

Tobacco -
FDA**CAMPAIGN For TOBACCO-FREE Kids****NATIONAL CENTER FOR TOBACCO-FREE KIDS****Facsimile Transmission**

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TO:

FROM:

DATE:

SUBJECT:

This is something I did for the ALA but I know the public health community has concerns about a "separate chapter" for FDA.



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**WHY A SEPARATE "CHAPTER" FOR TOBACCO PRODUCTS IS
NOT THE PREFERRED METHOD OF FDA REGULATION OF
TOBACCO PRODUCTS**

1. Tobacco products are medically, scientifically, and legally "drugs" and or "devices" under the Food Drug and Cosmetic Act. This view is supported by the public health community, the Food and Drug Administration as well as the tobacco industry's own internal documents and statements. The Food and Drug Administration has already claimed jurisdiction and is already using its existing authorities to regulate the sales and marketing of tobacco products to children. Treating such products as anything less than a "drug" would not be in the interests of the public health community, and would continue the special treatment and exceptions that have been provided to the tobacco industry for more than three decades.
2. The purpose of the "drug" and "device" provisions of the Act and the purpose and mission of the FDA itself is to not only ensure that safe and effective drug and device products are brought to the market place but to ensure that adulterated, misbranded and unsafe products are either kept off the market or appropriately controlled and regulated.
3. The definition of a drug and a device under the Food Drug and Cosmetic Act was intended by Congress to encompass and deal with products which were not listed in drug registries but which were intended by the manufacturer to "affect function and structure of the body" as well as intended "to mitigate or prevent disease". (i.e. low tar and nicotine). The legislative history of the Act as well as case law dating back to the 1950's clearly establishes the coverage of the FD&C Act over tobacco products.
4. FDA has a long standing history of regulating a myriad of products under its drug and device authorities; including the manufacturing sales and distribution, labeling and advertising and marketing of such products.
5. Tobacco products and the nicotine contained in them should be viewed as a "class" of drugs related to the use, abuse, and cessation of tobacco products. It makes sense to ensure that such products are regulated in a consistent and comprehensive manner – with the higher risk products being regulated more stringently and with the lower risk cessation products being subjected to less regulation.
6. There is well established regulatory and judicial case law for FDA regulation of "drugs" and "devices" Retaining FDA authorities over tobacco as "drugs" and or "devices" allows the agency to draw on years of regulatory experience as well as well established case law governing the regulation of "drugs" and "devices". Establishing a new chapter could subject the FDA to endless lawsuits from the tobacco companies, who if their past actions are any indication would challenge every rule and regulation issued under a new regulatory scheme. Relying on well established authorities and procedures will limit such actions by the companies and more effectively ensure protection of the public health.



White House Press Release

REMARKS BY THE PRESIDENT ON TOBACCO SETTLEMENT REVIEW

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

September 17, 1997

REMARKS BY THE PRESIDENT ON **TOBACCO** SETTLEMENT REVIEW

The Oval Office

10:55 A.M. EDT

THE PRESIDENT: Thank you very much. Mr. Vice President, Secretary Shalala, Secretary Glickman, thank you for your work. Thank you, Bruce Reed. I'd like to say a special word of thanks to David Kessler for the work he did -- historic work he did at the FDA when he was here. Thank you, Dr. Koop, and members of the public community who are here. To members of Congress, the Attorneys General, the representatives of plaintiffs in the private litigation -- and we have one of the injured parties here representing all of the them. We thank all of them for coming today.

This is a time of prosperity and hope and optimism for America, with our economy improving, making progress on our social problems, our efforts to lead the world to a more prosperous and peaceful future making headway. But I think we all know that this country still has some significant challenges, especially in the health field. And if we think about what we want America to be like in the 21st century, the health of our people and especially the health of our children must be paramount in our thinking, in our vision, and in our efforts.

That's why, a year ago, I worked with the FDA and we launched this nationwide effort to protect our children from the dangers of **tobacco** by reducing youth access to **tobacco** products, by preventing companies from advertising to our children.

The purpose of the FDA rule was to reduce youth smoking

would be willing to work with us. But we cannot have the FDA crippled here, and we have to have real and meaningful penalties if the targets for youth smoking are not met. And so I feel very good about that.

I think the Congress -- I think it's highly likely that they will take action. When they take action depends, I think, upon when they can work through the issues for themselves and how they decide how to divide up the work among the committees. But it's not too soon to start. We could have hearings on this fairly soon, and I would hope to work with the Congress to develop a bill that would embody these principles.

Q Mr. President, you haven't said what you're willing to agree to for the **tobacco** industry. Are you will to agree to immunity from future **liability**?

THE PRESIDENT: Well, I don't think they've asked for future **liability**, I think they've asked for immunity from **liability** for past suits. And the question there would be, what are they willing to agree to. They need to come and meet with us. We need to discuss it, and we need to see whether we can embody these five principles. These are the things I'm interested in.

To me, I'll say again, this is not primarily about money. This is about changing the behavior of the United States, both the behavior of the **tobacco** companies, the behavior of the American people, the future behavior of our children. I'm trying to create an environment here with these five principles that I believe would achieve that. And if they want to be our partners in it, I think we can get there. And I hope they will be.

Q Are you willing to put your prestige on the line to ensure that this becomes law?

THE PRESIDENT: Well, I think my personal prestige on this has been on the line for more than a year now. (Laughter.) There for a while, I thought more than my prestige was on the line. (Laughter.) You know, for a person involved in public life in Washington today, personal prestige may be an oxymoron. (Laughter.) But at least you still have your neck most days.

Q What do you say to the people -

Q -- protect the well-being of **tobacco** farmers - sounds like you're going to take away their livelihood.

THE PRESIDENT: Well, there are a number of things which can be done, and I don't want to get into the details. Secretary Glickman can talk about it. But we have had farmers in various sectors in our agriculture society facing constricted incomes before, and we have done things which helped them. There was a -- for example, I remember a few years ago something that affected dairy farmers in my state. There was a massive buy-out program for dairy farmers, and in a lot of states like Arkansas, there were any number of small farmers that were having a very difficult time who had a chance to start their life on a different basis.

I don't want to minimize this. **Tobacco** has a very high return per acre. So it's not a simple thing. You can't just say to a **tobacco** farmer to go plant soybeans, even if the soil will hold them. This is, from an agricultural point of view, economically complex. But, nonetheless, we have a responsibility to these people. They haven't done anything wrong. They haven't done anything illegal. They're good, hard-working, tax-paying citizens, and they

105TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. JEFFORDS introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act and the Food, Drug and Cosmetic Act to provide for reductions in youth smoking, for advancements in tobacco-related research, and the development of safer tobacco products, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “_____ Act”.

6 (b) TABLE OF CONTENTS.—The Table of contents
7 for this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Goals and purposes.

Sec. 4. National goals for the reduction in underage tobacco use.

Sec. 5 Definitions

TITLE I—REGULATION OF TOBACCO PRODUCTS AND TOBACCO
PRODUCT DEVELOPMENT

Sec. 101. Regulation of tobacco products and tobacco product development.

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

“Sec. 900. Definitions.

“SUBCHAPTER A—TOBACCO PRODUCT REGULATION

“Sec. 901. Statement of general duties.

“Sec. 902. Tobacco product health risk management standards.

“Sec. 903. Good manufacturing practice standards.

“Sec. 904. Tobacco product labeling, warning, and packaging standards.

“Sec. 905. Restriction on marketing and advertising.

“Sec. 906. Reduced risk tobacco products.

“Sec. 907. Tobacco product marketing restrictions.

“Sec. 908. Tobacco Products Scientific Advisory Committee.

“Sec. 909. Reports.

“Sec. 910. Judicial review.

“Sec. 911. Authority to assess and use fees.

“Sec. 912. Preemption.

Sec. 102. Technical provisions.

Sec. 103. Federal licensing of military and other entities.

TITLE II—NATIONAL EFFORTS TO REDUCE YOUTH SMOKING

Sec. 201. Short title.

Sec. 201. Amendment to Public Health Service Act

“TITLE XXVIII—NATIONAL EFFORTS TO REDUCE YOUTH
SMOKING

“Sec. 2801. Definitions.

“Subtitle A—Required Reduction in Underage Use of Tobacco Products

“Sec. 2811. Purpose.

“Sec. 2812. Determination of underage use base percentages.

“Sec. 2813. Annual daily incidence of underage use of tobacco products.

“Sec. 2814. Required reduction in underage tobacco use.

“Sec. 2815. Application of surcharges.

“Sec. 2816. Abatement procedures.

“Sec. 2817. Incentive for exceeding reduction goals.

“Subtitle B—Restriction on Access to Tobacco Products

“Sec. 2821. [to be supplied]

“Subtitle C—State and Community Action Program

“Sec. 2831. Funding from Tobacco Settlement Trust Fund.

“Sec. 2832. Allotments.

“Sec. 2833. Payments under allotments to States.

- “Sec. 2834. Use of allotments.
- “Sec. 2835. Application for payments; State plan.
- “Sec. 2836. Reports, data, and audits.
- “Sec. 2837. Withholding.
- “Sec. 2838. Nondiscrimination.
- “Sec. 2839. Criminal penalty for false Statements.

“Subtitle D—Smoking Cessation Programs

- “Sec. 2841. Funding from tobacco settlement trust fund.
- “Sec. 2842. Allotments.
- “Sec. 2843. Payments under allotments to States.
- “Sec. 2844. Use of allotments.
- “Sec. 2845. Application for payments; State plan.
- “Sec. 2846. Reports, data, and audits.
- “Sec. 2847. Withholding.
- “Sec. 2848. Nondiscrimination.
- “Sec. 2849. Criminal penalty for false Statements.

“Subtitle E—Tobacco-Related Research Initiatives

- “Sec. 2851. Interagency council for reducing smoking and use of tobacco products for the long term. **[to be supplied]**
- “Sec. 2852. Study by the institute of medicine. **[to be supplied]**
- “Sec. 2853. Demonstration grants for reducing smoking and use of tobacco products for the long term. **[to be supplied]**

“Subtitle F—National Public Education Campaign

- “Sec. 2861. **[to be supplied]**

**TITLE III—STANDARDS TO REDUCE INVOLUNTARY EXPOSURE TO
TOBACCO SMOKE**

Sec. 301. **[TO BE SUPPLIED]**

1 SEC. 2. FINDINGS.

2 Congress makes the following findings:

3 (1) Tobacco is an addictive substance the use of
4 which constitutes the Nation’s number 1 preventable
5 cause of death.

6 (2) The use of tobacco products by the nation’s
7 children is a serious and growing public health prob-
8 lem that results in new generations of tobacco-de-
9 pendent children and adults.

1 (3) There is a consensus within the scientific
2 and medical communities that currently marketed
3 tobacco products are inherently unsafe and cause
4 cancer, heart disease, and other serious adverse
5 health effects.

6 (4) Virtually all new users of tobacco products
7 are under the age of 18. Tobacco industry advertis-
8 ing and marketing is directed at adolescents and as
9 such, sweeping new restrictions on the sale, pro-
10 motion, and distribution of such products are need-
11 ed.

12 (5) The Office on Smoking and Health has
13 found that more than 70 percent of the nation's
14 50,000,000 current smokers have tried unsucces-
15 sfully to quit, and about 20,000,000 try to quit each
16 year, with little success.

17 (6) Current research shows that new and cost-
18 effective treatments are available that could dramati-
19 cally improve the success rate of smoking cessation
20 attempts.

21 (7) While State laboratory models, such as
22 those developed in California and Massachusetts,
23 demonstrate that comprehensive programs to reduce
24 tobacco use can be effective, tobacco-related re-
25 search, including policy-oriented, programmatic, be-

1 havioral, and biomedical research should be a sub-
2 stantial component of a national program to reduce
3 the use of tobacco products.

4 (8) Enhancing the available prevention, re-
5 search, and treatment resources with respect to to-
6 bacco will allow our Nation to address more effec-
7 tively the problems associated with the use of to-
8 bacco products.

