall appear in the predominant language of the publication; or

"(ii) in the case of any other advertisement that is not in English, such statements shall appear in the same language

as that principally used in the advertisement.

"(4) ROTATION OF LABEL STATEMENTS.—

"(A) LABELING.—The label statements specified in subparagraph (A) of paragraph (1) shall be randomly displayed in each 12 month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which such product is marketed in accordance with a plan submitted by the manufacturer, importer, distributor or retailer and approved by the Secretary.

"(B) ADVERTISING.—The label statements specified in subparagraph (B) of paragraph (1) shall be rotated quarterly in alternating sequence in advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer, importer, distributor or retailer and approved by the Secretary.

"(C) APPROVAL OF PLANS.—The Secretary shall review each plan submitted by a manufacturer, importer, distributor or retailer of cigarettes under this paragraph and approve such plan if the plan will provide for the equal

distribution and display on packaging and the rotation required in advertising under this paragraph and if such plan assures that all of the labels required under subparagraphs (A) and (B) will be displayed by the manufacturer, importer, distributor or retailer at the same time.

"(b) SMOKELESS TOBACCO PRODUCTS.—

"(1) IN GENERAL.—

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

"WARNING: This Product Can Cause Mouth Cancer.

"WARNING: This Product Can Kill You.

"WARNING: This Product Can Cause Gum Disease And Tooth Loss.

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

"WARNING: This Product Contains Cancer-Causing Chemicals.

"WARNING: Smokeless Tobacco Is Addictive.

"(B) ADVERTISING.—It shall be unlawful for any manufacturer, importer, distributor or retailer of smokeless tobacco products to advertise or cause to be advertised any smokeless tobacco product unless the advertising bears, in accordance with the requirements of this subsection, one of the following labels:

"WARNING: This Product Can Cause Mouth Cancer.

"WARNING: This Product Can Kill You.

"WARNING: This Product Can Cause Gum Disease And Tooth Loss.

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

"WARNING: This Product Contains Cancer-Causing Chemicals.

"WARNING: Smokeless Tobacco Is Addictive.

"(C) ADDITIONAL WARNINGS.—Beginning on the date that is 18 months after the date of enactment of this chapter, the Secretary may substitute for, or require warnings in addition to, those otherwise required under subparagraphs (A) and (B) if the Secretary determines

that such warnings would be more effective in deterring the use of smokeless tobacco products.

"(2) REQUIREMENTS FOR LABELING.—

"(A) LOCATION.—Each label statement required by subparagraph (A) of paragraph (1) shall be located on the 2 most prominent display panels of the product and occupy not less than 25 percent of such panels.

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

"(3) ADVERTISING AND ROTATION.—The provisions of paragraph (3) and (4) of subsection (a) shall apply to advertisements for smokeless tobacco

products and the rotation of the label statements required under paragraph (1)(A) on such products.

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

"(d) CONSTRUCTION.—

"(1) IN GENERAL.—Noting in this section shall be construed to limit the ability of the Secretary to change the text or layout of any of the warning statements, or any of the labeling provisions, under subsections (a) and (b) and other provisions of this Act, if determined necessary by the Secretary in order to make such statements or labels larger, more prominent, more conspicuous, or more effective.

"(2) UNFAIR ACTS.—Nothing in this section (other than the requirements of subsections (a), (b) and (c)) shall be construed to limit or restrict the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco products.

"(e) LIMITED PREEMPTION.—

"(1) STATE AND LOCAL ACTION.—No warning label with respect to cigarettes or smokeless tobacco

products, or any other tobacco product for which warning labels have been required under this section, other than the warning labels required under this Act, shall be required by any State or local statute or regulation to be included on any package of cigarettes or a smokeless tobacco product.

"(2) EFFECT ON LIABILITY LAW.—Nothing in this section shall relieve any person from liability at common law or under State statutory law to any other person.

"(f) ELECTRONIC MEDIUM ADVERTISING.—It shall be unlawful to advertise tobacco products on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

"SEC. 906. PRESERVATION OF STATE AND LOCAL AUTHORITY.

"Except as otherwise provided for in section 905(e), nothing in this chapter shall be construed as prohibiting a State or locality from imposing requirements, prohibitions, penalties or other measures to further the purposes of this chapter that are in addition to the requirements, prohibitions, or penalties required under this chapter. State and local governments may impose additional tobacco product control measures to further restrict or limit the use of such products.

"SEC. 907. RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS.

"(a) IN GENERAL.—The Secretary shall restrict the access of minors to tobacco products.

"(b) STATE LICENSING.—

"(1) IN GENERAL.—Except as provided in paragraph (2), in order to receive any amounts under section 111 of the Healthy Kids Act, a State shall have in place a program that meets or exceeds (as determined by the Secretary) the requirements of the model State program described in paragraph (3) under which a retailer would be required to obtain a State or local license to sell or otherwise distribute tobacco products directly to consumers in such State.

"(2) START-UP PERIOD.—

"(A) IN GENERAL.—The Secretary may waive the requirement of paragraph (1) for such time as the Secretary determines is necessary, after promulgation of the model program described in paragraph (3), to permit the legislature of a State to meet and enact laws to comply with paragraph (1) and to permit the State to implement the program described in paragraph (1).

"(B) ELIGIBILITY.—To be eligible for a waiver under subparagraph (A), the Governor of the State involved shall certify to the Secretary in writing that the State intends to implement a program that meets the requirements of this section at the earliest possible opportunity. If, subsequent to such notification, the Secretary determines that the State has failed to implement such a program, the Secretary may recover any funds distributed to the State under section 111 of the Healthy Kids Act.

"(3) MODEL PROGRAM.—Not later than 12 months after the date of enactment of this chapter, the Secretary shall promulgate a model State program. Such model State program shall at a minimum—

"(A) provide for the collection of licensing fees by the State or locality to defray the costs of administering the program;

"(B) prohibit retailers from selling or otherwise distributing tobacco products directly to consumers in a State unless such retailers have in effect tobacco licenses issued or renewed in accordance with State or local laws;

"(C) provide for the notification of every person in the State who is engaged in the distribution at retail of tobacco products of the license requirement and of the date by which such person shall have obtained a license in order to continue to distribute such products;

"(D) prohibit licensed retailers from selling or otherwise distributing tobacco products to minors;

"(E) provide for penalties of up to $50,000 for each violation of the requirements under such program relating to the sale or distribution of tobacco products without a license and for appropriate penalties for other violations of laws relating to youth access to tobacco products;

"(F) require retailers to comply with the applicable requirements of this section and any regulations relating to this section; and

"(G) provide for the suspension or revocation of a license in the case of a retailer that repeatedly sells or distributes tobacco products to individuals in violation of subsection (a) or State or local law.

"(c) PENALTIES.—The Secretary shall promulgate regulations providing for the application of penalties for the sale or distribution of tobacco products to minors in violation of the requirements of subsection (a) that are consistent with the following:

"(1) EMPLOYEES OF RETAILERS.—In the case of an employee of a retailer who distributes a tobacco product to a minor in violation of subsection (a), the regulations shall provide for the application of a civil money penalty of—

"(A) $25 for the 1st violation;

"(B) $50 for the 2nd violation; and

"(C) $150 for the 3rd and subsequent violations.

"(2) MINORS.—In the case of a minor who purchases or attempts to purchase a tobacco product in violation of subsection (a) (other than a minor engaged in an authorized sting or a law enforcement operation), the regulations may provide for civil money penalties, loss of driving privileges, or other penalties.

"(3) RETAILERS.—In the case of a retailer who distributes a tobacco product to a minor in violation of subsection (a), the regulations shall provide for the application of a civil money penalty of at least—

"(A) $250 for the 1st violation;

"(B) $500 for the 2nd violation;

"(C) $1,500 for the 3rd violation;

"(D) $5,000 for the 4th violation; and

"(E) $10,000 for the 5th and subsequent violations.

"(d) ENFORCEMENT.—

"(1) IN GENERAL.—The Secretary may enter into agreements with, and provide grants to, States to enforce this section. Any State that elects to enforce the provisions of this section within the State shall conduct sting operations and other compliance checks and enforce State laws under this section through the use of penalties described in subsection (c) so as to ensure that minors are successful in purchasing tobacco products less than 5 percent of the time.

"(2) REQUIREMENTS.—The Secretary may by regulation implement such requirements as the Secretary determines necessary to ensure that any compliance checks performed by the State under paragraph (1) are accurate.

"(3) VIOLATIONS.—If the Secretary determines that the provisions of subsection (a) are being vio-

lated within a State, the Secretary shall have the authority to enforce such provisions in the State.

"(e) STATE COMPLIANCE.—Beginning with the 3rd full calendar year following the date of enactment of this chapter, if, with respect to a State, the Secretary determines that minors are successful in purchasing tobacco products more than 5 percent of the time, the Secretary shall notify the State and reduce payments to the State under section 111 of the Healthy Kids Act by 1 percent for each percentage point by which the State is not in compliance with this subsection.

"(f) PREEMPTION.—The provisions of this section shall not preempt any provision of State or local law that provides greater restrictions than those required in this section.

"(g) FEDERAL LICENSING OF ENTITIES.—

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

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

"(B) in any United States embassy;

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

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

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

"(2) REQUIREMENTS.—The program established under paragraph (1) shall apply requirements (including those for penalties, suspensions, and revocations) similar to those required to be implemented by States under this section.

"(3) INDIAN TRIBES AND TRIBAL LANDS.—For purposes of applying and enforcing the provisions of this section to entities that sell or otherwise distribute tobacco products on Indian reservations (as defined in section 403(9) of the Indian Child Protection and Family Violence Prevention Act (25 U.S.C. 3202(9))), an Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b)) shall be treated as a State.

"SEC. 908. PUBLIC DISCLOSURE OF HEALTH RESEARCH.

"(a) SUBMISSION BY MANUFACTURERS.—Not later than 3 months after the date of the enactment of this chapter and thereafter as required by the Secretary, each manufacturer of a tobacco product shall submit to the Secretary a copy of each document in the manufacturer's possession—

"(1) relating, referring, or pertaining to—

"(A) any health effects in humans or animals, including addiction, caused by the use of tobacco products or components of tobacco products;

"(B) the engineering, manipulation or control of nicotine in tobacco products;

"(C) the sale or marketing of tobacco products;

"(D) any research involving safer tobacco products; or

"(E) such other matters as the Secretary may prescribe; or

"(2) produced, or ordered to be produced, by the tobacco product manufacturer in any health-related civil or criminal proceeding, judicial or administrative, that has been commenced by the United States, an agency of the United States, a State or local governmental entity, or any person, or on be-

half of such an entity or person, including attorney-client and other documents produced or ordered to be produced for in camera inspection.

"(b) ADDITIONAL INFORMATION.—For the purpose of obtaining additional information relating to the matters in subsection (a), the Secretary may hold hearings, require testimony, the deposition of witnesses, the answering of interrogatories, or enter into and inspect facilities.

"(c) DISCLOSURE BY THE SECRETARY.—Starting not later than 6 months after the date of the enactment of this chapter, the Secretary shall begin to make available to the public, using the Internet and other means, the documents submitted under subsection (a).