9 **SEC. 3. GOALS AND PURPOSES.**

10 (a) GOALS.—It is a goal of this Act to—

11 (1) decrease youth smoking and reduce the
12 marketing of tobacco products to young Americans;

13 (2) decrease tobacco use by all Americans by
14 encouraging public education and smoking cessation
15 programs and to decrease the exposure of individuals
16 to environmental (second-hand) smoke;

17 (3) develop effective strategies to prevent the
18 underage use of tobacco products;

19 (4) advance our knowledge of the health effects
20 of nicotine and tobacco products on the human body,
21 the factors that influence behavior related to the use
22 and nonuse of tobacco products, and the factors that
23 influence successful cessation efforts;

1 (5) establish the authority of the Food and
2 Drug Administration with respect to the types of to-
3 bacco products that may be lawfully sold; and

4 (6) invest tobacco revenues in important public
5 health priorities, such as smoking cessation, public
6 education, counter-advertising.

7 (b) PURPOSES.—It is the purpose of this Act to—

8 (1) provide for the funding by the tobacco in-
9 dustry of an aggressive **【Federal enforcement pro-**
10 **gram】** relating to tobacco advertising and distribu-
11 tion, including a State-administered retail licensing
12 system to prevent minors from obtaining tobacco
13 products;

14 (2) subject the tobacco industry to severe finan-
15 cial penalties in the event that underage tobacco
16 usage does not decline radically over the next 10
17 years;

18 (3) provide annual payments to the States to
19 fund comprehensive tobacco education and use pre-
20 vention programs at the State and community levels;

21 (4) provide annual payments to States to fund
22 effective smoking cessation treatment efforts;

23 (5) provide for the establishment of national
24 standards to control the manufacturing of tobacco
25 products and the ingredients used in such products;

1 (6) provide certain regulatory powers to the
2 Secretary of Health and Human Services to encour-
3 age the development and marketing by the tobacco
4 industry of "less hazardous tobacco products", in-
5 cluding the power to regulate the level of nicotine in
6 such products;

7 (7) provide for the establishment of a national
8 education-oriented counter advertising and tobacco
9 use prevention campaign to be funded through the
10 National Tobacco Settlement Trust Fund; and

11 (8) establish a minimum Federal standard to
12 limit smoking in public places, including the halls of
13 Congress.

14 **SEC. 4. NATIONAL GOALS FOR THE REDUCTION IN UNDER-**
15 **AGE TOBACCO USE.**

16 (a) **IN GENERAL.**—With respect to the average an-
17 nual incidence of the daily use of tobacco products by indi-
18 viduals who are under 18 years of age, it shall be the na-
19 tional goals of the United States that such use be reduced
20 as follows:

21 (1) **CIGARETTES.**—With respect to cigarettes—

22 (A) in the fifth and sixth calendar years
23 after the date of enactment of this Act the per-
24 centage decrease in the use of cigarette prod-
25 ucts shall be at least 30 percent;

1 (B) in the seventh, eighth and ninth cal-
2 endar years after the date of enactment of this
3 Act the percentage decrease in the use of ciga-
4 rette products shall be at least 50 percent; and

5 (C) in the tenth and subsequent calendar
6 years after the date of enactment of this Act
7 the percentage decrease in the use of cigarette
8 products shall be at least 60 percent.

9 (2) SMOKELESS TOBACCO PRODUCTS.—With re-
10 spect to smokeless tobacco products—

11 (A) in the fifth and sixth calendar years
12 after the date of enactment of this Act the per-
13 centage decrease in the use of smokeless to-
14 bacco products shall be at least 25 percent;

15 (B) in the seventh, eighth and ninth cal-
16 endar years after the date of enactment of this
17 Act the percentage decrease in the use of
18 smokeless tobacco products shall be at least 35
19 percent; and

20 (C) in the tenth and subsequent calendar
21 years after the date of enactment of this Act
22 the percentage decrease in the use of smokeless
23 tobacco products shall be at least 45 percent.

24 (b) DETERMINATIONS.—Determinations as to wheth-
25 er the national goals described in subsection (a) have been

1 met shall be made in accordance with the provisions of
2 subtitle B of title III.

3 **TITLE I—REGULATION OF TO-**
4 **BACCO PRODUCTS AND TO-**
5 **BACCO PRODUCT DEVELOP-**
6 **MENT**

→ Sec. 5 Definitions

7 **SEC. 101. REGULATION OF TOBACCO PRODUCTS AND TO-**
8 **BACCO PRODUCT DEVELOPMENT.**

9 (a) PROHIBITED ACTS.—Section 301 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
11 ed by adding at the end the following:

12 “(x) The introduction or delivery for introduction into
13 interstate commerce of any tobacco product that does not
14 comply with the provisions of chapter IX.

15 “(y) The failure by the manufacturer of a tobacco
16 product to comply with a tobacco product health risk man-
17 agement standard, a good manufacturing practice stand-
18 ard, a tobacco product labeling, warning or packaging
19 standard, or any other requirement of chapter IX.”.

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

23 (1) in subparagraph (A), by striking “or cos-
24 metics” each place that such appears and inserting
25 “, cosmetics, or tobacco products”; and

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

4 (c) REGULATION OF TOBACCO PRODUCTS.—The
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
6 et seq.) is amended—

7 (1) by redesignating chapter IX as chapter X;

8 (2) by redesignating sections 901, 902, 903,
9 904, and 905 as sections 1001, 1002, 1003, 1004,
10 and 1005, respectively; and

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

13 “CHAPTER IX—HEALTH AND SAFETY REGU-
14 LATORY REQUIREMENTS RELATING TO TO-
15 BACCO PRODUCTS

16 “SEC. 900. DEFINITIONS.

17 “In this chapter:

18 “(1) CIGARETTE.—The term ‘cigarette’ means
19 any product which contains nicotine, is intended to
20 be burned under ordinary conditions of use, and con-
21 sists of—

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

24 “(B) any roll of tobacco wrapped in any
25 substance containing tobacco which, because of

1 its appearance, the type of tobacco used in the
2 filler, or its packaging and labeling, is likely to
3 be offered to, or purchased by, consumers as a
4 cigarette described in subparagraph (A).

5 “(2) CIGARETTE TOBACCO.—The term ‘ciga-
6 rette tobacco’ means any product that consists of
7 loose tobacco that contains or delivers nicotine and
8 is intended for use by persons in a cigarette. Unless
9 otherwise stated, the requirements of this title per-
10 taining to cigarettes shall also apply to cigarette to-
11 bacco.

12 “(3) NICOTINE.—The term ‘nicotine’ means the
13 chemical substance named 3-(1-Methyl-2-
14 pyrrolidinyl)pyridine or $C_{10}H_{14}N_2$, including any salt
15 or complex of nicotine.”.

16 “(4) SMOKELESS TOBACCO.—The term ‘smoke-
17 less tobacco’ means any product that consists of cut,
18 ground, powdered, or leaf tobacco that contains nico-
19 tine and that is intended to be placed in the oral or
20 nasal cavity.

21 “(5) TAR.—The term ‘tar’ means mainstream
22 total particulate matter minus nicotine and water.

23 “(6) TOBACCO ADDITIVE.—The term ‘tobacco
24 additive’ means any substance the intended use of
25 which results or may reasonably be expected to re-

1 sult, directly or indirectly, in the substance becoming
2 a component of, or otherwise affecting the character-
3 istics of, any tobacco product, including any sub-
4 stance that may have been removed from the tobacco
5 product and then readded in the substance's original
6 or modified form.

7 “(7) TOBACCO PRODUCT.—The term ‘tobacco
8 product’ means cigarettes and smokeless tobacco
9 products for which no therapeutic claim is made.

10 **“Subchapter A—Tobacco Product Regulation**

11 **“SEC. 901. STATEMENT OF GENERAL DUTIES.**

12 “As part of the comprehensive health promotion and
13 disease prevention program established under this chapter
14 and the _____ Act (and the amendments made
15 by such Act) relating to diseases and conditions associated
16 with the use of tobacco products, and that places a special
17 emphasis on discouraging the use of such products by
18 young Americans, the Secretary shall—

19 “(1) develop and implement health risk man-
20 agement standards for tobacco products under sec-
21 tion 902;

22 “(2) develop and implement good manufactur-
23 ing practice standards for tobacco products under
24 section 903;

1 “(3) develop and implement tobacco product la-
2 beling, warning, and packaging standards under sec-
3 tion 904;

4 “(4) develop and implement standards that en-
5 courage the development and use of reduced risk to-
6 bacco products under section 906;

7 “(5) develop and implement tobacco product
8 marketing standards under section 907;

9 “(6) establish and oversee a tobacco products
10 scientific advisory committee under section 908 to
11 provide advice on the establishment of tobacco prod-
12 uct marketing standards under section 902, 903,
13 904, and 906; and

14 “(7) submit reports to Congress evaluating the
15 effectiveness of this chapter and the
16 _____ Act as described in section 909.

17 **“SEC. 902. TOBACCO PRODUCT HEALTH RISK MANAGE-**
18 **MENT STANDARDS.**

19 “(a) **AUTHORITY.—**

20 “(1) **IN GENERAL.—**The Secretary shall by reg-
21 ulation (promulgated under the authority of section
22 701(a) and consistent with the procedures described
23 in section 553 of title 5, United States Code) estab-
24 lish tobacco product health risk standards.

1 “(2) CONSULTATION.—In developing and pro-
2 mulgating regulations under this chapter, the Sec-
3 retary shall consult (as the Secretary determines ap-
4 propriate) with—

5 “(A) Federal public health and safety offi-
6 cials; and

7 “(B) other public health and safety ex-
8 perts, including State and local public health
9 and safety officials, and other interested mem-
10 bers of the public and affected parties.

11 “(b) PROCEDURES FOR THE ESTABLISHMENT OF
12 STANDARDS.—

13 “(1) PUBLICATION OF NOTICE.—

14 “(A) IN GENERAL.—The Secretary shall
15 publish in the Federal Register a notice of pro-
16 posed rulemaking for the establishment, amend-
17 ment, or revocation of any health risk manage-
18 ment standard for a tobacco product under this
19 section. The Secretary shall publish an advance
20 notice of proposed rulemaking in order to solicit
21 broad input at an earlier stage in the rule-
22 making process.

23 “(B) CONTENTS OF NOTICE.—A notice of
24 proposed rulemaking for the establishment or
25 amendment of a health risk management stand-

1 ard for a tobacco product shall be accompanied
2 by a justification of the proposed action and
3 shall—

4 “(i) invite interested persons to sub-
5 mit to the Secretary, within 30 days of the
6 publication of the notice, requests for
7 changes in the standard based on new in-
8 formation relevant to the standard; and

9 “(ii) invite interested persons to sub-
10 mit an existing health risk management
11 standard for the tobacco product, including
12 a draft or proposed health risk manage-
13 ment standard, for consideration by the
14 Secretary.

15 “(C) NOTICE OF REVOCATION.—A notice
16 of proposed rulemaking for the revocation of a
17 health risk management standard shall set
18 forth a finding with supporting justification
19 that the health risk management standard is no
20 longer necessary with respect to the tobacco
21 product.

22 “(D) COMMENTS.—The Secretary shall
23 provide for a comment period of not less than
24 60 days after the date on which a notice has
25 been published under this paragraph.

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

10 “(3) REGULATION FOR ESTABLISHMENT.—

11 “(A) IN GENERAL.—After the expiration of
12 the period for comment on a notice of proposed
13 rulemaking published under paragraph (1) with
14 respect to a health risk management standard,
15 and after consideration of such comments and
16 any report from the tobacco products advisory
17 committee under section 908, the Secretary
18 shall—

19 “(i) promulgate a regulation establish-
20 ing a health risk management standard
21 and publish in the Federal Register find-
22 ings on the matters referred to in sub-
23 section (b); or

24 “(ii) publish a notice terminating the
25 proceeding for the development of the

1 standard together with the reasons for
2 such termination.

3 “(B) CONTENTS.—A regulation establish-
4 ing a health risk management standard under
5 subparagraph (A) shall set forth the date or
6 dates upon which the standard shall take effect,
7 but no such regulation may take effect before
8 the expiration of the 1-year period beginning on
9 the date of its publication unless the Secretary
10 determines that an earlier effective date is nec-
11 essary for the protection of the public health.
12 Such date or dates shall be established so as to
13 minimize economic loss to, and disruption or
14 dislocation of, domestic and international trade.

15 “(4) AMENDING OR REVOKING OF STAND-
16 ARDS.—

17 “(A) IN GENERAL.—The Secretary, upon
18 the initiative of the Secretary or upon petition
19 of an interested person, may by regulation, pro-
20 mulgated in accordance with the requirements
21 of paragraphs (1), (2), and (3), amend or re-
22 voke a health risk management standard for a
23 tobacco product.

24 “(B) EFFECTIVENESS OF AMENDMENT.—
25 The Secretary may declare a proposed amend-

1 ment of a health risk management standard
2 under this section to be effective on and after
3 its publication in the Federal Register and until
4 the effective date of any final action taken on
5 such amendment if the Secretary determines
6 that making it so effective is in the public inter-
7 est. A proposed amendment of a health risk
8 management standard made so effective under
9 the preceding sentence may not prohibit, during
10 the period in which it is so effective, the intro-
11 duction or delivery for introduction into inter-
12 state commerce of a tobacco product which con-
13 forms to such standard without the change or
14 changes provided by such proposed amendment.

15 “(c) REGULATION OF THE COMPOSITION OF TO-
16 BACCO PRODUCTS.—

17 “(1) IN GENERAL.—The Secretary may adopt a
18 health risk management standard under this section
19 that requires—

20 “(A) the modification of a tobacco product
21 in a manner that involves—

22 “(i) the gradual reduction of nicotine
23 yields of the product; or

24 “(ii) the reduction or elimination of
25 other harmful constituents, ingredients (in-

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

“(B) effective not earlier than the expiration of the 10-year period beginning on the date of enactment of this chapter, the elimination of nicotine yields of a tobacco product; or

“(C) effective not earlier than the expiration of the 10-year period beginning on the date of enactment of this chapter, the prohibition of a tobacco product.

“(2) CONSIDERATIONS.—Tobacco product health risk management standards established under this section shall—

“(A) include provisions, subject to notice and comment, that are designed to reduce the overall health risks to the public, including the reduction in risk to the consumers of such products, individuals who reduce or cease the use of

1 such products, and individuals who do not initi-
2 ate the use of such products, and based upon—

3 “(i) the best available technology; and

4 “(ii) the consideration of whether

5 such provisions will result in the creation
6 of a significant demand for, and supply of,
7 contraband products or other tobacco prod-
8 ucts that do not meet the requirements of
9 this chapter;

10 “(B) where necessary to meet the objec-
11 tives in subparagraph (A), include require-
12 ments—

13 “(i) if technologically and commer-
14 cially feasible, with respect to the construc-
15 tion, components, constituents, ingredients
16 (including tobacco additives), and prop-
17 erties of the product, including the estab-
18 lishment of levels of nicotine and other
19 components, ingredients (including tobacco
20 additives), and constituents of the product,
21 or smoke emitted by such products;

22 “(ii) specifying the procedures for the
23 testing of such products, including devising
24 procedures to be used by tobacco product
25 manufacturers, the Secretary, or other ap-

1 appropriate entities, to measure relevant
2 health-related characteristics of such prod-
3 ucts;

4 “(iii) for the testing of such products,
5 including devising procedures to be used by
6 manufacturers, the Secretary, or other ap-
7 propriate entities to measure the relevant
8 health related characteristics of such prod-
9 ucts to assess the conformity of such prod-
10 ucts with the applicable health risk man-
11 agement standards; and

12 “(iv) to limit the sale and distribution
13 of tobacco products to the extent author-
14 ized by this chapter;

15 “(C) as required under section 904, pre-
16 scribe certain conditions pertaining to the label-
17 ing and advertising of tobacco products; and

18 “(D) comply with regulations promulgated
19 by the Secretary that specify the health risk as-
20 sessment procedures for the testing of tobacco
21 and nontobacco constituents contained in to-
22 bacco products and determinations concerning
23 such products under subsection (d).

1 “(3) PROCEDURE FOR GENERAL PROHIBITION
2 OF TOBACCO PRODUCTS AND ELIMINATION OF NICO-
3 TINE.—

4 “(A) NONDELEGATION.—The Secretary
5 may not delegate the authority provided under
6 this section to promulgate a regulation that re-
7 sults in a general prohibition of a class of to-
8 bacco products or elimination of nicotine.

9 “(B) CONGRESSIONAL REVIEW.—In ac-
10 cordance with section 801 of title 5, United
11 States Code, Congress shall review, and may
12 disapprove, any rule of the Secretary establish-
13 ing, amending, or revoking a tobacco product
14 health risk management standard, except that
15 with respect to a standard that results in a gen-
16 eral prohibition of a class of tobacco products
17 or the elimination of nicotine, such standard
18 shall only take effect upon the date of enact-
19 ment of a joint resolution of approval of such
20 standard. The provisions of section 802 of title
21 5, United States Code, relating to certain dis-
22 approval resolutions shall apply to the consider-
23 ation of any joint resolution of approval under
24 this subsection.

1 “(d) TOBACCO PRODUCTS RISK ASSESSMENT
2 STANDARDS.—

3 “(1) TOBACCO CONSTITUENTS.—The health
4 risk management standards promulgated under sub-
5 section (c)(4) with respect to the testing of tobacco
6 products shall include provisions relating to the as-
7 sessment of the health risks posed by the compo-
8 nents of tobacco, including but not limited to nico-
9 tine and tar, and by tobacco use including carbon-
10 monoxide.

11 “(2) NONTOBACCO INGREDIENTS.—

12 “(A) IN GENERAL.—The health risk man-
13 agement regulations under subsection (c)(4)
14 with respect to the testing of nontobacco ingre-
15 dients used in tobacco products—

16 “(i) during the 5-year period begin-
17 ning on the date of enactment of this chap-
18 ter, shall apply to new ingredients (those
19 ingredients that were not previously used
20 in such products on such date of enact-
21 ment) used in such products or such other
22 ingredients for which testing has been re-
23 quired; and

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

4 “(B) IMPLEMENTATION.—In carrying out
5 this section, all requirements with respect to
6 nontobacco ingredients, substances, and com-
7 pounds shall be implemented in accordance with
8 subparagraph (A).

9 “(3) HEALTH RISK ASSESSMENTS.—

10 “(A) REQUIREMENT.—Not later than 5
11 years after the date of enactment of this chap-
12 ter, and annually thereafter, each manufacturer
13 shall submit to the Secretary a health risk as-
14 sessment for each ingredient, substance, or
15 compound that is listed under subsection
16 (e)(1)(A) with respect to each brand of tobacco
17 product manufactured by each such manufac-
18 turer.

19 “(B) AVAILABILITY OF NEW INFORMA-
20 TION.—The Secretary may include in the regu-
21 lations promulgated under this section, provi-
22 sions that permit manufacturers to, in subse-
23 quent years, revise information that was sub-
24 mitted under subparagraph (A) in previous
25 years if new data becomes available to that

1 manufacturer. Such regulations may require
2 that a manufacturer submit a simple notifica-
3 tion to the Secretary where the manufacturer
4 determines that no new data has become avail-
5 able during the previous year.

6 “(C) JOINT SUBMISSION.—At the discre-
7 tion of the Secretary, the health risk assess-
8 ments under this paragraph may be conducted
9 by qualified third party organizations on behalf
10 of more than 1 manufacturer for 1 or more
11 product or ingredient, substance or compound if
12 a joint submission is consistent with the public
13 health. Such joint submissions shall be subject
14 to the brand specific requirements of subpara-
15 graph (A).

16 “(D) BASIS OF ASSESSMENT.—The health
17 risk assessment of an ingredient, substance, or
18 compound described in subparagraph (A)
19 shall—

20 “(i) be based on the best scientific evi-
21 dence available at the time of the submis-
22 sion of the assessment; and

23 “(ii) ascertain whether there is a rea-
24 sonable certainty in the minds of com-
25 petent scientists that the ingredient, sub-

1 stance, or compound is not harmful in the
2 quantities used under the intended condi-
3 tions of use.

4 “(4) REGULATORY ACTION.—

5 “(A) ABSENCE OF A RISK ASSESSMENT.—

6 Not later than 12 months after the date of en-
7 actment of this chapter and subject to the re-
8 quirements of paragraphs (1) and (3)(A), the
9 Secretary shall promulgate regulations to pro-
10 hibit the use of any ingredient, substance, or
11 compound in the tobacco product of a manufac-
12 turer if no health risk assessment has been sub-
13 mitted as required under this subsection by the
14 manufacturer for the ingredient, substance, or
15 compound.

16 “(B) REVIEW OF HEALTH RISK ASSESS-
17 MENTS.—

18 “(i) APPROVAL, CONDITIONAL AP-
19 PROVAL, OR DISAPPROVAL.—The Secretary
20 shall approve or disapprove of, or condi-
21 tion, the use of the ingredient, substance,
22 or compound that was the subject of the
23 assessment under this subsection within
24 180 days of the date on which the health
25 risk assessment is received and provide no-

1 tice of such approval or disapproval to the
2 manufacturer. The manufacturer may con-
3 tinue to use ingredients, substances, or
4 compounds that are the subject of such an
5 assessment until the Secretary disapproves
6 or conditions such ingredient, substance, or
7 compound.

8 “(ii) GENERAL APPLICABILITY.—At
9 the discretion of the Secretary, the ap-
10 proval, conditional, approval, or dis-
11 approval of a particular ingredient, sub-
12 stance, or compound under clause (i) may
13 by regulation be made generally applicable
14 to tobacco product manufacturers or a sub-
15 group of such manufacturers. In the case
16 of a conditional approval, the Secretary
17 shall develop a procedure to enable manu-
18 facturers to certify that the condition will
19 be complied with.

20 “(iii) INACTION BY SECRETARY.—If
21 the Secretary fails to act with respect to
22 an assessment during the period referred
23 to in clause (i), the manufacturer submit-
24 ting the assessment may continue to use
25 the ingredient, substance, or compound in-

1 volved until such time as the succeeding
2 annual risk assessment is submitted by the
3 manufacturer and the ingredient, sub-
4 stance, or compound is subsequently dis-
5 approved or conditioned.

6 “(e) ANNUAL SUBMISSION.—

7 “(1) IN GENERAL.—Each manufacturer of a to-
8 bacco product shall annually provide the Secretary
9 with—

10 “(A) a list of all ingredients, substances,
11 and compounds (other than tobacco, water or
12 reconstituted tobacco sheet made wholly from
13 tobacco) that are added in the manufacture of
14 the tobacco product, for each brand of tobacco
15 product so manufactured;

16 “(B) a description of the quantity of the
17 ingredients, substances, and compounds that
18 are listed under subparagraph (A) with respect
19 to each brand of tobacco product;

20 “(C) a description of the nicotine content
21 of the product, measured in milligrams of nico-
22 tine; and

23 “(D) any other information determined ap-
24 propriate by the Secretary and included as a re-

1 quirement in a regulation promulgated under
2 this section.

3 “(2) GENERAL DISCLOSURE AND CONFIDEN-
4 TIALITY.—

5 “(A) REQUIREMENT.—Regulations under
6 subsection (c)(4) shall require that each person
7 who manufacturers, packages, or imports ciga-
8 rettes or smokeless tobacco products shall an-
9 nually provide the Secretary with the informa-
10 tion required under this section, including infor-
11 mation as to all ingredients, substances and
12 compounds in a tobacco product.

13 “(B) CONFIDENTIALITY.—

14 “(i) PETITION BY MANUFACTURER.—

15 Upon the submission of the information re-
16 quired under subsection (d)(1), or the sub-
17 mission of any other information under
18 any other provisions of this chapter, a
19 manufacturer may petition the Secretary
20 to exempt certain ingredients, substances,
21 or compounds or other information submit-
22 ted from public disclosure under this sub-
23 section on the basis that such information
24 should be considered confidential as a
25 trade secret. Such petition may be accom-

panied by such data as the manufacturer elects to submit.

“(ii) DETERMINATION.—Not later than 90 days after receiving a petition under clause (i), the Secretary, in consultation with the Attorney General, shall make a determination with respect to whether the information described in the petition should be exempt from disclosure under clause (i) as a trade secret. The Secretary shall provide the manufacturer involved with notice of such determination, but the decision of the Secretary shall be final.

“(iii) PROCEDURES FOR CONFIDENTIAL INFORMATION.—The Secretary shall develop procedures to maintain the confidentiality of information that is treated as a trade secret under a determination under clause (ii). Such procedures shall include—

“(I) a requirement that such information be maintained in a secure facility; and

“(II) a requirement that only the Secretary, or the authorized agents of

1 the Secretary, will have access to the
2 information and shall be instructed to
3 maintain the confidentiality of such
4 information.