"(d) PROTECTION OF CERTAIN INFORMATION.—The Secretary shall not disclose information obtained under this section if such information is entitled to protection as a trade secret or under the attorney-client privilege unless the Secretary determines that the disclosure of such information is necessary to promote the public health.

"(e) ENFORCEMENT.—Notwithstanding any other provision of law, manufacturers of tobacco products shall provide any deposition, documents, or other information, answer any interrogatories, and allow any entry or inspection required pursuant to this section.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to interfere in any way with the discovery rights of courts or parties in civil or criminal proceedings, administrative or judicial, involving tobacco products, or the right of access to such documents under any other provision of law.

"(g) DEFINITION.—In this section:

"(1) DOCUMENTS.—The term 'documents' includes originals and drafts of any kind of written or graphic matter, regardless of the manner of production or reproduction, of any kind of description, whether sent or received or neither, and all copies thereof that are different in any way from the original (whether by interlineation, receipt stamp, notation, indication of copies sent or received or otherwise) regardless of whether 'confidential', 'privileged', or otherwise, including any paper, book, account, photograph, blueprint, drawing, agreement, contract, memorandum, advertising material, letter, telegram, object, report, record, transcript, study, note, notation, working paper, intra-office communication, intra-department communication, inter-department communication, chart, minute, index sheet, routing sheet, computer software, computer data, delivery ticket, flow sheet, price list, quotation,

bulletin, circular, manual, summary, recording of telephone or other conversation or of interviews, or of conferences, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, regardless of the manner produced or reproduced. Such term shall also include any tape, recording, videotape, computerization, or other electronic recording, whether digital or analog or a combination of the two.

"(2) MANUFACTURER OF A TOBACCO PRODUCT.—The term 'manufacturer of a tobacco product' also includes the Tobacco Institute, the Council for Tobacco Research, the Smokeless Tobacco Council, the Center for Indoor Air Research, or any other trade association or entity that is primarily funded by persons who manufacture a tobacco product.

"SEC. 909. CITIZEN SUITS.

"(a) AUTHORITY.—Any individual on his or her own behalf may commence a civil action—

"(1) against any person who is alleged to be in violation of this chapter, in the district court for the district in which the alleged violation occurred or in which the defendant resides or is found; or

"(2) against the Secretary or the Commissioner where there is alleged a failure of the Secretary or

Commissioner to perform any act or duty required under this chapter, in a district court for the district in which an alleged failure to perform occurred or in the district court of the District of Columbia.

"(b) JURISDICTION.—The district courts of the United States shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce the provisions of this chapter, or to order the Secretary to perform such act or duty, as the case may be, and to apply any appropriate civil penalties. The district courts of the United States shall have jurisdiction to compel action by an agency where such action is found to be unreasonably delayed, except that such an action may not be maintained unless the plaintiff has provided the Secretary with a notice of the intent of the plaintiff to file such action at least 90 days prior to the filing of such action.

"(c) COSTS AND DAMAGES.—A court under subsection (b) may award costs of litigation, including reasonable attorney's fees, to any party where the court determines that such an award is appropriate. No damages of any kind, whether compensatory or punitive, may be awarded to the individual in actions described in subsection (a)(2). Any damages awarded to the Federal Government shall be paid to the Treasury.

"SEC. 910. AGRICULTURAL PRODUCERS.

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

"SEC. 911. AUTHORITY OF SECRETARY.

"To carry out this chapter, the Secretary may hold hearings, administer oaths, issue subpoenas, require the testimony or deposition of witnesses, the production of documents, or the answering of interrogatories, or, upon presentation of the proper credentials, enter and inspect facilities. In the case of a refusal of a person to obey a subpoena, any district court of the United States for the district in which such person is found, resides or conducts business, upon application by the Commissioner, shall have jurisdiction to issue an order requiring such person to appear and give testimony or to appear and produce evidence or both. The failure to obey such an order of the court may be punished by the court as contempt thereof, and by penalties of up to $25,000 per day.

"SEC. 912. RULES OF CONSTRUCTION.

"Nothing in this chapter shall be construed—

"(1) to permit the Secretary to ban the sale of tobacco products to adults; or

"(2) to permit the Secretary to require that tobacco products be sold only by prescription.".

SEC. 207. REPEALS.

The following provisions of law shall be repealed:

(1) The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.).

(2). The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq.).

SEC. 208. AUTHORITY OF FEDERAL TRADE COMMISSION.

Nothing in this title, or an amendment made by this title, shall be construed to in any way reduce the jurisdiction of the Federal Trade Commission over the advertising of tobacco products.

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TITLE II—FDA JURISDICTION OVER TOBACCO PRODUCTS

SEC. 201. REFERENCE.

Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 202. NO EFFECT ON NON-TOBACCO PRODUCTS.

Nothing in this Act, the amendments made to the Federal Food, Drug and Cosmetic Act, or any regulation issued pursuant to this Act or amendments, shall be construed to affect the regulation, interpretation, or enforcement of any regulation of any product that is not a tobacco product by the Secretary under the Federal Food, Drug and Cosmetic Act.

SEC. 203. STATEMENT OF GENERAL AUTHORITY.

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

SEC. 204. TREATMENT OF TOBACCO PRODUCTS AS DRUGS AND DEVICES.

(a) DEFINITIONS.—

(1) DRUG.—Section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended by striking "; and (D)" and inserting "; (D) nicotine in tobacco products; and (E)".

(2) DEVICES.—Section 201(h) (21 U.S.C. 321(h)) is amended—

(A) in paragraph (2), by striking "or" at the end;

(B) in paragraph (3), by striking "and" at the end and inserting "or"; and

(C) by inserting after paragraph (3), the following:

"(4) a delivery component of a tobacco product; and".

(3) OTHER DEFINITIONS.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

"(kk) The term 'tobacco product' means any product made or derived from tobacco leaf made for human consumption including, but not limited to, cigarettes, cigarillos, cigarette tobacco, cigars, little cigars, pipe tobacco, and smokeless tobacco, and roll-your-own tobacco.".

(b) REGULATORY AUTHORITY.—Section 503(g) (21 U.S.C. 353(g)) is amended by adding at the end the following:

"(5) The Secretary may regulate any tobacco product as a drug, device, or both, and may designate the office of the Administration that shall be responsible for regulating such products.".

(c) DEVICES.—Section 520(e)(1) (21 U.S.C. 360j(e)(1)) is amended by striking "or use—" and inserting "or use, including restrictions on the access to, and the advertising and promotion of, tobacco products—".

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

"(u) In the case of a tobacco product, it is sold, distributed, advertised, or labeled in violation of this Act or the regulations promulgated under this Act.

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

the reduced probability that existing users of tobacco products will quit.".

(e) ENFORCEMENT.—Section 301 (42 U.S.C. 331) is amended by adding at the end the following:

"(aa) The failure to comply with the requirements of section 581.

"(bb) The failure or refusal to comply with any of the requirements of subsections (a), (b) or (e) of section 908.".

(f) STATE AND LOCAL REQUIREMENTS.—Section 521 (21 U.S.C. 360k) is amended—

(1) in subsection (a), by striking "subsection (b)" and inserting "subsections (b) and (c)"; and

(2) by adding at the end the following:

"(c) This section shall not apply to devices that are tobacco products.".

SEC. 205. RECALL AUTHORITY.

Section 518(e)(1) (21 U.S.C. 360h(e)(1)) is amended by inserting after "adverse health consequences or death," the following: "and for tobacco products that the best public health result would be achieved,".

SEC. 206. GENERAL HEALTH AND SAFETY REGULATION OF TOBACCO PRODUCTS.

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

(1) by redesignating chapter IX as chapter X;

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

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

"CHAPTER IX—TOBACCO PRODUCTS

"SEC. 901. PROMULGATION OF REGULATIONS.

"(a) IN GENERAL.—Any regulations necessary to implement this chapter shall be promulgated not later than 12 months after the date of enactment of this chapter using notice and comment rulemaking (in accordance with chapter 5 of title 5, United States Code). Such regulations may be revised thereafter as determined necessary by the Secretary.

"(b) BLACK MARKETS.—[To be supplied]

"SEC. 902. SCIENTIFIC ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this chapter, the Secretary shall establish an advisory committee, to be known as the 'Scientific Advisory Committee', to assist the Secretary.

"(b) MEMBERSHIP.—

"(1) IN GENERAL.—The Secretary shall appoint as members of the Scientific Advisory Committee any individuals with expertise in the medical, sci-

entific, or other technological data involving the manufacture and use of tobacco products, and of appropriately diversified professional backgrounds.

"(2) LIMITATIONS.—Notwithstanding section 5(b) of the Federal Advisory Committee Act (5 U.S.C. App. 3), the Secretary may not appoint to the Committee any individual who—

"(A) is in the regular full-time employ of the Federal Government;

"(B) is, or is in the employ of, a manufacturer, distributor, or retailer of a tobacco product, or organization substantially funded by manufacturers, distributors, or retailers of tobacco products;

"(C) is, or is in the employ of, an attorney representing an entity described in subparagraph (B); or

"(D) is, or is in the employ of, a consultant employed by or under retainer to an entity described in subparagraph (B).

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

"(c) COMPENSATION AND EXPENSES.—Members of the Scientific Advisory Committee shall be entitled to the

same compensation and expenses as the compensation and expenses provided to members of the advisory committees established under section 514(b)(5)(B).

"(d) DUTIES.—The Scientific Advisory Committee shall—

"(1) provide assistance to the Secretary;

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

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

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

"SEC. 903. PERFORMANCE STANDARDS AND SAFETY AND EFFICACY.

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

"(1) the reduction or elimination of nicotine yields of the product;

"(2) the reduction or elimination of other constituents or harmful components of the product; or

"(3) standards relating to any other requirement pursuant to section 512(a)(2).

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

"(c) SAFETY AND EFFICACY.—

"(1) IN GENERAL.—With respect to a device that is a tobacco product, the assurance in the 1st sentence of section 513(a)(1)(B) need not be found if the Secretary finds that special controls achieve the best public health result.

"(2) APPLICATION OF STANDARD TO TOBACCO PRODUCTS.—For purposes of section 513(a)(1)(B), subsections (c)(2)(C), (d)(2)(B), (e)(2)(A), (f)(3)(B)(i), and (f)(3)(C)(i) of section 513, and sections 514, 519(a), 520(e), and 520(f), the safety and effectiveness of a device that is a tobacco product need not be found if the Secretary finds that the action to be taken under any such provision would achieve the best public health result by reducing the overall risks to human health. The finding as to

whether the best public health result has been achieved shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

"(A) the increased or decreased likelihood that existing consumers of tobacco products will stop using such products; and

"(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

"(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed as in any way limiting or altering the safety and efficacy standard in effect under section 513 on the date of enactment of this chapter as such standard relates to drugs and devices that are not tobacco products.

"SEC. 904. DISCLOSURE AND REPORTING OF TOBACCO AND NONTOBACCO INGREDIENTS AND CONSTITUENTS.