5 “(iv) HEALTH DISCLOSURE.—Not-
6 withstanding a determination under clause
7 (ii), the Secretary may require that any in-
8 gredient, substance, or compound con-
9 tained in a tobacco product that is deter-
10 mined to be exempt from disclosure be dis-
11 closed if the Secretary determines that it is
12 in the interest of public health to disclose
13 such ingredient, substance, or compound.

14 “(v) OTHER DISCLOSURE.—The Sec-
15 retary (or any employee of the Department
16 of Health and Human Services) shall not
17 disclose any information described in sub-
18 clause (I) if such disclosure is prohibited
19 under any provision of law. Any informa-
20 tion that is not required to be disclosed to
21 the public under this subsection, shall be
22 exempt from disclosure pursuant to sub-
23 section (a) of section 552 of title 5, United
24 States Code, by reason of subsection (b)(4)
25 of such section, and shall be considered

1 confidential and shall not be disclosed, ex-
2 cept that such information may be dis-
3 closed to other officers or employees as
4 provided for in clause (iii)(II) or when rel-
5 evant in any proceeding under this chap-
6 ter.

7 “(3) GENERAL DISCLOSURE OF SAFETY.—With
8 respect to each annual submission under paragraph
9 (1) during the 5-year period beginning on the date
10 of enactment of this chapter, the manufacturer shall,
11 for each ingredient, substance, or compound con-
12 tained on the list of the manufacturer for the year
13 involved, disclose whether the manufacturer has de-
14 termined that the ingredient, substance, or
15 compound would be exempt from public disclosure
16 under this chapter.

17 “(f) COMPLIANCE.—

18 “(1) IN GENERAL.—Health risk management
19 standards under this section shall apply to all to-
20 bacco products to which such standards are relevant.

21 “(2) LIMITATION.—During the period in which
22 a regulation promulgated under this section estab-
23 lishing a health risk standard is in effect, a tobacco
24 product shall not be considered to be in violation of

1 section 301 if such product is in compliance with
2 such regulation.

3 “(g) EVALUATION.—The Secretary shall periodically
4 evaluate the effectiveness of tobacco product health risk
5 standards to determine whether such standards should be
6 amended to reflect new medical, scientific, or technological
7 information.

8 **“SEC. 903. GOOD MANUFACTURING PRACTICE STANDARDS.**

9 “(a) AUTHORITY.—

10 “(1) IN GENERAL.—The Secretary shall, in ac-
11 cordance with subsections (a) and (b) of section 902,
12 prescribe regulations requiring that the methods
13 used in, and the facilities and controls used for, the
14 manufacture, packing, and storage of a tobacco
15 product conform to current good manufacturing
16 practice, as prescribed in such regulations, to ensure
17 that such products will be in compliance with this
18 chapter.

19 “(2) REGISTRATION.—The regulations promul-
20 gated under paragraph (1) shall require that all to-
21 bacco product manufacturers register with the Sec-
22 retary.

23 “(3) SPECIAL CONSULTATION PROCEDURES.—
24 In developing and promulgating any regulation
25 under paragraph (1) the Secretary shall afford the

1 Tobacco Products Scientific Advisory Committee es-
2 tablished under section 908 an opportunity (with a
3 reasonable time period) to submit recommendations
4 in response to the notice of proposed rulemaking.

5 “(4) LIMITATION.—Good manufacturing prac-
6 tice regulations described in paragraph (1) shall be
7 appropriate for the manufacture of a product de-
8 rived from a raw agricultural commodity for which
9 no therapeutic claim is made.

10 “(b) PESTICIDE RESIDUES.—The regulations pro-
11 mulgated under subsection (a) shall at a minimum re-
12 quire, after consultation with the Administrator of the En-
13 vironmental Protection Agency, the development and ad-
14 herence to applicable tolerances with respect to pesticide
15 chemical residues in finished tobacco products, except that
16 such tolerances shall only apply if the Administrator deter-
17 mines that such tolerances are necessary to prevent such
18 residues from being injurious to health when used in to-
19 bacco products.

20 “(c) PETITIONS FOR EXEMPTIONS AND
21 VARIANCES.—

22 “(1) IN GENERAL.—Any person subject to any
23 requirement prescribed by regulations under sub-
24 section (a) may petition the Secretary for an exemp-
25 tion or variance from such requirement. Such a peti-

tion shall be submitted to the Secretary in such form and manner as the Secretary shall by regulation prescribe and shall—

“(A) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner’s determination that compliance with the requirement is not required to ensure that the tobacco product is in compliance with section 902;

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

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

“(2) TOBACCO PRODUCT REQUIREMENTS WAIVER BOARD.—

“(A) AUTHORITY.—The Secretary shall establish a Tobacco Product Requirements Waiver Board (referred to in this paragraph as the ‘Waiver Board’) to provide advice and make recommendations to the Secretary with respect

1 to the approval or disapproval of petitions sub-
2 mitted under paragraph (1).

3 “(B) MEMBERSHIP.—The Waiver Board
4 shall be composed of 9 members to be ap-
5 pointed by the Secretary, of which—

6 “(i) 3 members shall be appointed
7 from among individuals who are officers or
8 employees of the Federal Government or a
9 State or local government;

10 “(ii) 2 members shall be appointed
11 from among individuals who are represent-
12 atives of the interests of the cigarette and
13 smokeless tobacco industries;

14 “(iii) 2 members shall be appointed
15 from among individuals who are represent-
16 atives of the interests of physicians and
17 other health professionals; and

18 “(iv) 2 members shall be appointed
19 from among individuals who are represent-
20 atives of the interests of the general public.

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

24 “(D) COMPENSATION AND EXPENSES.—

1 “(i) COMPENSATION.—Members of
2 the Waiver Board who are not officers or
3 employees of the United States, while at-
4 tending conferences or meetings of the
5 Waiver Board or otherwise serving at the
6 request of the Secretary, shall be entitled
7 to receive compensation at rates to be fixed
8 by the Secretary, which rates may not ex-
9 ceed the daily equivalent of the rate of pay
10 for level 4 of the Senior Executive Sched-
11 ule under section 5382 of title 5, United
12 States Code, for each day (including trav-
13 eltime) they are so engaged.

14 “(ii) EXPENSES.—While conducting
15 the business of the Waiver Board away
16 from their homes or regular places of busi-
17 ness, each member may be allowed travel
18 expenses, including per diem in lieu of sub-
19 sistence, as authorized by section 5703 of
20 title 5 of the United States Code for per-
21 sons in the Government service employed
22 intermittently.

23 “(3) ACTION ON PETITION.—

24 “(A) IN GENERAL.—Not later than 120
25 days of the date on which the Secretary receives

1 the recommendations of the Waiver Board, the
2 Secretary shall issue an order approving or de-
3 nying a petition submitted under paragraph (1).

4 The Secretary may approve—

5 “(i) a petition for an exemption for a
6 tobacco product from a requirement if the
7 Secretary determines that absolute compli-
8 ance with such requirement is not required
9 to assure that the product will comply with
10 this section and is otherwise consistent
11 with the public health; and

12 “(ii) a petition for a variance for a to-
13 bacco product from a requirement if the
14 Secretary determines that the methods to
15 be used in, and the facilities and controls
16 to be used for, the manufacture, packing,
17 and storage of the product in lieu of the
18 methods, controls, and facilities prescribed
19 by the requirement are sufficient to ensure
20 that the product will comply with this sec-
21 tion and is otherwise in compliance with
22 the public health.

23 “(B) CONDITIONS.—An order of the Sec-
24 retary approving a petition for a variance shall
25 prescribe such conditions respecting the meth-

1 ods used in, and the facilities and controls used
2 for, the manufacture, packing, and storage of
3 the tobacco product to be granted the variance
4 under the petition as may be necessary to en-
5 sure that the product will comply with this sec-
6 tion.

7 “(4) INFORMAL HEARING.—After the issuance
8 of an order under paragraph (3) respecting a peti-
9 tion, the petitioner shall have an opportunity for an
10 informal hearing on such order.

11 “(d) RECORDKEEPING AND REPORTING.—The regu-
12 lations promulgated under subsection (a) shall require
13 that manufacturers maintain such files and records as the
14 Secretary may reasonably require relating to tobacco prod-
15 uct safety. Such regulations may require manufacturers
16 to report serious adverse events that are not well-known
17 or well-documented by the scientific community (including
18 events related to contamination or a change in any ingre-
19 dient or any major change in manufacturing processes).

20 “(e) INSPECTION AUTHORITY.—As provided in sec-
21 tion 704, the officers and employees of the Secretary shall
22 have the authority to conduct unannounced inspections of
23 any factory, warehouse, or other establishment of any to-
24 bacco product manufacturer and shall have access to the

1 records, files, papers, processes, controls, and facilities re-
2 lating to tobacco product manufacturing.

3 “(f) AGRICULTURAL PRODUCERS.—The Secretary
4 may not promulgate any regulation under this section that
5 has the effect of placing regulatory burdens on tobacco
6 producers (as such term is used for purposes of the Agri-
7 cultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.)
8 and the Agricultural Act of 1949 (7 U.S.C. 1441 et seq.))
9 in excess of the regulatory burdens generally placed on
10 other agricultural commodity producers.

11 “(g) EFFECTIVE DATE OF CERTAIN REGULA-
12 TIONS.—Regulations promulgated under this section shall
13 be implemented over a 2-year period in consultation with
14 manufacturers of tobacco products and tobacco producers.

15 **“SEC. 904. TOBACCO PRODUCT LABELING, WARNING, AND**
16 **PACKAGING STANDARDS.**

17 “(a) CIGARETTES.—

18 “(1) IN GENERAL.—

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

25 “WARNING: Cigarettes Are Addictive.

1 “WARNING: Tobacco Smoke Can Harm
2 Your Children.

3 “WARNING: Cigarettes Cause Fatal Lung
4 Disease.

5 “WARNING: Cigarettes Cause Cancer.

6 “WARNING: If You Think Smoking Is
7 Dead, You Are Cool.

8 “WARNING: Cigarettes Cause Strokes
9 And Heart Disease.

10 “WARNING: Smoking During Pregnancy
11 Can Harm Your Baby.

12 “WARNING: Smoking Can Kill You.

13 “WARNING: Tobacco Smoke Causes
14 Fatal Lung Disease In Nonsmokers.

15 “WARNING: Quitting Smoking Now
16 Greatly Reduces Serious Risks To Your
17 Health.

18 “(B) ADVERTISING.—It shall be unlawful
19 for any manufacturer or importer of cigarettes
20 to advertise or cause to be advertised within the
21 United States any cigarette unless the advertis-
22 ing bears, in accordance with the requirements
23 of this subsection, one of the following state-
24 ments:

25 “WARNING: Cigarettes Are Addictive.

1 “WARNING: Tobacco Smoke Can Harm
2 Your Children.

3 “WARNING: Cigarettes Cause Fatal Lung
4 Disease.

5 “WARNING: Cigarettes Cause Cancer.

6 “WARNING: If You Think Smoking Is
7 Dead, You Are Cool.

8 “WARNING: Cigarettes Cause Strokes
9 And Heart Disease.

10 “WARNING: Smoking During Pregnancy
11 Can Harm Your Baby.

12 “WARNING: Smoking Can Kill You.

13 “WARNING: Tobacco Smoke Causes
14 Fatal Lung Disease In Nonsmokers.

15 “WARNING: Quitting Smoking Now
16 Greatly Reduces Serious Risks To Your
17 Health.

18 “(2) REQUIREMENTS FOR LABEL STATE-
19 MENTS.—

20 “(A) LOCATION.—Each label statement re-
21 quired by subparagraph (A) of paragraph (1)
22 shall be located on the upper portion of the
23 front panel of the cigarette package (or carton)
24 and occupy not less than 25 percent of such
25 front panel.

1 “(B) TYPE AND COLOR.—With respect to
2 each label statement required by subparagraph
3 (A) of paragraph (1), the phrase ‘WARNING’
4 shall appear in capital letters and the label
5 statement shall be printed in 17 point type with
6 adjustments as determined appropriate by the
7 Secretary to reflect the length of the required
8 statement. All the letters in the label statement
9 shall appear in conspicuous and legible type, in
10 contrast by typography, layout, or color with all
11 other printed material on the package, and be
12 printed in an alternating black-on-white and
13 white-on-black format as determined appro-
14 priate by the Secretary.

15 “(C) EXCEPTION.—The provisions of sub-
16 paragraph (A) shall not apply in the case of a
17 flip-top cigarette package (offered for sale on
18 April 1, 1997) where the front portion of the
19 flip-top does not comprise at least 25 percent of
20 the front panel. In the case of such a package,
21 the label statement required by subparagraph
22 (A) of paragraph (1) shall occupy the entire
23 front portion of the flip top.

24 “(3) REQUIREMENTS FOR ADVERTISING.—

1 “(A) LOCATION.—Each label statement re-
2 quired by subparagraph (B) of paragraph (1)
3 shall occupy not less than 20 percent of the
4 area of the advertisement involved.

5 “(B) TYPE AND COLOR.—

6 “(i) TYPE.—With respect to each
7 label statement required by subparagraph
8 (B) of paragraph (1), the phrase ‘WARN-
9 ING’ shall appear in capital letters and the
10 label statement shall be printed in the fol-
11 lowing types:

12 “(I) With respect to whole page
13 advertisements on broadsheet news-
14 paper—45 point type.

15 “(II) With respect to half page
16 advertisements on broadsheet news-
17 paper—39 point type.

18 “(III) With respect to whole page
19 advertisements on tabloid news-
20 paper—39 point type.

21 “(IV) With respect to half page
22 advertisements on tabloid news-
23 paper—27 point type.

24 “(V) With respect to DPS maga-
25 zine advertisements—31.5 point type.

1 “(VI) With respect to whole page
2 magazine advertisements—31.5 point
3 type.

4 “(VII) With respect to 28cm x 3
5 column advertisements—22.5 point
6 type.

7 “(VIII) With respect to 20cm x 2
8 column advertisements—15 point
9 type.

10 The Secretary may revise the required type
11 sizes as the Secretary determines appro-
12 priate within the 20 percent requirement.

13 “(ii) COLOR.—All the letters in the
14 label statement under this subparagraph
15 shall appear in conspicuous and legible
16 type, in contrast by typography, layout, or
17 color with all other printed material in the
18 advertisement, and be printed in an alter-
19 nating black-on-white and white-on-black
20 format as determined appropriate by the
21 Secretary.

22 “(4) ROTATION OF LABEL STATEMENTS.—

23 “(A) IN GENERAL.—Except as provided in
24 subparagraph (B), the label statements speci-
25 fied in subparagraphs (A) and (B) of paragraph

1 (1) shall be rotated by each manufacturer or
2 importer of cigarettes quarterly in alternating
3 sequence on packages of each brand of ciga-
4 rettes manufactured by the manufacturer or
5 importer and in the advertisements for each
6 such brand of cigarettes in accordance with a
7 plan submitted by the manufacturer or im-
8 porter and approved by the Secretary. The Sec-
9 retary shall approve a plan submitted by a
10 manufacturer or importer of cigarettes which
11 will provide the rotation required by this para-
12 graph and which assures that all of the label
13 statements required by subparagraphs (A) and
14 (B) will be displayed by the manufacturer or
15 importer at the same time.

16 “(B) APPLICATION OF OTHER ROTATION
17 REQUIREMENTS.—

18 “(i) IN GENERAL.—A manufacturer
19 or importer of cigarettes may apply to the
20 Secretary to have the rotation schedule de-
21 scribed in clause (iii) apply with respect to
22 a brand style of cigarettes manufactured
23 or imported by such manufacturer or im-
24 porter if—

1 “(I) the number of cigarettes of
2 such brand style sold in the fiscal year
3 of the manufacturer or importer pre-
4 ceding the submission of the applica-
5 tion is less than $\frac{1}{4}$ of 1 percent of all
6 the cigarettes sold in the United
7 States in such year; and

8 “(II) more than $\frac{1}{2}$ of the ciga-
9 rettes manufactured or imported by
10 such manufacturer or importer for
11 sale in the United States are
12 packaged into brand styles which meet
13 the requirements of subclause (I).

14 If an application is approved by the Sec-
15 retary, the rotation schedule described in
16 clause (iii) shall apply with respect to the
17 applicant during the 1-year period begin-
18 ning on the date of the application ap-
19 proval.

20 “(ii) PLAN.—An applicant under
21 clause (i) shall include in its application a
22 plan under which the label statements
23 specified in subparagraph (A) of paragraph
24 (1) will be rotated by the applicant manu-

1 facturer or importer in accordance with the
2 label rotation described in clause (iii).

3 “(iii) OTHER ROTATION REQUIRE-
4 MENTS.—Under the rotation schedule
5 which the manufacturer or importer with
6 an approved application may put into ef-
7 fect, each of the label statements specified
8 in subparagraph (A) of paragraph (1) shall
9 appear on the packages of each brand style
10 of cigarettes with respect to which the ap-
11 plication was approved an equal number of
12 times within the 12-month period begin-
13 ning on the date of the approval by the
14 Secretary of the application.

15 “(5) APPLICATION OF REQUIREMENT.—Para-
16 graph (1) does not apply to a distributor or retailer
17 of cigarettes who does not manufacture, package, or
18 import cigarettes for sale or distribution within the
19 United States.

20 “(6) TELEVISION AND RADIO ADVERTISING.—It
21 shall be unlawful to advertise cigarettes and little ci-
22 gars on any medium of electronic communications
23 subject to the jurisdiction of the Federal Commu-
24 nications Commission.

25 “(b) SMOKELESS TOBACCO PRODUCTS.—

1 “(1) IN GENERAL.—

2 “(A) PACKAGING.—It shall be unlawful for
3 any person to manufacture, package, or import
4 for sale or distribution within the United States
5 any smokeless tobacco product the package of
6 which fails to bear, in accordance with the re-
7 quirements of this subsection, one of the follow-
8 ing statements:

9 WARNING: This Product May Cause
10 Mouth Cancer.

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

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

15 WARNING: Smokeless Tobacco Is Addict-
16 ive.

17 “(B) ADVERTISING.—It shall be unlawful
18 for any manufacturer or importer of smokeless
19 tobacco products to advertise or cause to be ad-
20 vertised within the United States any smokeless
21 tobacco product unless the advertising bears, in
22 accordance with the requirements of this sub-
23 section, one of the following statements:

24 WARNING: This Product May Cause
25 Mouth Cancer.

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

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

5 WARNING: Smokeless Tobacco Is Addict-
6 ive.

7 “(2) REQUIREMENTS FOR LABEL STATE-
8 MENTS.—

9 “(A) LOCATION.—Each label statement re-
10 quired by subparagraph (A) of paragraph (1)
11 shall be located on the principal display panel
12 of the product and occupy not less than 25 per-
13 cent of such panel.

14 “(B) TYPE AND COLOR.—With respect to
15 each label statement required by subparagraph
16 (A) of paragraph (1), the phrase ‘WARNING’
17 shall appear in capital letters and the label
18 statement shall be printed in 17 point type with
19 adjustments as determined appropriate by the
20 Secretary to reflect the length of the required
21 statement. All the letters in the label statement
22 shall appear in conspicuous and legible type in
23 contrast by typography, layout, or color with all
24 other printed material on the package and be
25 printed in an alternating black on white and

1 white on black format as determined appro-
2 priate by the Secretary.

3 “(3) ADVERTISING AND ROTATION.—The provi-
4 sions of paragraphs (3) and (4)(A) of subsection (a)
5 shall apply to advertisements for smokeless tobacco
6 products and the rotation of the statements required
7 under paragraph (1)(A) on such products.

8 “(4) APPLICATION OF REQUIREMENT.—Para-
9 graph (1) does not apply to a distributor or retailer
10 of smokeless tobacco products who does not manu-
11 facture, package, or import such products for sale or
12 distribution within the United States.

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

18 “(c) ADDITIONAL TOBACCO PRODUCT STATE-
19 MENTS.—

20 “(1) REQUIREMENT.—Each manufacturer, dis-
21 tributor, and retailer advertising or causing to be
22 advertised, disseminating or causing to be dissemi-
23 nated advertising concerning, tobacco products oth-
24 erwise permitted under this chapter shall include, in
25 a type size and format as the Secretary may pre-

1 scribe in a regulation promulgated under subsection
2 (d), the product name and a statement of the gen-
3 eral use of the product as provided for in paragraph
4 (2).

5 “(2) GENERAL USE STATEMENTS.—

6 “(A) CIGARETTES.—A statement of gen-
7 eral use for cigarettes or cigarette tobacco is as
8 follows (whichever is appropriate):

9 ‘Cigarettes—A Dangerous Tobacco Product In-
10 tended For Use Only By Persons 18 or Older.

11 ‘Cigarette Tobacco—A Dangerous Tobacco
12 Product Intended For Use Only By Persons 18
13 or Older.

14 “(B) SMOKELESS TOBACCO.—A statement
15 of general use for a smokeless tobacco product
16 is as follows (whichever is appropriate):

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

20 ‘Plug Chewing Tobacco—A Dangerous Tobacco
21 Product Intended For Use Only By Persons 18
22 or Older.

23 ‘Twist Chewing Tobacco—A Dangerous To-
24 bacco Product Intended For Use Only By Per-
25 sons 18 or Older.

1 ‘Moist Snuff—A Dangerous Tobacco Product
2 Intended For Use Only By Persons 18 or
3 Older.

4 ‘Dry Snuff—A Dangerous Tobacco Product In-
5 tended For Use Only By Persons 18 or Older.

6 “(d) REGULATIONS.—

7 “(1) IN GENERAL.—Not later than 180 days
8 after the date of the enactment of this title, the Sec-
9 retary shall promulgate such regulations as may be
10 necessary to implement subsections (a), (b), and (c).

11 “(2) AUTHORITY TO REVISE TOBACCO PRODUCT
12 LABELING STATEMENTS.—

13 “(A) IN GENERAL.—The Secretary may by
14 rule change the text of any of the statements
15 required under subsections (a) and (b). A rule
16 promulgated under this subparagraph shall not
17 become effective prior to the expiration of the
18 1-year period beginning on the date on which
19 the final rule is published in the Federal Reg-
20 ister.

21 “(B) LIMITATION.—The Secretary may
22 not promulgate any rule under subparagraph
23 (A) during the 5-year period beginning on the
24 effective date of the _____ Act un-

1 less the Secretary can demonstrate extraor-
2 dinary circumstances.

3 “(3) COMMON OR USUAL NAMES.—The Sec-
4 retary, in accordance with the procedures set forth
5 in section 902, shall promulgate regulations requir-
6 ing the disclosure to the public of the common or
7 usual name of each ingredient (other than tobacco,
8 water, or reconstituted tobacco sheet made wholly
9 from tobacco) contained in a tobacco product in de-
10 scending order of predominance by weight, except
11 that such regulations—

12 “(A) may provide for the disclosure of
13 spices, flavorings, and colorings without naming
14 each spice, flavoring, or coloring; and

15 “(B) may exempt from disclosure inciden-
16 tal additives, including processing aids and
17 chemical preservatives, that are present in a to-
18 bacco product at insignificant levels that the
19 Secretary determines do not have any func-
20 tional effect or health risk.

21 “(e) PREEMPTION.—No statement relating to the use
22 of cigarettes or smokeless tobacco products and health,
23 other than the statements required by subsections (a), (b),
24 or (c), shall be required on any package or in any adver-
25 tisement of cigarettes or a smokeless tobacco product.

1 “(f) EXPORTS.—Packages of cigarettes or smokeless
2 tobacco products manufactured, imported, or packaged—
3 “(1) for export from the United States; or
4 “(2) for delivery to a vessel or aircraft, as sup-
5 plies, for consumption beyond the jurisdiction of the
6 internal revenue laws of the United States;
7 shall be exempt from the requirements of this chapter, but
8 such exemptions shall not apply to cigarettes or smokeless
9 tobacco products manufactured, imported, or packaged for
10 sale or distribution to members or units of the Armed
11 Forces of the United States located outside of the United
12 States.

13 **“SEC. 905. RESTRICTION ON MARKETING AND ADVERTIS-**
14 **ING.**

15 “(a) PROHIBITIONS ON ADVERTISING.—

16 “(1) PROHIBITION ON OUTDOOR ADVERTIS-
17 ING.—

18 “(A) IN GENERAL.—No manufacturer, dis-
19 tributor, or retailer may use any form of out-
20 door tobacco product advertising, including bill-
21 boards, posters, or placards.