"(a) DISCLOSURE OF ALL INGREDIENTS.—

"(1) IMMEDIATE AND ANNUAL DISCLOSURE.—Not later than 30 days after the date of enactment of this chapter, and annually thereafter, each manufacturer of a tobacco product shall submit to the

Secretary an ingredient list for each brand of tobacco product it manufactures that contains the information described in paragraph (2).

"(2) REQUIREMENTS.—The list described in paragraph (1) shall, with respect to each brand or variety of tobacco product of a manufacturer, include—

"(A) a list of all ingredients, constituents, substances, and compounds that are found in or added to the tobacco or tobacco product (including the paper, filter, or packaging of the product if applicable) in the manufacture of the tobacco product, for each brand or variety of tobacco product so manufactured, including, if determined necessary by the Secretary, any material added to the tobacco used in the product prior to harvesting;

"(B) the quantity of the ingredients, constituents, substances, and compounds that are listed under subparagraph (A) in each brand or variety of tobacco product;

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

"(D) for each brand or variety of cigarettes—

"(i) the filter ventilation percentage (the level of air dilution in the cigarette as provided by the ventilation holes in the filter, described as a percentage);

"(ii) the pH level of the smoke of the cigarette; and

"(iii) the tar, nicotine, and carbon monoxide delivery level under Federal Trade Commission parameters and any other smoking conditions established by the Secretary, reported in milligrams of tar, nicotine, and carbon monoxide per cigarette;

"(E) for each brand or variety of smokeless tobacco products—

"(i) the pH level of the tobacco;

"(ii) the moisture content of the tobacco expressed as a percentage of the weight of the tobacco; and

"(iii) the nicotine content—

"(I) for each gram of the product, measured in milligrams of nicotine;

"(II) expressed as a percentage of the dry weight of the tobacco; and

"(III) with respect to unionized (free) nicotine, expressed as a percentage per gram of the tobacco and expressed in milligrams per gram of the tobacco; and

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

"(3) METHODS.—The Secretary shall have the authority to promulgate regulations to establish the methods to be used by manufacturers in making the determinations required under paragraph (2).

"(b) SAFETY ASSESSMENTS.—

"(1) APPLICATION TO NEW INGREDIENTS.—

"(A) IN GENERAL.—Not later than 1 year after the date of enactment of this chapter, and annually thereafter, each manufacturer shall submit to the Secretary a safety assessment for each new ingredient, constituent, substance, or compound that such manufacturer desires to make a part of a tobacco product. Such new ingredient, constituent, substance, or compound shall not be included in a tobacco product prior to approval by the Secretary of such a safety assessment.

"(B) METHOD OF FILING.—A safety assessment submitted under subparagraph (A) shall be signed by an officer of the manufacturer who is acting on behalf of the manufacturer and who has the authority to bind the manufacturer, and contain a statement that ensures that the information contained in the assessment is true, complete and accurate.

"(C) DEFINITION OF NEW INGREDIENT.—For purposes of subparagraph (A), the term 'new ingredient, constituent, substance, or compound' means an ingredient, constituent substance, or compound listed under subsection (a)(1) that was not used in the brand or variety of tobacco product involved prior to January 1, 1998.

"(2) APPLICATION TO OTHER INGREDIENTS.—With respect to the application of this section to ingredients, constituents substances, or compounds listed under subsection (a) to which paragraph (1) does not apply, all such ingredients, constituents, substances, or compounds shall be reviewed through the safety assessment process within the 5-year period beginning on the date of enactment of this chapter. The Secretary shall develop a procedure for

the submission of safety assessments of such ingredients, constituents, substances, or compounds that staggers such safety assessments within the 5-year period.

"(3) BASIS OF ASSESSMENT.—The safety assessment of an ingredient, constituents, substance, or compound described in paragraphs (1) and (2) shall—

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

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

"(c) PROHIBITION.—

"(1) REGULATIONS.—Not later than 12 months after the date of enactment of this chapter, the Secretary shall promulgate regulations to prohibit the use of any ingredient, constituent, substance, or compound in the tobacco product of a manufacturer—

"(A) if no safety assessment has been submitted by the manufacturer for the ingredient, constituent, substance, or compound as otherwise required under this section; or

"(B) if the Secretary finds that the manufacturer has failed to demonstrate the safety of the ingredient, constituent, substance, or compound that was the subject of the assessment under paragraph (2).

"(2) REVIEW OF ASSESSMENTS.—

"(A) GENERAL REVIEW.—Not later than 180 days after the receipt of a safety assessment under subsection (b), the Secretary shall review the findings contained in such assessment and approve or disapprove of the safety of the ingredient, constituents, substance, or compound that was the subject of the assessment. The Secretary may, for good cause, extend the period for such review. The Secretary shall provide notice to the manufacturer of an action under this subparagraph.

"(B) INACTION BY SECRETARY.—If the Secretary fails to act with respect to an assessment of an existing ingredient, constituent, substance, or additive during the period referred to

in subparagraph (A), the manufacturer of the tobacco product involved may continue to use the ingredient, constituents, substance, or compound involved until such time as the Secretary makes a determination with respect to the assessment.

"(d) RIGHT TO KNOW; FULL DISCLOSURE OF INGREDIENTS TO THE PUBLIC.—

"(1) IN GENERAL.—Except as provided in paragraph (3), a package of a tobacco product shall disclose all ingredients, constituents, substances, or compounds contained in the product in accordance with regulations promulgated under section 701(a) by the Secretary.

"(2) DISCLOSURE OF PERCENTAGE OF DOMESTIC AND FOREIGN TOBACCO.—The regulations referred to in paragraph (1) shall require that the package of a tobacco product disclose, with respect to the tobacco contained in the product—

"(A) the percentage that is domestic tobacco; and

"(B) the percentage that is foreign tobacco.

"(3) HEALTH DISCLOSURE.—Notwithstanding section 301(j), the Secretary may require the public

disclosure of any ingredient, constituent, substance, or compound contained in a tobacco product that relates to a trade secret or other matter referred to in section 1905 of title 18, United States Code, if the Secretary determines that such disclosure will promote the public health.

"SEC. 905. TOBACCO PRODUCT WARNINGS, LABELING AND PACKAGING.

"(a) CIGARETTE WARNINGS.—

"(1) IN GENERAL.—

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

"WARNING: Cigarettes Are Addictive.

"WARNING: Tobacco Smoke Can Harm Your Children.

"WARNING: Cigarettes Cause Fatal Lung Disease.

"WARNING: Cigarettes Cause Cancer.

"WARNING: Cigarettes Cause Strokes And Heart Disease.

"WARNING: Smoking During Pregnancy Can Harm Your Baby.

"WARNING: Smoking Can Kill You.

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

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

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

"WARNING: Cigarettes Are Addictive.

"WARNING: Tobacco Smoke Can Harm Your Children.

"WARNING: Cigarettes Cause Fatal Lung Disease.

"WARNING: Cigarettes Cause Cancer.

"WARNING: Cigarettes Cause Strokes And Heart Disease.

"WARNING: Smoking During Pregnancy Can Harm Your Baby.

"WARNING: Smoking Can Kill You.

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

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

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

"(2) REQUIREMENTS FOR LABELING.—

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

"(B) TYPE AND COLOR.—With respect to each label statement required by subparagraph (A) of paragraph (1), the phrase 'WARNING' shall appear in capital letters and the label

statement shall be printed in 17 point type with adjustments as determined appropriate by the Secretary to reflect the length of the required statement. All the letters in the label shall appear in conspicuous and legible type, in contrast by typography, layout, or color with all other printed material on the package, and be printed in an alternating black-on-white and white-on-black format as determined appropriate by the Secretary.

"(C) EXCEPTION.—With respect to cigarettes manufactured and distributed prior to January 1, 2000, the provisions of subparagraph (A) shall not apply with respect to the front panel in the case of a flip-top cigarette package (offered for sale on June 1, 1997) where the front portion of the flip-top does not comprise at least 25 percent of the front panel. In the case of such a package, the label statement required by subparagraph (A) of paragraph (1) shall occupy the entire front portion of the flip-top.

"(3) REQUIREMENTS FOR ADVERTISING.—

"(A) LOCATION.—Each label statement required by subparagraph (B) of paragraph (1)

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

"(B) TYPE, COLOR AND FORMAT.—

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

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

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

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

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

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

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

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

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

Within the 20 percent requirement described in subparagraph (A), the Secretary may revise the required type sizes if the Secretary determines that such revisions will enhance public health protections.

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

"(iii) FORMAT.—The label statements under subparagraph (B) of paragraph (1) shall be black when the background is white and white when the background is black, and shall be in the point size required under this subparagraph. The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first down stroke of the capital 'W' of the word 'WARNING' in the label statements.

"(C) LANGUAGE REQUIREMENT.—The label statements required under paragraph (1)(B) shall be in English, except that—

"(i) in the case of an advertisement that appears in a newspaper, magazine, periodical or other publication that is not in English, such statements shall appear in the predominant language of the publication; or

"(ii) in the case of any other advertisement that is not in English, such statements shall appear in the same language

as that principally used in the advertisement.

"(4) ROTATION OF LABEL STATEMENTS.—

"(A) LABELING.—The label statements specified in subparagraph (A) of paragraph (1) shall be randomly displayed in each 12 month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which such product is marketed in accordance with a plan submitted by the manufacturer, importer, distributor or retailer and approved by the Secretary.

"(B) ADVERTISING.—The label statements specified in subparagraph (B) of paragraph (1) shall be rotated quarterly in alternating sequence in advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer, importer, distributor or retailer and approved by the Secretary.

"(C) APPROVAL OF PLANS.—The Secretary shall review each plan submitted by a manufacturer, importer, distributor or retailer of cigarettes under this paragraph and approve such plan if the plan will provide for the equal

distribution and display on packaging and the rotation required in advertising under this paragraph and if such plan assures that all of the labels required under subparagraphs (A) and (B) will be displayed by the manufacturer, importer, distributor or retailer at the same time.

"(b) SMOKELESS TOBACCO PRODUCTS.—

"(1) IN GENERAL.—

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

"WARNING: This Product Can Cause Mouth Cancer.

"WARNING: This Product Can Kill You.

"WARNING: This Product Can Cause Gum Disease And Tooth Loss.

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

"WARNING: This Product Contains Cancer-Causing Chemicals.

"WARNING: Smokeless Tobacco Is Addictive.

"(B) ADVERTISING.—It shall be unlawful for any manufacturer, importer, distributor or retailer of smokeless tobacco products to advertise or cause to be advertised any smokeless tobacco product unless the advertising bears, in accordance with the requirements of this subsection, one of the following labels:

"WARNING: This Product Can Cause Mouth Cancer.

"WARNING: This Product Can Kill You.

"WARNING: This Product Can Cause Gum Disease And Tooth Loss.

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

"WARNING: This Product Contains Cancer-Causing Chemicals.

"WARNING: Smokeless Tobacco Is Addictive.

"(C) ADDITIONAL WARNINGS.—Beginning on the date that is 18 months after the date of enactment of this chapter, the Secretary may substitute for, or require warnings in addition to, those otherwise required under subparagraphs (A) and (B) if the Secretary determines

that such warnings would be more effective in deterring the use of smokeless tobacco products.