22 “(B) STADIA AND ARENAS.—Except as
23 otherwise provided in this chapter, a manufac-
24 turer, distributor, or retailer shall not advertise
25 tobacco products in any arena or stadium where

1 athletic, musical, artistic, or other social or cul-
2 tural events or activities occur.

3 “(2) PROHIBITION ON USE OF HUMAN IMAGES
4 AND CARTOONS.—No manufacturer, distributor, or
5 retailer may use a human image or a cartoon char-
6 acter or cartoon-type character in its advertising, la-
7 beling, or promotional material with respect to a to-
8 bacco product.

9 “(3) PROHIBITION ON ADVERTISING ON THE
10 INTERNET.—No manufacturer, distributor, or re-
11 tailer may use the Internet to advertise tobacco
12 products unless such an advertisement is inaccessible
13 in or from the United States.

14 “(4) PROHIBITION ON POINT-OF-SALE ADVER-
15 TISING.—

16 “(A) IN GENERAL.—Except as otherwise
17 provided in this paragraph, no manufacturer,
18 distributor, or retailer may use point-of-sale ad-
19 vertising of tobacco products.

20 “(B) ADULT-ONLY STORES AND TOBACCO
21 OUTLETS.—Subparagraph (A) shall not apply
22 to point of sale advertising at adult-only stores
23 and tobacco outlets.

24 “(C) PERMISSIBLE ADVERTISING.—

1 “(i) IN GENERAL.—Each manufac-
2 turer of tobacco products may display not
3 more than 2 separate point-of-sale adver-
4 tisements in or at each location at which
5 tobacco products are offered for sale.

6 “(ii) MARKET SHARE MANUFACTUR-
7 ERS.—A manufacturer with at least 25
8 percent of the market share of the tobacco
9 product involved may display an additional
10 point-of-sale advertisement in or at each
11 location at which tobacco products are of-
12 fered for sale.

13 “(iii) RETAILERS.—A retailer may
14 have not more than 1 point-of-sale adver-
15 tisement relating to the retailer’s own or
16 its wholesaler’s contracted retailer or pri-
17 vate label brand of tobacco product. No
18 manufacturer or distributor may enter into
19 any arrangement with a retailer to limit
20 the ability of the retailer to display any
21 form of permissible point-of-sale advertise-
22 ment or promotional material originating
23 with another manufacturer or distributor.

24 “(D) LIMITATIONS.—

1 “(i) IN GENERAL.—A point of sale ad-
2 vertisement permitted under this para-
3 graph shall be comprised of a display area
4 than is not larger than 576 square inches
5 (either individually or in the aggregate)
6 and shall consist only of black letters on a
7 white background or other recognized typo-
8 graphical marks. Such advertisement shall
9 not be attached to nor located within 2 feet
10 of any fixture on which candy is displayed
11 for sale.

12 “(ii) AUDIO AND VIDEO FORMATS.—
13 Audio and video advertisements permitted
14 under subsection (c)(3) may be distributed
15 to individuals who are 18 years of age or
16 older at point of sale but may not be
17 played or viewed at such point of sale.

18 “(iii) DISPLAY FIXTURES.—Display
19 fixtures in the form of signs consisting of
20 brand name and price and not larger than
21 2 inches in height are permitted.

22 “(E) DEFINITION.—For purposes of this
23 paragraph, the term ‘point-of-sale advertising’
24 means all printed or graphical materials bearing
25 the brand name (alone or in conjunction with

1 any other word), logo, motto, selling message,
2 recognizable color or pattern of colors, or any
3 other indicia of product identification similar or
4 identical to those used for tobacco products
5 which, when used for its intended purpose, can
6 reasonably be anticipated to be seen by cus-
7 tomers at a location at which tobacco products
8 are offered for sale.

9 “(b) GENERAL RESTRICTIONS.—

10 “(1) RESTRICTION ON PRODUCT NAMES.—A
11 manufacturer shall not use a trade or brand name
12 of a nontobacco product as the trade or brand name
13 for a cigarette or smokeless tobacco product, except
14 for a tobacco product whose trade or brand name
15 was on both a tobacco product and a nontobacco
16 product that were sold in the United States on or
17 before January 1, 1995.

18 “(2) ADVERTISING LIMITED TO FDA SPECIFIED
19 MEDIA.—

20 “(A) IN GENERAL.—A manufacturer, dis-
21 tributor, or retailer may, in accordance with
22 this chapter, disseminate or cause to be dis-
23 seminated advertising or labeling which bears a
24 tobacco product brand name (alone or in con-
25 junction with any other word) or any other indi-

1 cia of tobacco product identification only in
2 newspapers, in magazines, in periodicals or
3 other publications (whether periodic or limited
4 distribution), on billboards, posters and plac-
5 ards in accordance with subsection (a)(1), in
6 nonpoint-of-sale promotional material (including
7 direct mail), in point-of-sale promotional mate-
8 rial, and in audio or video formats delivered at
9 a point-of-sale.

10 “(B) LIMITATION.—A manufacturer, dis-
11 tributor, or retailer that intends to disseminate,
12 or to cause to be disseminated, advertising or
13 labeling for a tobacco product in a medium that
14 is not described in subparagraph (A) shall no-
15 tify the Commissioner not less than 30 days
16 prior to the date on which such medium is to
17 be used. Such notice shall describe the medium
18 and discuss the extent to which the advertising
19 or labeling may be seen by individuals who are
20 under 18 years of age.

21 “(3) RESTRICTION ON PLACEMENT IN ENTER-
22 TAINMENT MEDIA.—

23 “(A) IN GENERAL.—No payment shall be
24 made by any manufacturer, distributor, or re-

1 tailer for the placement of any tobacco product
2 or tobacco product package or advertisement—

3 “(i) as a prop in any television pro-
4 gram or motion picture produced for view-
5 ing by the general public; or

6 “(ii) in a video or on a video game
7 machine.

8 “(B) VIDEO GAME.—The term ‘video
9 game’ means any electronic amusement device
10 that utilizes a computer, microprocessor, or
11 similar electronic circuitry and its own cathode
12 ray tube, or is designed to be used with a tele-
13 vision set or a monitor, that interacts with the
14 user of the device.

15 “(4) RESTRICTIONS ON GLAMORIZATION OF TO-
16 BACCO PRODUCTS.—No direct or indirect payment
17 shall be made by any manufacturer, distributor, or
18 retailer to any entity for the purpose of promoting
19 the image or use of a tobacco product through print
20 or film media that appeals to individuals under 18
21 years of age or through a live performance by an en-
22 tertainment artist that appeals to such individuals.

23 “(c) FORMAT AND CONTENT REQUIREMENTS FOR
24 LABELING AND ADVERTISING.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graphs (2) and (3), each manufacturer, distributor,
3 and retailer advertising or causing to be advertised,
4 disseminating or causing to be disseminated, any la-
5 beling or advertising for a tobacco product shall use
6 only black text on a white background.

7 “(2) CERTAIN ADVERTISING EXCEPTED.—

8 “(A) IN GENERAL.—Paragraph (1) shall
9 not apply to advertising—

10 “(i) in any facility where vending ma-
11 chines and self-service displays are per-
12 mitted under this chapter if the advertising
13 involved—

14 “(I) is not visible from outside of
15 the facility; and

16 “(II) is affixed to a wall or fix-
17 ture in the facility; and

18 “(ii) that appears in any publication
19 (whether periodic, limited, or controlled
20 distribution) that the manufacturer, dis-
21 tributor, or retailer demonstrates is an
22 adult publication.

23 “(B) ADULT PUBLICATION.—For purposes
24 of subparagraph (A)(ii), the term ‘adult publi-

1 cation' means a newspaper, magazine, periodi-
2 cal, or other publication—

3 “(i) whose readers under 18 years of
4 age constitute 15 percent or less of the
5 total readership as measured by competent
6 and reliable survey evidence; and

7 “(ii) that is read by fewer than
8 2,000,000 individuals who are under 18
9 years of age as measured by competent
10 and reliable survey evidence.

11 “(3) AUDIO OR VIDEO FORMATS.—Each manu-
12 facturer, distributor, and retailer advertising or
13 causing to be advertised any advertising for a to-
14 bacco product in an audio or video format shall com-
15 ply with the following:

16 “(A) With respect to an audio format, the
17 advertising shall be limited to words only with
18 no music or sound effects.

19 “(B) With respect to a video format, the
20 advertising shall be limited to static black text
21 only on a white background. Any audio with the
22 video advertising shall be limited to words only
23 with no music or sound effects.

1 “(d) BAN ON NONTOBACCO ITEMS AND SERVICES,
2 CONTESTS AND GAMES OF CHANCE, AND SPONSORSHIP
3 OF EVENTS.—

4 “(1) BAN ON ALL NONTOBACCO MERCHAN-
5 DISE.—No manufacturer, importer, distributor, or
6 retailer shall market, license, distribute, sell, or
7 cause to be marketed, licensed, distributed or sold
8 any item (other than tobacco products) or service
9 which bears the brand name (alone or in conjunction
10 with any other word), logo, symbol, motto, selling
11 message, recognizable color or pattern of colors, or
12 any other indicia of product identification similar or
13 identifiable to those used for any brand of tobacco
14 products.

15 “(2) GIFTS, CONTESTS, AND LOTTERIES.—No
16 manufacturer, distributor, or retailer shall offer or
17 cause to be offered to any person purchasing tobacco
18 products any gift or item (other than a tobacco
19 product) in consideration of the purchase of such
20 products, or to any person in consideration of fur-
21 nishing evidence, such as credits, proofs-of-purchase,
22 or coupons, of such a purchase.

23 “(3) SPONSORSHIP.—

24 “(A) IN GENERAL.—No manufacturer, dis-
25 tributor, or retailer shall sponsor or cause to be

1 sponsored any athletic, musical, artistic, or
2 other social or cultural event, or any entry or
3 team in any event, in which the brand name
4 (alone or in conjunction with any other word),
5 logo, motto, selling message, recognizable color
6 or pattern of colors, or any other indicia of
7 product identification similar or identical to
8 those used for tobacco products is used.

9 “(B) USE OF CORPORATE NAME.—A man-
10 ufacturer, distributor, or retailer may sponsor
11 or cause to be sponsored any athletic, musical,
12 artistic, or other social or cultural event in the
13 name of the corporation which manufactures
14 the tobacco product if—

15 “(i) both the corporate name and the
16 corporation were registered and in use in
17 the United States prior to January 1,
18 1995; and

19 “(ii) the corporate name does not in-
20 clude any brand name (alone or in con-
21 junction with any other word), logo, sym-
22 bol, motto, selling message, recognizable
23 color or pattern of colors, or any other in-
24 dicia or product identification identical or

1 similar to, or identifiable with, those used
2 for any brand of tobacco products.

3 “(e) USE OF PRODUCT DESCRIPTORS.—

4 “(1) IN GENERAL.—With respect to a tobacco
5 product, the label of which bears a product descrip-
6 tion (such as ‘light’ or ‘low tar’), such label shall
7 also contain, and any advertisement concerning such
8 product shall contain, a mandatory disclaimer, to be
9 established by the Secretary, that states that such
10 product has not been shown to be less hazardous
11 than another product of that type.

12 “(2) RULE OF CONSTRUCTION.—Nothing in
13 this subsection shall be construed to limit the au-
14 thority of the Food and Drug Administration with
15 respect to words used as product descriptors.

16 **“SEC. 906. REDUCED RISK TOBACCO PRODUCTS.**

17 “(a) GENERAL RULE.—Except as provided in sub-
18 section (b), the regulations promulgated in accordance
19 with section 902 shall require that a tobacco product be
20 deemed to be in violation with this chapter if the labeling
21 of the package of the product, or the claims of the manu-
22 facturer in connection with the product, can reasonably
23 be interpreted as stating or implying that the product pre-
24 sents a reduced health risk as compared to other similar
25 products. No tobacco product that is subject to regulation

1 under this chapter may contain in its labeling any claim
2 for the diagnosis, cure, mitigation, treatment, or preven-
3 tion of a disease.

4 “(b) EXCEPTION.—

5 “(1) IN GENERAL.—Subsection (a) shall not
6 apply to the labeling of a tobacco product, or the
7 claims of the manufacturer in connection with the
8 product, if—

9 “(A) the manufacturer, based on scientific
10 evidence, demonstrates to the Secretary that
11 the product reduces the risk to the health of the
12 user as compared to other similar tobacco prod-
13 ucts; and

14 “(B) the Secretary approves the specific
15 claim that will be made a part of the labeling
16 of the product, or the specific claims of the
17 manufacturer in connection with the product.