"(2) REQUIREMENTS FOR LABELING.—

"(A) LOCATION.—Each label statement required by subparagraph (A) of paragraph (1) shall be located on the 2 most prominent display panels of the product and occupy not less than 25 percent of such panels.

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

"(3) ADVERTISING AND ROTATION.—The provisions of paragraph (3) and (4) of subsection (a) shall apply to advertisements for smokeless tobacco

products and the rotation of the label statements required under paragraph (1)(A) on such products.

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

"(d) CONSTRUCTION.—

"(1) IN GENERAL.—Noting in this section shall be construed to limit the ability of the Secretary to change the text or layout of any of the warning statements, or any of the labeling provisions, under subsections (a) and (b) and other provisions of this Act, if determined necessary by the Secretary in order to make such statements or labels larger, more prominent, more conspicuous, or more effective.

"(2) UNFAIR ACTS.—Nothing in this section (other than the requirements of subsections (a), (b) and (c)) shall be construed to limit or restrict the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco products.

"(e) LIMITED PREEMPTION.—

"(1) STATE AND LOCAL ACTION.—No warning label with respect to cigarettes or smokeless tobacco

products, or any other tobacco product for which warning labels have been required under this section, other than the warning labels required under this Act, shall be required by any State or local statute or regulation to be included on any package of cigarettes or a smokeless tobacco product.

"(2) EFFECT ON LIABILITY LAW.—Nothing in this section shall relieve any person from liability at common law or under State statutory law to any other person.

"(f) ELECTRONIC MEDIUM ADVERTISING.—It shall be unlawful to advertise tobacco products on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

"SEC. 906. PRESERVATION OF STATE AND LOCAL AUTHORITY.

"Except as otherwise provided for in section 905(e), nothing in this chapter shall be construed as prohibiting a State or locality from imposing requirements, prohibitions, penalties or other measures to further the purposes of this chapter that are in addition to the requirements, prohibitions, or penalties required under this chapter. State and local governments may impose additional tobacco product control measures to further restrict or limit the use of such products.

"SEC. 907. RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS.

"(a) IN GENERAL.—The Secretary shall restrict the access of minors to tobacco products.

"(b) STATE LICENSING.—

"(1) IN GENERAL.—Except as provided in paragraph (2), in order to receive any amounts under section 111 of the Healthy Kids Act, a State shall have in place a program that meets or exceeds (as determined by the Secretary) the requirements of the model State program described in paragraph (3) under which a retailer would be required to obtain a State or local license to sell or otherwise distribute tobacco products directly to consumers in such State.

"(2) START-UP PERIOD.—

"(A) IN GENERAL.—The Secretary may waive the requirement of paragraph (1) for such time as the Secretary determines is necessary, after promulgation of the model program described in paragraph (3), to permit the legislature of a State to meet and enact laws to comply with paragraph (1) and to permit the State to implement the program described in paragraph (1).

"(B) ELIGIBILITY.—To be eligible for a waiver under subparagraph (A), the Governor of the State involved shall certify to the Secretary in writing that the State intends to implement a program that meets the requirements of this section at the earliest possible opportunity. If, subsequent to such notification, the Secretary determines that the State has failed to implement such a program, the Secretary may recover any funds distributed to the State under section 111 of the Healthy Kids Act.

"(3) MODEL PROGRAM.—Not later than 12 months after the date of enactment of this chapter, the Secretary shall promulgate a model State program. Such model State program shall at a minimum—

"(A) provide for the collection of licensing fees by the State or locality to defray the costs of administering the program;

"(B) prohibit retailers from selling or otherwise distributing tobacco products directly to consumers in a State unless such retailers have in effect tobacco licenses issued or renewed in accordance with State or local laws;

"(C) provide for the notification of every person in the State who is engaged in the distribution at retail of tobacco products of the license requirement and of the date by which such person shall have obtained a license in order to continue to distribute such products;

"(D) prohibit licensed retailers from selling or otherwise distributing tobacco products to minors;

"(E) provide for penalties of up to $50,000 for each violation of the requirements under such program relating to the sale or distribution of tobacco products without a license and for appropriate penalties for other violations of laws relating to youth access to tobacco products;

"(F) require retailers to comply with the applicable requirements of this section and any regulations relating to this section; and

"(G) provide for the suspension or revocation of a license in the case of a retailer that repeatedly sells or distributes tobacco products to individuals in violation of subsection (a) or State or local law.

"(c) PENALTIES.—The Secretary shall promulgate regulations providing for the application of penalties for the sale or distribution of tobacco products to minors in violation of the requirements of subsection (a) that are consistent with the following:

"(1) EMPLOYEES OF RETAILERS.—In the case of an employee of a retailer who distributes a tobacco product to a minor in violation of subsection (a), the regulations shall provide for the application of a civil money penalty of—

"(A) $25 for the 1st violation;

"(B) $50 for the 2nd violation; and

"(C) $150 for the 3rd and subsequent violations.

"(2) MINORS.—In the case of a minor who purchases or attempts to purchase a tobacco product in violation of subsection (a) (other than a minor engaged in an authorized sting or a law enforcement operation), the regulations may provide for civil money penalties, loss of driving privileges, or other penalties.

"(3) RETAILERS.—In the case of a retailer who distributes a tobacco product to a minor in violation of subsection (a), the regulations shall provide for the application of a civil money penalty of at least—

"(A) $250 for the 1st violation;

"(B) $500 for the 2nd violation;

"(C) $1,500 for the 3rd violation;

"(D) $5,000 for the 4th violation; and

"(E) $10,000 for the 5th and subsequent violations.

"(d) ENFORCEMENT.—

"(1) IN GENERAL.—The Secretary may enter into agreements with, and provide grants to, States to enforce this section. Any State that elects to enforce the provisions of this section within the State shall conduct sting operations and other compliance checks and enforce State laws under this section through the use of penalties described in subsection (c) so as to ensure that minors are successful in purchasing tobacco products less than 5 percent of the time.

"(2) REQUIREMENTS.—The Secretary may by regulation implement such requirements as the Secretary determines necessary to ensure that any compliance checks performed by the State under paragraph (1) are accurate.

"(3) VIOLATIONS.—If the Secretary determines that the provisions of subsection (a) are being vio-

lated within a State, the Secretary shall have the authority to enforce such provisions in the State.

"(e) STATE COMPLIANCE.—Beginning with the 3rd full calendar year following the date of enactment of this chapter, if, with respect to a State, the Secretary determines that minors are successful in purchasing tobacco products more than 5 percent of the time, the Secretary shall notify the State and reduce payments to the State under section 111 of the Healthy Kids Act by 1 percent for each percentage point by which the State is not in compliance with this subsection.

"(f) PREEMPTION.—The provisions of this section shall not preempt any provision of State or local law that provides greater restrictions than those required in this section.

"(g) FEDERAL LICENSING OF ENTITIES.—

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

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

"(B) in any United States embassy;

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

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

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

"(2) REQUIREMENTS.—The program established under paragraph (1) shall apply requirements (including those for penalties, suspensions, and revocations) similar to those required to be implemented by States under this section.

"(3) INDIAN TRIBES AND TRIBAL LANDS.—For purposes of applying and enforcing the provisions of this section to entities that sell or otherwise distribute tobacco products on Indian reservations (as defined in section 403(9) of the Indian Child Protection and Family Violence Prevention Act (25 U.S.C. 3202(9))), an Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b)) shall be treated as a State.

"SEC. 908. PUBLIC DISCLOSURE OF HEALTH RESEARCH.

"(a) SUBMISSION BY MANUFACTURERS.—Not later than 3 months after the date of the enactment of this chapter and thereafter as required by the Secretary, each manufacturer of a tobacco product shall submit to the Secretary a copy of each document in the manufacturer's possession—

"(1) relating, referring, or pertaining to—

"(A) any health effects in humans or animals, including addiction, caused by the use of tobacco products or components of tobacco products;

"(B) the engineering, manipulation or control of nicotine in tobacco products;

"(C) the sale or marketing of tobacco products;

"(D) any research involving safer tobacco products; or

"(E) such other matters as the Secretary may prescribe; or

"(2) produced, or ordered to be produced, by the tobacco product manufacturer in any health-related civil or criminal proceeding, judicial or administrative, that has been commenced by the United States, an agency of the United States, a State or local governmental entity, or any person, or on be-

half of such an entity or person, including attorney-client and other documents produced or ordered to be produced for in camera inspection.

"(b) ADDITIONAL INFORMATION.—For the purpose of obtaining additional information relating to the matters in subsection (a), the Secretary may hold hearings, require testimony, the deposition of witnesses, the answering of interrogatories, or enter into and inspect facilities.

"(c) DISCLOSURE BY THE SECRETARY.—Starting not later than 6 months after the date of the enactment of this chapter, the Secretary shall begin to make available to the public, using the Internet and other means, the documents submitted under subsection (a).

"(d) PROTECTION OF CERTAIN INFORMATION.—The Secretary shall not disclose information obtained under this section if such information is entitled to protection as a trade secret or under the attorney-client privilege unless the Secretary determines that the disclosure of such information is necessary to promote the public health.

"(e) ENFORCEMENT.—Notwithstanding any other provision of law, manufacturers of tobacco products shall provide any deposition, documents, or other information, answer any interrogatories, and allow any entry or inspection required pursuant to this section.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to interfere in any way with the discovery rights of courts or parties in civil or criminal proceedings, administrative or judicial, involving tobacco products, or the right of access to such documents under any other provision of law.

"(g) DEFINITION.—In this section:

"(1) DOCUMENTS.—The term 'documents' includes originals and drafts of any kind of written or graphic matter, regardless of the manner of production or reproduction, of any kind of description, whether sent or received or neither, and all copies thereof that are different in any way from the original (whether by interlineation, receipt stamp, notation, indication of copies sent or received or otherwise) regardless of whether 'confidential', 'privileged', or otherwise, including any paper, book, account, photograph, blueprint, drawing, agreement, contract, memorandum, advertising material, letter, telegram, object, report, record, transcript, study, note, notation, working paper, intra-office communication, intra-department communication, inter-department communication, chart, minute, index sheet, routing sheet, computer software, computer data, delivery ticket, flow sheet, price list, quotation,

bulletin, circular, manual, summary, recording of telephone or other conversation or of interviews, or of conferences, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, regardless of the manner produced or reproduced. Such term shall also include any tape, recording, videotape, computerization, or other electronic recording, whether digital or analog or a combination of the two.

"(2) MANUFACTURER OF A TOBACCO PRODUCT.—The term 'manufacturer of a tobacco product' also includes the Tobacco Institute, the Council for Tobacco Research, the Smokeless Tobacco Council, the Center for Indoor Air Research, or any other trade association or entity that is primarily funded by persons who manufacture a tobacco product.

"SEC. 909. CITIZEN SUITS.

"(a) AUTHORITY.—Any individual on his or her own behalf may commence a civil action—

"(1) against any person who is alleged to be in violation of this chapter, in the district court for the district in which the alleged violation occurred or in which the defendant resides or is found; or

"(2) against the Secretary or the Commissioner where there is alleged a failure of the Secretary or

Commissioner to perform any act or duty required under this chapter, in a district court for the district in which an alleged failure to perform occurred or in the district court of the District of Columbia.

"(b) JURISDICTION.—The district courts of the United States shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce the provisions of this chapter, or to order the Secretary to perform such act or duty, as the case may be, and to apply any appropriate civil penalties. The district courts of the United States shall have jurisdiction to compel action by an agency where such action is found to be unreasonably delayed, except that such an action may not be maintained unless the plaintiff has provided the Secretary with a notice of the intent of the plaintiff to file such action at least 90 days prior to the filing of such action.

"(c) COSTS AND DAMAGES.—A court under subsection (b) may award costs of litigation, including reasonable attorney's fees, to any party where the court determines that such an award is appropriate. No damages of any kind, whether compensatory or punitive, may be awarded to the individual in actions described in subsection (a)(2). Any damages awarded to the Federal Government shall be paid to the Treasury.

"SEC. 910. AGRICULTURAL PRODUCERS.

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

"SEC. 911. AUTHORITY OF SECRETARY.

"To carry out this chapter, the Secretary may hold hearings, administer oaths, issue subpoenas, require the testimony or deposition of witnesses, the production of documents, or the answering of interrogatories, or, upon presentation of the proper credentials, enter and inspect facilities. In the case of a refusal of a person to obey a subpoena, any district court of the United States for the district in which such person is found, resides or conducts business, upon application by the Commissioner, shall have jurisdiction to issue an order requiring such person to appear and give testimony or to appear and produce evidence or both. The failure to obey such an order of the court may be punished by the court as contempt thereof, and by penalties of up to $25,000 per day.

"SEC. 912. RULES OF CONSTRUCTION.

"Nothing in this chapter shall be construed—

"(1) to permit the Secretary to ban the sale of tobacco products to adults, or so long as the product meets the req of the Act.

"(2) to permit the Secretary to require that tobacco products be sold only by prescription.".

SEC. 207. REPEALS.

The following provisions of law shall be repealed:

(1) The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.).

(2) The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq.).

SEC. 208. AUTHORITY OF FEDERAL TRADE COMMISSION.

Nothing in this title, or an amendment made by this title, shall be construed to in any way reduce the jurisdiction of the Federal Trade Commission over the advertising of tobacco products.

Tobacco - new legislation - Conrad bill

KENT CONRAD
NORTH DAKOTA
202-224-2043

COMMITTEES
AGRICULTURE, NUTRITION, AND FORESTRY
FINANCE
BUDGET
INDIAN AFFAIRS

United States Senate
WASHINGTON, DC 20510-3403

October 29, 1997

The Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Ave SW
Washington, DC 20201-0004

Bruce Reed
Assistant to the President for Domestic Policy
The White House
Washington, DC 20500

Dear Secretary Shalala and Mr. Reed:

I am writing to thank you for briefing the Senate Democratic Task Force on Tobacco during the course of the Administration's review of the proposed tobacco settlement, and to seek your further assistance as the task force moves forward to draft comprehensive tobacco legislation.

As I have said, I believe the President was right to focus on youth smoking. If we are to be reasonably confident that comprehensive tobacco legislation will result in significant declines in youth smoking rates, it is essential that the task force better understand the effects of price increases and penalties on youth smoking, and the overall economic effects of such changes. The task force has heard a great deal of sometimes conflicting information on these points. In order to help clarify this set of issues, it would be most helpful if you could provide me with your analysis on the following issues:

1. The President has called for an increase in tobacco prices of $1.50 in a combination of price increases and penalties. The tobacco industry argues that a number of exogenous factors, including inflation, should be counted in determining the size of the price increase. However, most economists believe that only real price increases, not nominal price increases, should be included in this calculation. As the Administration analyzes the effects of price increases on tobacco consumption, the incidence of smoking, and the profitability of the tobacco industry and other industries in the tobacco supply chain, which price increases are relevant to the analysis? In particular, should inflation or exogenous price increases (for example, the ongoing trend of increased state and local sales and excise taxes) be taken into account, or should only those price increases directly attributable to the proposed settlement or comprehensive legislation be considered?

2. What are the implications of different levels of price increases on tobacco consumption, adult smoking rates, youth smoking rates, tobacco industry profitability and share prices, tobacco

farmer profitability, tobacco wholesalers and retailers, and state and local tax revenues? For example, what would be the effects of the proposed settlement? What would be the effects of a 75 cent per pack increase? $1.00 per pack? $1.25 per pack? $1.50 per pack? $1.75 per pack? $2.00 per pack? $3.00 per pack?

3. Some analysts suggest that sudden, dramatic price increases have a greater effect on smoking rates than a series of smaller price increases. How is the above analysis affected by the timing of the price increases?

4. The proposed settlement envisions companies paying per pack amounts into a settlement fund, and covering these payments through an increase in the price of tobacco products. The settlement contains an anti-trust exemption, in part to ensure that companies raise prices in concert. Others have suggested that the price increase should be effectuated through an increase in the Federal excise tax or through a public health user fee imposed on a per pack basis. What are the pros and cons of these three approaches?

5. If price were the only factor affecting smoking rates, how big a price increase would be required to achieve the youth smoking targets called for in the settlement? How much "credit" should be given for the non-price policy changes proposed in the settlement?

6. How big a price increase would be required to offset the costs of smoking-related illnesses to the Federal government (including Medicare, Medicaid, veterans benefits, CHAMPUS and FEHBP) over the next 25 years?

7. The President called for a $1.50 per pack increase in cigarette prices in a combination of price increases and penalties for missing the youth smoking targets. What are the implications for cigarette consumption, smoking rates, industry profitability, farmers, retailers and wholesalers of different combinations of price increases and penalties? For example, how do the effects of a $1.00 price increase and a 50 cent penalty differ from the effects of a 50 cent price increase and a $1.00 penalty? What about 75 cents each? Or a $1.25 price increase and 25 cent penalties?

8. Look-back penalties for missing the youth smoking targets could be structured in several different ways. The following questions would help the task force understand the implications of some potential options for look-back penalties:

A. What are the pros and cons of imposing penalties on an industry-wide, company specific, or brand specific basis? Would some combination of these approaches make more sense, and why? If the penalties are imposed on a company or brand specific basis, is there justification for a de minimis exemption? Does this create a potential loophole?

B. What are the implications of collecting this penalty as a tax increase collected on each pack sold in the year following a year in which the youth smoking target was missed versus a one-time payment in the following year assessed on the basis of a per pack charge for each pack sold during the year in which the target was missed? If the former option were adopted, would there

be administrative difficulties with assessing different per pack taxes on different brands or computing the size of the tax in time to impose the tax at the beginning of a calendar year?

C. Penalties could be assessed as a flat fee or per pack charge that does not vary no matter how much the youth smoking target is missed, or it could be structured to ramp up steeply as the distance from the target increases. What are the pros and cons of different ways of graduating the penalty depending on the amount by which the target is missed?

Your input on these important economic questions will be most helpful to the task force.

In addition, it would be helpful if you could expand on the President's statement with respect to documents. Many members of our task force believe that the tobacco industry has abused the attorney client privilege to shield documents relating to public health, marketing to children, and the manipulation of nicotine levels. In their view, the document disclosure provisions in the proposed settlement are inadequate. However, many members of the task force are also concerned that removing this privilege might set a dangerous precedent for other situations where the attorney client privilege has been used appropriately. Do you have any suggestions for a system of disclosing important public health documents in the possession of the tobacco industry without undermining the attorney client privilege more generally?

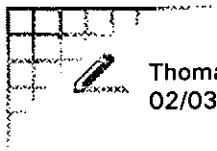
Again, thank you for your helpful input into the task force process. I look forward to working closely with you as the task force proceeds with drafting comprehensive tobacco legislation.

Sincerely,

KENT CONRAD
United States Senate

KC:wtom

Tobacco - settlement -
now legislation -
Conrad bill



Thomas L. Freedman
02/03/98 01:14:11 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Jerold R. Mande/OSTP/EOP

cc: Mary L. Smith/OPD/EOP
Subject: Conrad's Bill Update

1. The task force met and urged Conrad to change his spending to look more like the WH, (a good sign) so Conrad says they are-- the main difference becoming research-- they say they have about the same for NIH research as we do but not for other research purposes and put more into farmers and anti-tobacco. They are also putting some into save social security first. They say the

2. Mike Moore's lobbyist told Conrad's staff that the WH had agreed to a big tobacco summit -- anything I should transmit back?

Tobacco settlement - new legislation - Conrad bill

Thomas L. Freedman
02/10/98 10:53:20 AM

Record Type: Record

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

cc: Jerold R. Mande/OSTP/EOP, Mary L. Smith/OPD/EOP
Subject: Re: Several Technical Edits to Draft Conrad Bill

Technical changes suggested by OMB this a.m. that look fine if Conrad wants 'em. Yes?
---------- Forwarded by Thomas L. Freedman/OPD/EOP on 02/10/98 10:51 AM ----------

Patrick G. Locke
02/10/98 10:13:34 AM

Record Type: Record

To: richard j. turman/omb/eop

cc: See the distribution list at the bottom of this message
Subject: Re: Several Technical Edits to Draft Conrad Bill

Here are some suggested line edits for my three comments in the youth surcharge section, as well as a few others:

Inflation adjustment. Title I, sec. 102, p. 23 line 14. "(A) the **percentage increase in the** medical consumer price index ..."

Youth surcharge baseline. Title III, sec. 302, p. 2 line 3. Insert sentence specifying overall baseline level: **"The baseline level of tobacco product use (referred to in this title as the 'baseline level') is the percentage of individuals under 18 years of age determined to have used the tobacco product in the first annual performance survey for 1998."**

Youth usage reduction. Title III, sec. 303, p. 4 line 5. "required percentage reduction **from the baseline level** in the percentage underage use ..."

Youth penalties. Title III, sec. 304, p. 6 line 18 and p. 7 lines 6, 8, 10, and 12. Penalties should be stated in cents as "10 cents", not "$.10 cents"

Actual percentage reduction. Title III, sec. 304, p. 8 line 9. Insert "multiplied by 100" to convert fractional percent to integer percent for comparison to the reduction target.

I also have two other technical comments that raise policy issues.

1. Tax deductibility. We could suggest language to clarify the tax status of the basic

assessments. It seems the intent of the language is that they be deductible. OTA would probably be a lot happier if this were stated more clearly in the bill.

2. Youth reductions. The penalties on manufacturers for not meeting the youth targets would make the most sense if they were computed on a manufacturer-wide basis for all brands sold by that manufacturer. It is not clear from the bill whether this is the intent or not. If this is the intent, we could suggest language to that effect.

I am also sending these comments by fax to Thomas Freedman at DPC.