18 “(2) REDUCTION IN HEALTH RISK.—The Sec-
19 retary shall promulgate regulations to permit the in-
20 clusion of scientifically-based specific health claims
21 on the labeling of a tobacco product package, or the
22 making of such claims by the manufacturer in con-
23 nection with the product, where the Secretary deter-
24 mines that the inclusion or making of such claims

1 would reduce the health risk to consumers and oth-
2 erwise promote public health.

3 “(c) DEVELOPMENT OF REDUCED RISK TOBACCO
4 PRODUCT TECHNOLOGY.—

5 “(1) NOTIFICATION OF SECRETARY.—The man-
6 ufacturer of a tobacco product shall provide written
7 notice to the Secretary upon the development or ac-
8 quisition by the manufacturer of any technology that
9 would reduce the risk of such products to the health
10 of the user. Such notification shall not be required
11 until adequate intellectual property protections have
12 been secured by the manufacturer, such as the issu-
13 ance of a patent or the execution of a licensing
14 agreement.

15 “(2) CONFIDENTIALITY.—The Secretary shall
16 promulgate regulations to provide a manufacturer
17 with appropriate confidentiality protections with re-
18 spect to technology that is the subject of a notifica-
19 tion under paragraph (1) that contains evidence that
20 the technology involved is in the early developmental
21 stages.

22 “(3) LICENSING.—

23 “(A) IN GENERAL.—With respect to any
24 technology for which a notification has been
25 provided under paragraph (1), the manufac-

1 turer shall permit the use of such technology by
2 other manufacturers of tobacco products to
3 which this chapter applies.

4 “(B) FEES.—The Secretary of Commerce
5 shall promulgate regulations to provide for the
6 payment of a commercially reasonable fee by
7 each manufacturer that uses the technology de-
8 scribed under subparagraph (A) to the manu-
9 facturer that submits the notice under para-
10 graph (1) for such technology. Such regulations
11 shall contain procedures for the resolution of
12 fee disputes between manufacturers under this
13 subparagraph.

14 “(d) REQUIREMENT OF MANUFACTURE AND MAR-
15 KETING.—

16 “(1) PURPOSE.—It is the purpose of this sub-
17 section to provide for a mechanism to create incen-
18 tives that help ensure that tobacco products that are
19 designed to be less hazardous to the health of users
20 are developed, tested, and made available to consum-
21 ers.

22 “(2) DETERMINATION.—Upon a determination
23 by the Secretary that the manufacture of a tobacco
24 product that is less hazardous to the health of users
25 is technologically and commercially feasible, the Sec-

1 retary may, in accordance with this subsection and
2 through the issuance or amendment of a health risk
3 standard under section 902—

4 “(A) require the disclosure of the existence
5 of such technology;

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

8 “(C) require that manufacturers cease
9 manufacturing and marketing tobacco products
10 that do not incorporate such technology.

11 **“SEC. 907. TOBACCO PRODUCT MARKETING RESTRICTIONS.**

12 “(a) IN GENERAL.—The Secretary, acting through
13 the Office of Smoking and Health of the Centers for Dis-
14 ease Control and Prevention, shall by regulation imple-
15 ment the prohibitions described in this section concerning
16 the marketing of tobacco products to minors.

17 “(b) SALES TO MINORS PROHIBITED.—No retailer
18 may distribute a tobacco product to any individual who
19 is under 18 years of age.

20 “(c) PHOTO IDENTIFICATION.—

21 “(1) REQUIREMENT.—Except as provided in
22 paragraph (2), each retailer shall verify, by means of
23 a driver’s license or other form of identification is-
24 sued by a government authority containing the date

1 of birth of the bearer, that no individual purchasing
2 a tobacco product is under 18 years of age.

3 “(2) EXCEPTION.—No verification under para-
4 graph (1) is required for any individual who is at
5 least 21 years of age.

6 “(3) LOCATION OF PRODUCTS.—Except as pro-
7 vided in subsection (j), a retailer shall ensure that
8 all tobacco products are located in areas where cus-
9 tomers do not have access to the products.

10 “(d) FACE-TO-FACE TRANSACTIONS.—Except as
11 provided in subsection (i)(1), a retailer may sell tobacco
12 products only in a direct, face-to-face exchange without
13 the assistance of any electronic or mechanical device.

14 “(e) OUT-OF-PACKAGE DISTRIBUTION.—No retailer
15 may break or otherwise open a tobacco product to sell or
16 distribute to individuals portions of such product (includ-
17 ing individual cigarettes or a number of cigarettes that
18 is smaller than the quantity in the minimum package size,
19 or any quantity of cigarette tobacco or smokeless tobacco
20 that is smaller than the smallest package distributed by
21 the retailer for individual consumer use).

22 “(f) RETAILER COMPLIANCE WITH RESPECT TO
23 SELF-SERVICE.—Each retailer shall ensure that all to-
24 bacco-related self-service displays, advertising, labeling,
25 and other items that are located in the establishment of

1 the retailer and that do not comply with the requirements
2 of this section are removed or are brought into compliance
3 with the requirements of this section.

4 “(g) MINIMUM CIGARETTE PACKAGE SIZE.—Except
5 as otherwise provided in this section, no manufacturer,
6 distributor, or retailer may sell or cause to be sold, or dis-
7 tribute or cause to be distributed, any cigarette package
8 that contains fewer than 20 cigarettes.

9 “(h) PROHIBITION ON SAMPLING.—No manufac-
10 turer, distributor, or retailer may distribute or cause to
11 be distributed any free samples of any tobacco product.

12 “(i) PROHIBITION ON DISTRIBUTION THROUGH
13 SELF-SERVICE MODES OF SALE.—

14 “(1) VENDING MACHINES.—Except as provided
15 in subsection (j)(1)(B), no manufacturer, distribu-
16 tor, or retailer may distribute or cause to be distrib-
17 uted any tobacco product through a vending ma-
18 chine.

19 “(2) OTHER DISPLAYS.—Except as provided in
20 subsection (j)(1)(C), no manufacturer, distributor,
21 or retailer may distribute or cause to be distributed
22 any tobacco product through a self-service display.

23 “(j) PERMITTED SELF-SERVICE MODES OF SALE.—

1 “(1) IN GENERAL.—Notwithstanding any other
2 provision of this section, the following methods of
3 distributing tobacco products are permitted:

4 “(A) Mail-order sales as provided for in
5 paragraph (2), except that mail-order redemp-
6 tion of coupons and the distribution of free
7 samples through the mail shall be prohibited.

8 “(B) Distribution through vending ma-
9 chines that are located in facilities where the
10 retailer ensures that no individuals under 18
11 years of age are present or permitted to enter
12 at any time.

13 “(C) Distribution through self-service dis-
14 plays that are located in facilities where the re-
15 tailer ensures that no individuals under 18
16 years of age are present or permitted to enter
17 at any time.

18 “(2) MAIL-ORDER SALES.—

19 “(A) IN GENERAL.—A manufacturer, dis-
20 tributor, or retailer may distribute or cause to
21 be distributed a tobacco product through mail-
22 order sales only if such sales are subject to a
23 procedure for verifying that no individual pur-
24 chasing such products is under 18 years of age.

1 “(B) REVIEW BY SECRETARY.—Not later
2 than 2 years after the date of enactment of this
3 section, the Secretary shall review the verifica-
4 tion procedures implemented under subpara-
5 graph (A) to determine whether individuals
6 under 18 years of age are obtaining tobacco
7 products through the mail. If the Secretary de-
8 termines that a significant number of underage
9 individuals are obtaining such products through
10 the mail, the Secretary may promulgate regula-
11 tions in accordance with section 902 to prohibit
12 the distribution of tobacco products through the
13 mail.

14 **“SEC. 908. TOBACCO PRODUCTS SCIENTIFIC ADVISORY**
15 **COMMITTEE.**

16 “(a) ESTABLISHMENT.—Not later than 1 year after
17 the date of enactment of this chapter, the Secretary shall
18 establish an advisory committee, to be known as the ‘To-
19 bacco Products Scientific Advisory Committee’, to assist
20 the Secretary in establishing, amending, or revoking a reg-
21 ulation promulgated under section 902, 903, 904, or 906.

22 “(b) MEMBERSHIP.—

23 “(1) IN GENERAL.—The Secretary shall appoint
24 as members of the Tobacco Products Scientific Advi-
25 sory Committee—

1 “(A) individuals with expertise in the med-
2 icine, science, or technology involving the manu-
3 facture and use of tobacco products, who are of
4 appropriately diversified professional back-
5 grounds;

6 “(B) individuals with expertise in law or
7 ethics;

8 “(C) a representative of tobacco product
9 manufacturers;

10 “(D) a representative of the general public
11 selected from anti-tobacco organizations; and

12 “(E) a representative of the general public
13 selected from pro-tobacco organizations.

14 “(2) LIMITATION.—The Secretary may not ap-
15 point to the Advisory Committee any individual who
16 is in the regular full-time employ of the Federal
17 Government. The Secretary may appoint Federal of-
18 ficials as ex-officio members.

19 “(3) CHAIRPERSON.—The Secretary shall des-
20 ignate 1 of the members of advisory committee to
21 serve as chairperson of the Advisory Committee.

22 “(c) DUTIES.—The Tobacco Products Scientific Ad-
23 visory Committee shall—

1 “(1) assist the Secretary in establishing,
2 amending, or revoking regulations under section
3 902, 903, 904, or 906;

4 “(2) examine and make recommendations con-
5 cerning the effects of the alteration of the nicotine
6 yield levels in tobacco products;

7 “(3) examine and make recommendations con-
8 cerning whether there is a threshold level below
9 which nicotine yields do not produce dependence on
10 the tobacco product involved, and, if so, determine
11 what that level is; and

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

15 **“SEC. 909. REPORTS.**

16 “Not later than 18 months after the date of enact-
17 ment of this chapter, and biennially thereafter, the Sec-
18 retary shall prepare and submit to Congress a report con-
19 taining—

20 “(1) a description of the current sales, advertis-
21 ing, and marketing practices associated with tobacco
22 products;

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

1 “(3) a description of the effects of health pro-
2 motion and disease prevention efforts related to the
3 use of tobacco products;

4 “(4) an evaluation of the health promotion and
5 disease prevention efforts relating to tobacco prod-
6 ucts and the identification of areas appropriate for
7 further research; and

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

11 **“SEC. 910. JUDICIAL REVIEW.**

12 “(a) APPLICATION OF SECTION.—

13 “(1) IN GENERAL.—Not later than 60 days
14 after the effective date of any regulation under this
15 chapter establishing, amending, or revoking a health
16 risk management standard for a tobacco product,
17 any person adversely affected by such regulation
18 may file a petition with the United States Court of
19 Appeals for the District of Columbia or for the cir-
20 cuit wherein such person resides or has its principal
21 place of business for judicial review of such regula-
22 tion. A copy of the petition shall be transmitted by
23 the clerk of the court to the Secretary or other offi-
24 cer designated by him for that purpose.

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

6 “(3) DEFINITION.—For purposes of this sec-
7 tion, the term ‘record’ means all notices and other
8 matter published in the Federal Register with re-
9 spect to the regulation reviewed, all information sub-
10 mitted to the Secretary with respect to such regula-
11 tion, proceedings of any panel or advisory committee
12 with respect to such regulation, any hearing held
13 with respect to such regulation, and any other infor-
14 mation identified by the Secretary, in the adminis-
15 trative proceeding held with respect to such regula-
16 tion, as being relevant to such regulation.

17 “(b) ADDITIONAL DATA, VIEWS, AND ARGUMENTS.—
18 If the petitioner applies to the court under this section
19 for leave to adduce additional data, views, or arguments
20 respecting the regulation being reviewed and shows to the
21 satisfaction of the court that such additional data, views,
22 or arguments are material and that there were reasonable
23 grounds for the petitioner’s failure to adduce such data,
24 views, or arguments in the proceedings before the Sec-
25 retary, the court may order the Secretary to provide addi-

1 tional opportunity for the oral presentation of data, views,
2 or arguments and for written submissions. The Secretary
3 may modify such findings, or make new findings by reason
4 of the additional data, views, or arguments so taken and
5 shall file with the court such modified or new findings,
6 and the recommendations of the Secretary, if any, for the
7 modification or setting aside of the regulation or order
8 being reviewed, with the return of such additional data,
9 views, or arguments.