Message Copied To:

thomas l. freedman/opd/eop
jill m. pizzuto/omb/eop
barry t. clendenin/omb/eop
wm g. white/omb/eop
jim r. esquea/omb/eop
marc garufi/omb/eop
Hugh T. Connelly/OMB/EOP
Joshua Gotbaum/OMB/EOP

tobacco settlement –
new legislation –
Conrad bill

Record Type: Record

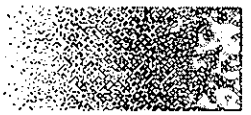
To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:
Subject: conrad

does the conrad bill still direct funding of what we call the unresticted state pool to health care and require HHS approval? if so, and we say nice things about the bill, govs will go nuts.

on talking to dem govs: you wiill be invited to talk to them in person the Saturday of NGA (Feb 21) at the DGA meeting. clearly we have to do this. they want to do something fact-to face--not on the phone. we should think over the next week if there is anything we can throw their way.

tol mr -
new leg -
Conrad bill



Jerold R. Mande

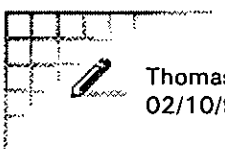
02/10/98 06:27:09 PM

Record Type: Record

To: See the distribution list at the bottom of this message
cc:
bcc:
Subject: Re: Conrad Bill Attendees

fyi

I spoke to Fazio's and Waxman's staff today. Fazio is mulling over whether he will introduce Conrad in the House. Waxman will be supportive but sees Conrad as a floor for negotiations and not a ceiling. In particular, Waxman would like to see the penalties and ETS sections strengthened and would like to do more on advertising that doesn't depend on industry consent.
Thomas L. Freedman

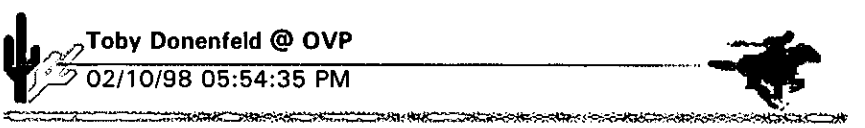


Thomas L. Freedman
02/10/98 05:54:30 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Jerold R. Mande/OSTP/EOP
cc: Laura Emmett/WHO/EOP
Subject: Conrad Bill Attendees

notice waxman and fazio.
---------- Forwarded by Thomas L. Freedman/OPD/EOP on 02/10/98 05:53 PM ----------



Toby Donenfeld @ OVP
02/10/98 05:54:35 PM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP
cc: David R Thomas/OVP @ OVP
Subject: Conrad Bill

According to Conrad's press person, (Tom Mahr isn't in) they have the following Senators confirmed to attend:

Daschle
Conrad
Bingaman
Durbin

Kennedy
Lautenberg
Leahy
Reed
and Fazio
Waxman

They're trying to find out how many others have signed on as cosponsors. I told him that we are concerned that the numbers are much lower than we originally thought.

Message Sent To:

Bruce N. Reed/OPD/EOP
Elena Kagan/OPD/EOP
Christopher C. Jennings/OPD/EOP
Donald H. Gips/OVP @ OVP
Toby Donenfeld/OVP @ OVP
Thomas L. Freedman/OPD/EOP

Tobacco - settlement -
new legislation -
Conrad bill

STATEMENT BY VICE PRESIDENT AL GORE
ANNOUNCEMENT OF "THE HEALTHY KIDS ACT"
WEDNESDAY, FEBRUARY 11, 1998

I want to thank Senator Daschle for his outstanding leadership of the Senate Democratic Caucus -- and for helping to make this issue such a priority for our party;

And I want to offer a special word of praise and gratitude to Senator Conrad, whose dedicated and extremely hard-working task force has brought us here today. Senator -- a job well-done.

[other acknowledgments to be provided by advance]

Today, we take a crucial step forward in the fight against teen smoking -- and the next big step toward writing tough anti-tobacco measures into law.

For years, America's parents and families have been outmatched -- by multi-million dollar ad campaigns targeted at our children. By secret strategies to hide the deadly effects of smoking. By nicotine addiction that captures 3,000 of our children every day -- and costs 1,000 of them their lives.

Over the past five years, President Clinton and I have been determined to change all that -- to protect our children from the number-one preventable cause of death in this country. We enacted the toughest-ever measures to cut-off children's access to tobacco, and the tobacco companies came to the bargaining table -- because they knew we meant business.

Now we have an opportunity to build on the landmark tobacco settlement that was reached last June. We have a chance to pass bipartisan, comprehensive legislation that dramatically reduces teen smoking -- and changes the way tobacco companies do business forever.

The President has made clear that there are five core principles that must be met for any bill to receive his signature: One, it must raise the price of cigarettes by up to $1.50 a pack over the next 10 years, including penalties on the tobacco industry if it keeps marketing to children. Two, it must give the FDA full authority to regulate nicotine as a drug. Three, it must require tobacco companies to disclose information on the dangers of their products. Four, it must advance other crucial health goals, like reducing second-hand smoke. And five, it must protect the economic welfare of tobacco farmers and their communities.

The President asked me to take the lead in rallying Congressional and public support behind these principles, and in the past five months, I have held bipartisan tobacco forums all across this country. This much is certain: support for tough anti-tobacco measures crosses all lines of party and politics. There is no such thing as Democratic or Republican nicotine addiction.

Today, just two weeks after Congress has come back to work, Senator Conrad and his colleagues have come forward with legislation that meets all five of the President's principles -- and therefore meets America's challenge of reducing teen smoking. I can say that the President would be proud to sign this bill, as he would be proud to sign any bill that does as much to meet his goals and principles.

And while I stand here today with dedicated Democrats who are fighting to reduce teen smoking, I know there is strong commitment to this issue on both sides of the aisle. In the coming days and weeks, I hope and expect that many Republicans will join us -- on this or other bills that meet our core principles. Ultimately, any successful bill must have broad, bipartisan support. The President and I are committed to working with members of both parties to shape the best ideas and proposals into a truly bipartisan bill.

And like Senator Conrad's bill, any successful bill must meet all five of the President's principles. Teen smoking is a comprehensive problem, and it demands a comprehensive solution. The President and I cannot get behind a watered-down, piecemeal bill -- one that ducks the problem of teen smoking, instead of dealing with it. That is why we are insisting that Congress meet all five principles -- including a substantial price increase on a pack of cigarettes, and other measures to cut teen smoking in half.

Our call for a price increase is not about money; it's about our children's health. Without a substantial increase in the price of a pack of cigarettes, we simply will not achieve our goal of dramatically reducing teen smoking. And that has always been our sole and central goal.

I ask every member of Congress, of both parties: follow the example of these Senators. Support this legislation, or come forward with your own bill that meets our five principles. We've got to seize this historic opportunity, and build on this growing coalition. This can be the Congress that finally protects our children from nicotine addiction and disease -- and gives America the healthy kids and families we deserve.

Senate Democratic Task Force Tobacco Legislation

Democratic Caucus Review
2/10/98

Tobacco minimum - new legislation - Conrad bill

What Conrad wants to want.

The HEALTHY Kids Act

Responsible Tobacco Policy

- Protects Children
- Promotes the Public Health
- Helps Tobacco Farmers
- Resolves Federal, State and Local Legal Claims
- Invests in Children and Health Care
- Savings for Social Security and Medicare
- Reimburses Taxpayers

The HEALTHY Kids Act

Protects Children

1. A Healthy Price Increase
   - $1.50/pack health fee (phased in over three years)
2. Full FDA Authority
3. Strong Look-back Penalties
   - targets 2/3 reduction in youth smoking
   - penalties of 10 cents/pack on industry, 40 cents/pack on companies
4. Comprehensive Anti-tobacco Programs
   - counter-advertising, prevention, cessation, research
5. Retailer Compliance
   - State licensure
   - No sales to minors

The HEALTHY Kids Act
Promotes the Public Health

1. Second Hand Smoke
   - covers most public facilities
   - exempts bars, casinos, bingo parlors, hotel guest rooms, non-fast food small restaurants, prisons, tobacco shops, and private clubs
   - no state or local pre-emption
2. Document Disclosure
   - all relevant documents go to FDA
   - FDA makes public all documents
   - public health interest over-rides trade secret or attorney client privileges
3. International Tobacco Marketing Controls
   - no promotion of US tobacco exports
   - code of conduct: no marketing to foreign children
   - funds international tobacco control efforts
   - requires warning labels

The HEALTHY Kids Act

Helps Tobacco Farmers

1. Provides $10 billion over five years for assistance to farmers and their communities
2. Authorizes funding for--
   - Transition payments to farmers and quota holders
   - Rural and community economic development
   - Retraining for tobacco factory workers and tobacco farmers
   - College scholarships for farm families

The HEALTHY Kids Act

No Immunity

1. No special protection for future misconduct
2. No special protection against individuals' lawsuits for past misconduct
3. Resolves Federal, State and Local legal claims
   - States can opt-out of money and continue lawsuits
   - Cities and counties get a fair share of reimbursement
4. Attorney's Fees
   - Resolved by arbitration panel using ABA guidelines

The HEALTHY Kids Act

Invests in Children and Health, Savings for Social Security and Medicare, Reimburses Taxpayers

1. Payments to States (~~38~~ 41.5%)
   - unrestricted (~~15~~%) 14.5%
   - children's health care, child care, education (~~23~~%) 27%
2. Anti-tobacco Programs (~~17~~%) 15.5%
3. NIH Research (~~22~~%) 21%
4. Medicare (4% initially; grows to 10[redacted]%)
5. Social Security (6% initially; grows to 12[redacted]%)
6. Farmers ([redacted]% for first ten years, then phases out) 12%

Comparison of Tobacco Revenue and Spending

President's Budget and Healthy Kids Act

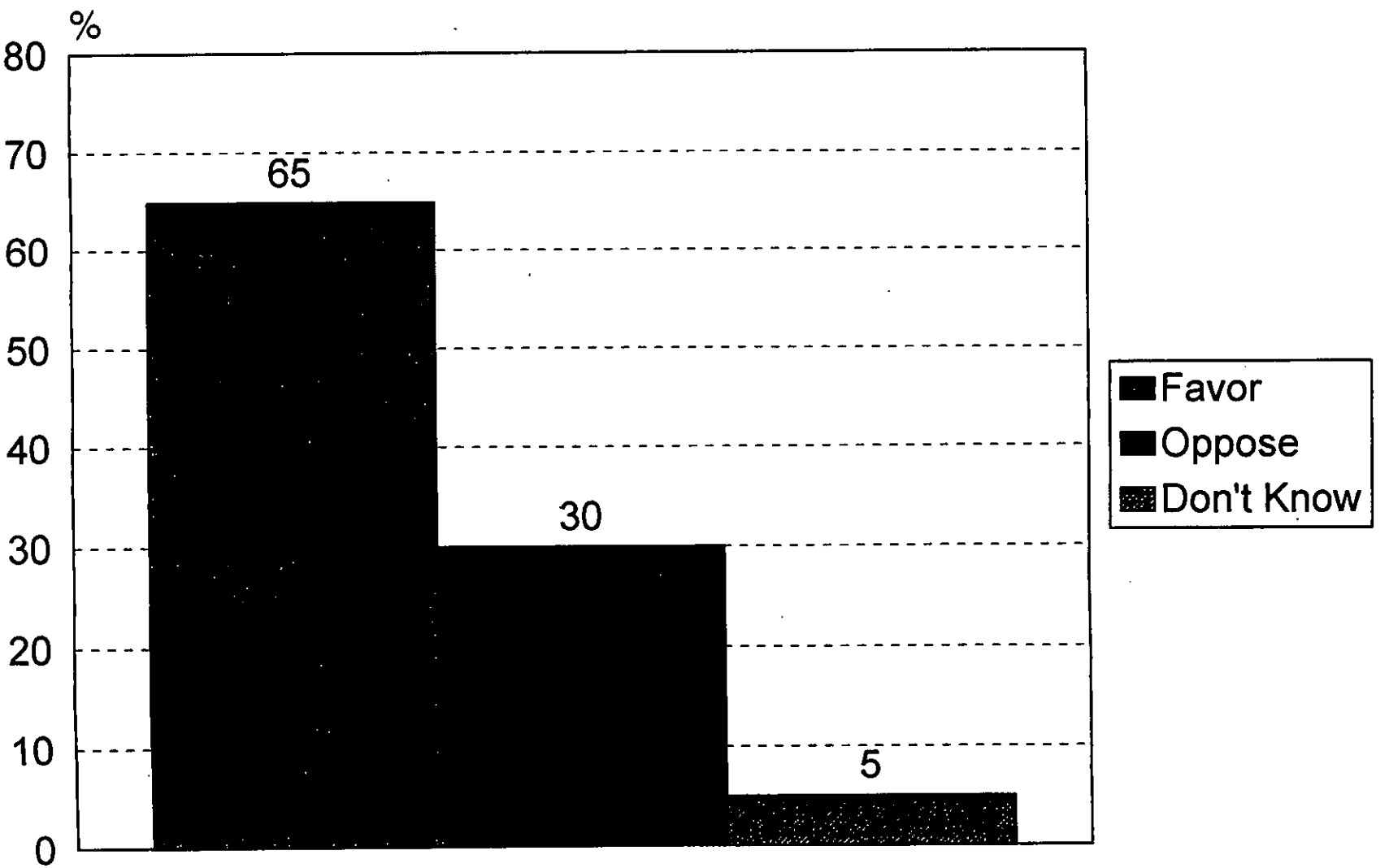
	Healthy Kids Act	President's Budget
Total Revenue (over five years)	about ~~$78~~ 82 billion (estimate pending)	$65.5 billion
States -- unrestricted	$12 billion	$11.8 billion
States -- for child care, education, health insurance (5B) (3B) (14B)	~~$18~~ 22 billion	$15.7 billion
Research	$17 billion for NIH research	$25.3 billion ($17 B for NIH; $8 B for non-health)
Medicare	$3 billion	$0.8 billion
Farmers Anti-tobacco	$10 billion $13 billion	$12.1 billion for both
Savings for Social Security	$5 billion	0

Five Year Projections

Polling Data Shows High Level of Support for:

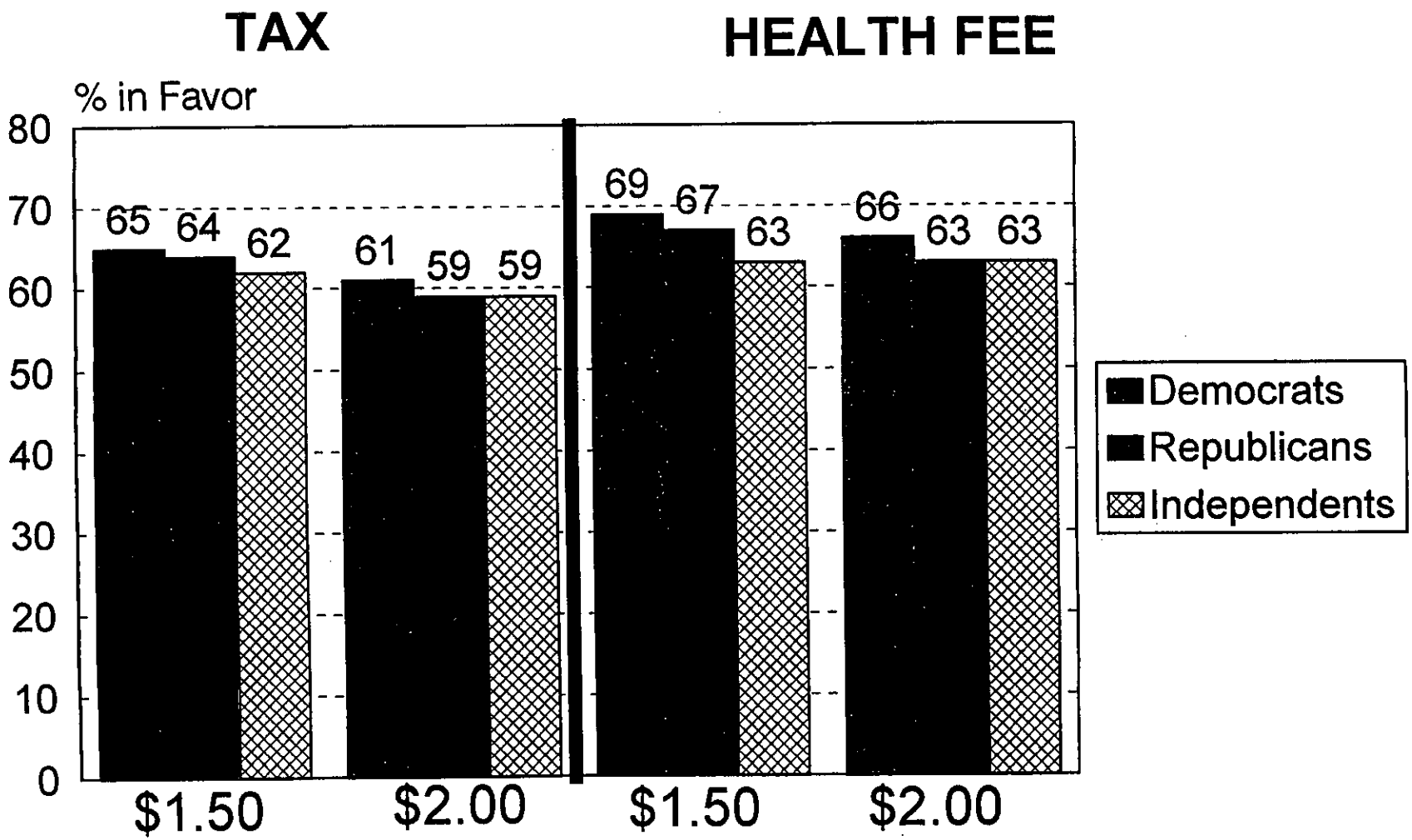
- Significant Per Pack Price Increase
- Strong Lookback Penalties
- No Industry Special Protections

Voters Support a $1.50 Health Fee for Youth Smoking Deterrence & Health Programs by a 2-1 Margin



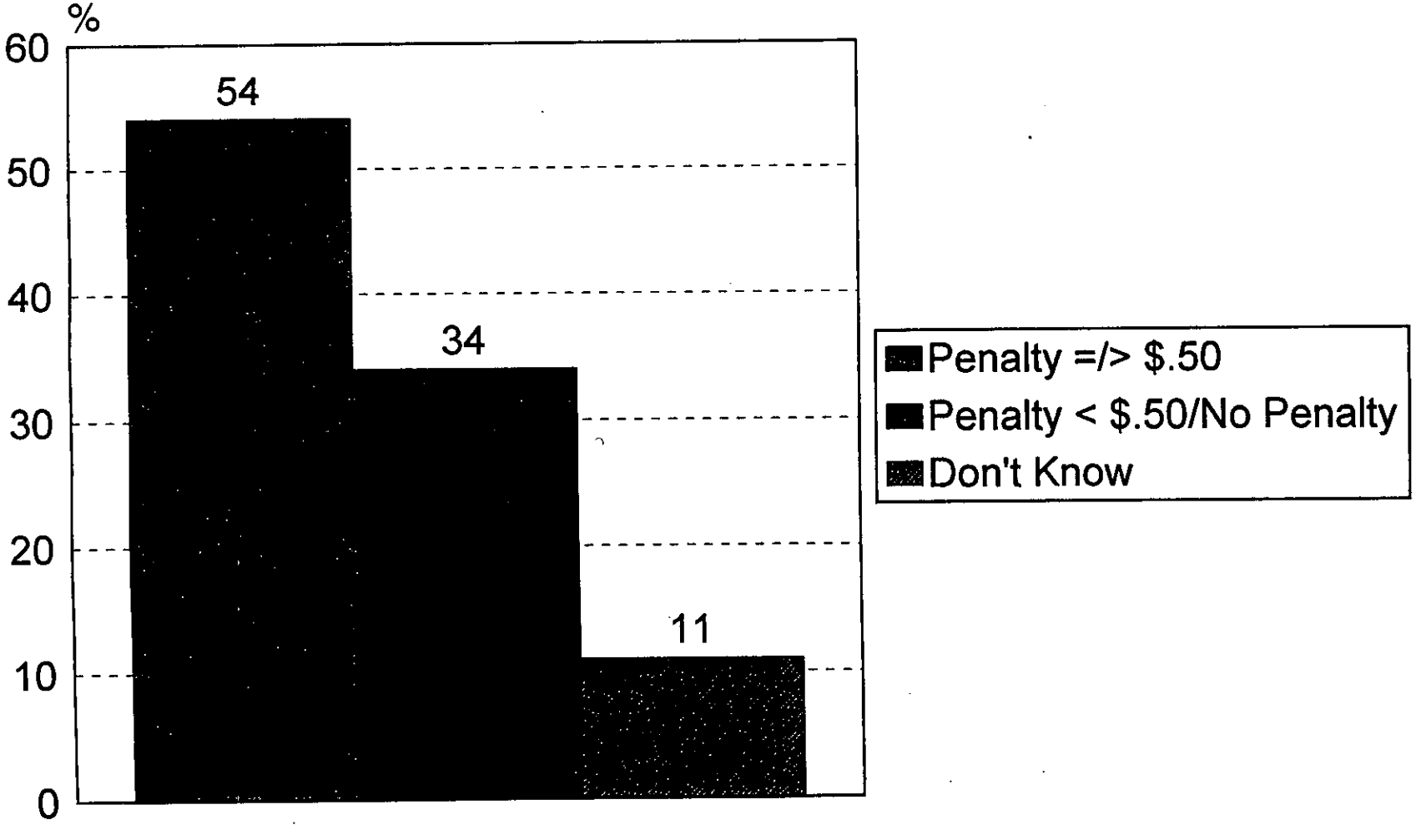
Source: Lake, Sosin, Snell, Perry Assoc. Survey, 1/98

Price Increase Support for Youth Smoking Deterrence and Health Programs Cuts Across Party Lines



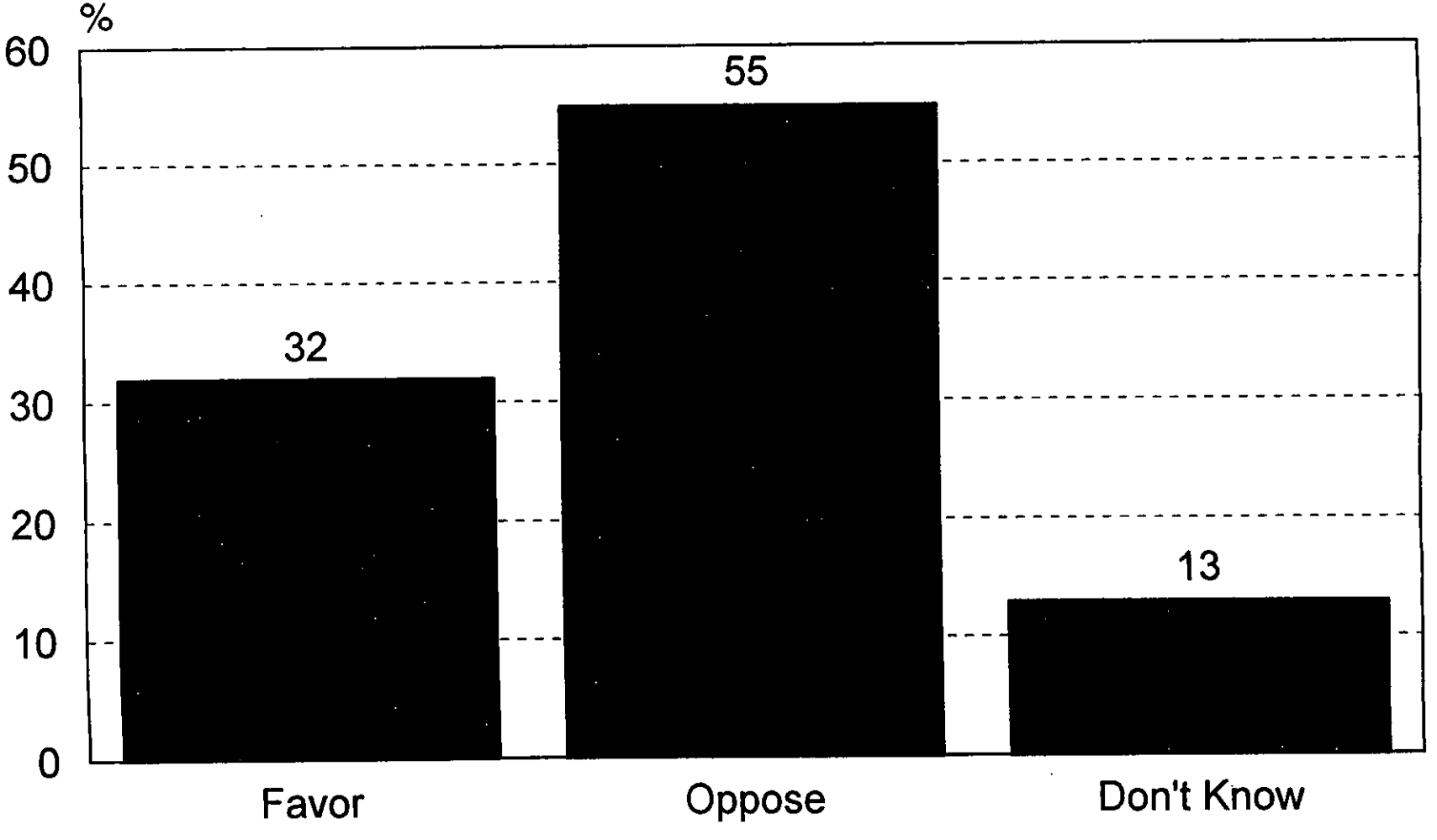
Source: Lake, Sosin, Snell, Perry Assoc. Survey, 1/98

Strong Support for Lookback Penalty of $.50 or More



Source: Lake, Sosin, Snell, Perry Assoc. Survey, 1/98

Voters Are Opposed to Providing Special Protections to the Tobacco Industry



Source: Lake, Sosin, Snell, Perry Assoc. Survey, 1/98

HEALTHY Kids Act Accomplishes President Clinton's Objectives

President Clinton's Tobacco Principles	HEALTHY Kids Act
Reduce Teen Smoking Including Tough Penalties	X
Full FDA Authority	X
Change Industry Culture	X
Meet Additional Health Goals	X
Protect Tobacco Farmers and Communities	X

Tobacco settlement - new legislation - Conrad bill

EK - Draft cheat sheet for 3:30 mtg. Tom

DRAFT ONLY
February 9, 1998 (2:47pm)

How money is spent	Conrad bill	Clinton Administration FY 1999 Budget
Allocated to States	38%	
Allocated to Federal programs	17% to following three public health programs	
FDA enforcement	$300,000,000 of 17%	$100,000,000 in 1st year $200,000,000 in 2nd year $300,000,000 in years 3-5
Indian Health Service	$200,000,000 of 17%	N/A
Health programs	rest of 17%	
Research Fund for NIH	22%	Budget goes to NIH research and other research (Conrad bill is just to NIH) 3,600,000,000 in 1st year 4,600,000,000 in 2nd year 5,000,000,000 in 3rd year 5,700,000,000 in 4th year 6,300,000,000 in 5th year
Agricultural Programs	1) To the Tobacco Community Revitalization Trust Fund -- 15% for the 1st 10 years; 5% for yrs 11-15; and 3% for yrs 16-25	Part of "Other Uses" Section which totals 22.3B over 5 yrs
Hospital Insurance Trust Fund (Medicare)	2% for 1st 10 yrs; 7% for yrs 11-15, 8% for yrs 16-25, and 9.5% thereafter	
Reducing Public Debt	6% for 1st 10 yrs; 11% for yrs 11-15; 12% for yrs 16-25, and 13.5% thereafter	

February 9, 1998 (2:47pm)

Issue	Conrad Bill	Administration Plan
Admin. #1: Plan to reduce youth smoking	1) Penalties -at least 20% in years 2000-2001; at least 35% in years 2002-2003; at least 50% in 2004-2006; at least 67 for 2007 and thereafter 2) Per pack Price increases $0.50 in 1999 $1.00 in 2000 $1.50 in 2001	1) Penalties: 30% in 5 yrs, 50% in 7 yrs, and 60% in 10 yrs 2)FY 99 Budget price per pack increases: 62 in 1999, 85 in 2000 97 in 2001 $1.00 in 2002 $1.10 in 2003 3) Advertising campaign 4) FDA efforts to reduce youth access
Admin. #2: FDA Authority	Full FDA Authority	Full FDA Authority
Admin #3: Tobacco Industry Chg the Way It Does Business	1) disclosure of existing and future documents (s.711)	1) broad document disclosure 2) comprehensive corporate compliance programs
Admin. #4: Other Public Health Goals	1) reduces second-hand smoke in public facilities excluding bars 2) smoking cessation 3) 0.67% to WHO and foreign countries; also 0.33% establish non-profit American Ctr. On Global Health and Tobacco (ACT) 4) NIH research	1) reduction of second-hand smoke 2) smoking cessation 3) International efforts to control tobacco 4) Funds for health research
Admin. #5: Farmers	Tobacco Community Revitalization Trust Fund: to provide transition assistance to producers and communities, including econ dev assistance, retraining, and scholarships	Protect financial well-being of farmers

Minorities	$200,000,000 to Indian Health Service (s.101(d)(2)); FDA regulations, licensing requirements apply. Also tribes are entitled to public health payments	
Exports	May not promote the export or use of tobacco in a foreign country (smuggling not mentioned)	
Drugs and devices	FDCA is amended to treat tobacco as a drug and device (s.203)	

Tobacco settlement - new legislation - Conrad bill

Tom Arrendale

BR/EK
Conrad summary
They asked for close hold.
Tom

Summary of Proposed Tobacco Legislation

I. HEALTHY Kids Payment and Trust Fund.

Establishes a Health Enhancement and Lowered Tobacco Hazards for Young (HEALTHY) Kids Trust Fund. The trust fund will be financed by a HEALTHY Kids license payment (not a tax, but structured as a per pack payment), and will be used to pay for tobacco control programs, partial reimbursement of state and Federal health costs, compensation for farmers, other public health efforts, and child care. The HEALTHY Kids payment will be 50 cents per pack in 1999, $1.00 per pack in 2000 and $1.50 per pack in 2001. Thereafter it will be indexed to inflation. Equivalent payments will be made on other tobacco products. These payments will not be tax deductible.

II. FDA Regulation of Tobacco

Statutorily affirm the authority of the FDA to regulate tobacco as a drug and drug delivery device, including the manufacture, sale, distribution, marketing, and advertisement of tobacco products. Language will be included to restore provisions of the rule invalidated by the Federal District Court. FDA will have the authority to require product modification. Regulation would be via standard, informal "notice and comment" rulemaking. FDA would have the full civil and criminal authorities to enforce its regulations, including required warning labels. Manufacturers would be required to make full disclosure to FDA concerning all aspects of tobacco product development, including disclosing ingredients to FDA. FDA could make information public provided that it takes appropriate action to guard against leaking trade secrets (similar to current law on food and cosmetic ingredient labeling). Enforcement of these regulations would be funded from the HEALTHY Kids Trust Fund.

III. Youth Smoking Reduction Incentives

Sets targets for youth smoking reductions in years 3, 5, 7 and 10. Gives tobacco manufacturers an incentive to meet these targets by imposing non-tax deductible penalty payments for missing the targets. The penalties will escalate as distance from the target increases. They would be assessed on a company-specific basis, and possibly an industry-wide basis.

IV. Assistance to Farmers and Farming Communities

Incorporates the Ford proposal to help tobacco farmers and communities impacted by reductions in tobacco consumption.

V. Environmental Tobacco Smoke

Restrict smoking in public buildings to areas that are separately ventilated. Bars, hotel guest rooms, casinos, and prisons would be exempted. Prohibit smoking in schools, child care facilities, and other facilities utilized primarily by children and on public transportation. Specifically allow states and localities to enact stricter regulations.

VI. Document Disclosure and Industry Compliance

Manufacturers would be required to disclose relevant documents to FDA, which would make

public all non-privileged documents in a document depository in Washington, D.C. FDA would be granted subpoena power to seek all information (documents and witnesses) relevant to tobacco product development, addiction, health risks, and marketing to kids. FDA and DOJ would be given authority to enforce the disclosure provisions. The FDA could require that privileged documents be made public when there is a public health interest in doing so (but preserving legitimate non-health-related trade secrets).

VII. Retailers

States would be required to set up a licensing scheme for tobacco retailers as a condition of receiving funds from the HEALTHY Kids Trust Fund. The licensing scheme would follow the general outlines of the June 20th proposal but would reflect input from convenience store operators with respect to penalties for employees and sanctions for youths who illegally purchase tobacco products.

VIII. International Tobacco Control

Prohibit all forms of Federal assistance for overseas promotion of US tobacco products. Restrict the ability of USTR to challenge other countries' domestic tobacco regulation to cases of National Treatment violations. Small contribution from HEALTHY Kids Trust Fund to international tobacco control efforts (direct government-to-government, through WHO and via NGOs).

IX. State and Local

No pre-emption of state and local tobacco control laws

X. Liability Protection

As a condition of receiving funds under this act, States would be forbidden from bringing suit against tobacco companies for past actions of tobacco companies. States would be required to establish a mechanism for reimbursing counties and localities for any similar claims, which would likewise be barred. States that choose not to accept the monies made available under this act would be free to pursue all litigation against tobacco companies.