10 “(c) STANDARD FOR REVIEW.—Upon the filing of the
11 petition under subsection (a) judicial review of a regula-
12 tion, the court shall have jurisdiction to review the regula-
13 tion in accordance with chapter 7 of title 5, United States
14 Code, and to grant appropriate relief, including interim
15 relief, as provided for in such chapter. A regulation pro-
16 mulgated under this chapter shall not be affirmed if it is
17 found to be unsupported by substantial evidence on the
18 record taken as a whole.

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

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

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

10 **“SEC. 911. AUTHORITY TO ASSESS AND USE FEES.**

11 “(a) IN GENERAL.—The Secretary ~~may~~ assess and
12 collect fees in accordance with this section to be used as
13 the sole source of funding with respect to the regulation
14 and control of tobacco products under this Act.

*shall within 60 days of
the enactment
of this Act*

15 “(b) TOBACCO PRODUCT FEE.—

16 “(1) IN GENERAL.—With respect to tobacco
17 products sold in the United States, each manufac-
18 turer of such products shall be subject to a fee for
19 the sale of such products.

20 “(2) AMOUNT OF FEE.—With respect to a man-
21 ufacturer, the amount of the fee under paragraph
22 (1) for a fiscal year shall be equal to an amount that
23 bears the same ratio to \$100,000,000 as the number
24 of tobacco products sold by such manufacturer for
25 the year involved bears to the total number of to-

1 bacco products sold by all manufacturers in such
2 year.

3 “(c) PAYMENT SCHEDULE.—The Secretary shall pro-
4 mulgate regulations to implement procedures for the as-
5 sessment and collection of fees under this section.

6 “(d) COLLECTION OF UNPAID FEES.—In any case
7 where the Secretary does not receive payment of a fee as-
8 sessed under subsection (b) within 30 days after it is due,
9 such fee shall be treated as a claim of the United States
10 Government subject to subchapter II of chapter 37 of title
11 31, United States Code.

12 **“SEC. 912. PREEMPTION.**

13 “(a) LIMITATION.—No requirement with respect to
14 a tobacco product shall be applied by any State or local
15 statute or regulation if such requirement conflicts with the
16 requirements of section 902, 903, 904, 905, or 906.

17 “(b) RULE OF CONSTRUCTION.—Nothing in this sec-
18 tion shall be construed as prohibiting a State or political
19 subdivision of a State from enacting statutes or regula-
20 tions concerning tobacco products so long as such statutes
21 or regulations do not conflict with the requirements of sec-
22 tion 902, 903, 904, or 906.”.

23 **SEC. 102. TECHNICAL PROVISIONS.**

24 (a) APPLICATION OF FEDERAL CIGARETTE LABEL-
25 ING AND ADVERTISING ACT.—The provisions of the Fed-

1 eral Cigarette Labeling and Advertising Act (15 U.S.C.
2 1331 et seq.) that apply to cigarettes shall be superseded
3 by the provisions of this title (and the amendments made
4 by this title).

5 (b) REPEAL.—The Comprehensive Smokeless To-
6 bacco Health Education Act of 1986 (15 U.S.C. 4401 et
7 seq.) is repealed.

8 **SEC. 103. FEDERAL LICENSING OF MILITARY AND OTHER**
9 **ENTITIES.**

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

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

17 (2) in any United States embassy;

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

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

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

1 (b) REQUIREMENTS OF PROGRAM.—The program es-
2 tablished under subsection (a) shall apply requirements
3 (including those for penalties, suspensions, and revoca-
4 tions) similar to those required to be implemented by
5 States under this subtitle.

6 (c) INDIAN TRIBES AND TRIBAL LANDS.—For pur-
7 poses of applying and enforcing the provisions of this sub-
8 title to entities that sell or otherwise distribute tobacco
9 products on Indian reservations (as defined in section
10 403(9) of the Indian Child Protection and Family Violence
11 Prevention Act (25 U.S.C. 3202(9))), an Indian tribe or
12 tribal organization shall be treated as a State.

13 **TITLE II—NATIONAL EFFORTS** 14 **TO REDUCE YOUTH SMOKING**

15 **SEC. 201. SHORT TITLE.**

16 This title may be cited as the “Tobacco Use by Mi-
17 nors Prevention Act”.

18 **SEC. 201. AMENDMENT TO PUBLIC HEALTH SERVICE ACT**

19 The Public Health Service Act (42 U.S.C. 201 et
20 seq.) is amended by adding at the end the following:

21 **“TITLE XXVIII—NATIONAL EF-** 22 **FORTS TO REDUCE YOUTH** 23 **SMOKING**

24 **“SEC. 2801. DEFINITIONS.**

25 **“[To be supplied]**

1 **“Subtitle A—Required Reduction**
2 **in Underage Use of Tobacco**
3 **Products**

4 **“SEC. 2811. PURPOSE.**

5 “It is the purpose of this title to encourage the
6 achievement of dramatic and immediate reductions in the
7 number of underage consumers of tobacco products
8 through the imposition of substantial financial surcharges
9 on participating manufacturers if certain underage to-
10 bacco-use reduction targets are not met.

11 **“SEC. 2812. DETERMINATION OF UNDERAGE USE BASE PER-**
12 **CENTAGES.**

13 “(a) CIGARETTES.—For purposes of this section, the
14 underage use base percentage for cigarettes shall be a per-
15 centage determined by the Secretary, weighted by the rel-
16 ative population of the age groups involved as determined
17 using data compiled in 1995 by the Bureau of the Census,
18 based on—

19 “(1) the average of the percentages of 12th
20 graders (individuals who are 16 or 17 years of age)
21 who used cigarette products on a daily basis for each
22 of the calendar years 1986 through 1996;

23 “(2) the average of the percentages of 10th
24 graders (individuals who are 14 or 15 years of age)

1 who used cigarette products on a daily basis for each
2 of the calendar years 1991 through 1996; and

3 “(3) the average of the percentages of 8th grad-
4 ers (individuals who are 13 years of age) who used
5 cigarette products on a daily basis for each of the
6 calendar years 1991 through 1996.

7 “(b) SMOKELESS TOBACCO.—For purposes of this
8 section, the underage use base percentage for smokeless
9 tobacco products shall be a percentage determined by the
10 Secretary, weighted by the relative population of the age
11 groups involved as determined using data compiled in
12 1995 by the Bureau of the Census, based on—

13 “(1) the average of the percentages of 12th
14 graders (individuals who are 16 or 17 years of age)
15 who used smokeless tobacco products on a daily
16 basis in 1996;

17 “(2) the average of the percentages of 10th
18 graders (individuals who are 14 or 15 years of age)
19 who used smokeless tobacco products on a daily
20 basis in 1996; and

21 “(3) the average of the percentages of 8th grad-
22 ers (individuals who are 13 years of age) who used
23 smokeless tobacco products on a daily basis in 1996.

24 “(c) USE OF CERTAIN DATA OR METHODOLOGY.—
25 For purposes of determining the percentages under para-

1 graphs (1) through (3) of subsections (a) and (b), the Sec-
2 retary shall use the data contained in the National High
3 School Drug Use Survey entitled Monitoring the Future
4 by the University of Michigan or such other comparable
5 index, as determined appropriate by the Secretary after
6 notice and an opportunity for a hearing, that utilizes
7 methodology identical to that used by the University of
8 Michigan in such survey.

9 **"SEC. 2813. ANNUAL DAILY INCIDENCE OF UNDERAGE USE**
10 **OF TOBACCO PRODUCTS.**

11 "(a) ANNUAL DETERMINATION.—Not later than the
12 expiration of the 5-year period beginning on the date of
13 enactment of this Act, and annually thereafter, the Sec-
14 retary shall determine the average annual incidence of the
15 daily use of tobacco products by individuals who are under
16 18 years of age.

17 "(b) CIGARETTES.—With respect to cigarette prod-
18 ucts, a determination under subsection (a) for a year shall
19 be based on the percentage, as weighted by the relative
20 population of the age groups involved as determined using
21 data compiled in 1995 by the Bureau of the Census, of—

22 "(1) 12th graders (individuals who are 16 or 17
23 years of age) who used cigarette products on a daily
24 basis during the year involved;

1 “(2) 10th graders (individuals who are 14 or 15
2 years of age) who used cigarette products on a daily
3 basis during the year involved; and

4 “(3) 8th graders (individuals who are 13 years
5 of age) who used cigarette products on a daily basis
6 during the year involved.

7 “(c) SMOKELESS TOBACCO.—With respect to smoke-
8 less tobacco products, a determination under subsection
9 (a) for a year shall be based on the percentage, as weight-
10 ed by the relative population of the age groups involved
11 as determined using data compiled in 1995 by the Bureau
12 of the Census, of—

13 “(1) 12th graders (individuals who are 16 or 17
14 years of age) who used smokeless tobacco products
15 on a daily basis during the year involved;

16 “(2) 10th graders (individuals who are 14 or 15
17 years of age) who used smokeless tobacco products
18 on a daily basis during the year involved; and

19 “(3) 8th graders (individuals who are 13 years
20 of age) who used cigarette smokeless tobacco on a
21 daily basis during the year involved.

22 “(d) USE OF CERTAIN DATA OR METHODOLOGY.—

23 “(1) IN GENERAL.—For purposes of determin-
24 ing the percentages under paragraphs (1) through
25 (3) of subsections (b) and (c), the Secretary shall

1 use the data contained in the National High School
2 Drug Use Survey entitled Monitoring the Future by
3 the University of Michigan (if such survey is still
4 being undertaken) or such other comparable index,
5 as determined appropriate by the Secretary after no-
6 tice and an opportunity for a hearing, that utilizes
7 methodology identical to that used by the University
8 of Michigan in such survey.

9 “(2) ALTERATION OF METHODOLOGY.—If the
10 Secretary determines that the methodology used by
11 the University of Michigan in the survey referred to
12 in paragraph (1) has been altered in a material
13 manner from the methodology used during the pe-
14 riod from 1986 to 1996 (including by altering States
15 or regions on which the survey is based), the Sec-
16 retary, after notice and an opportunity for a hear-
17 ing, shall use percentages based on an index devel-
18 oped by the Secretary that utilizes methodology
19 identical to that used by the University of Michigan
20 in such survey.

21 **“SEC. 2814. REQUIRED REDUCTION IN UNDERAGE TO-**
22 **BACCO USE.**

23 “(a) IN GENERAL.—For purposes of assessing sur-
24 charges under section 405, the Secretary shall determine
25 whether the required percentage reduction in the underage

1 use of tobacco products for a year (based on the national
2 goals described in section 4 of the _____
3 Act) has been achieved for the year involved. Such deter-
4 mination shall be based on—

5 “(1) with respect to cigarette products, the av-
6 erage annual incidence of the daily use of tobacco
7 products by individuals who are under 18 years of
8 age for the year involved (as determined under sec-
9 tion 403(b)) as compared to the underage use base
10 percentage for cigarette products (as determined
11 under section 402(a)); and

12 “(2) with respect to smokeless tobacco prod-
13 ucts, the average annual incidence of the daily use
14 of smokeless tobacco products by individuals who are
15 under 18 years of age for the year involved (as de-
16 termined under section 403(c)) as compared to the
17 underage use base percentage for smokeless tobacco
18 products (as determined under section 402(b)).

19 “(b) PERCENTAGE REDUCTION IN UNDERAGE USE
20 OF TOBACCO PRODUCTS.—For purposes of subsection (a),
21 the required percentage reduction in the underage use of
22 tobacco products with respect to each tobacco product
23 shall be determined based on the national goals for the
24 reduction in underage tobacco use under section 4.

1 **"SEC. 2815. APPLICATION OF SURCHARGES.**

2 “(a) IN GENERAL.—If the Secretary determines that
3 the percentage reduction in the underage use of tobacco
4 products for a year has not been achieved as required
5 under section 2814, the Secretary shall impose a sur-
6 charge on the participating manufacturers of the tobacco
7 products involved.

8 “(b) AMOUNT OF SURCHARGE.—

9 “(1) IN GENERAL.—

10 “(A) CIGARETTES.—With respect to ciga-
11 rettes, the amount of any surcharge to be im-
12 posed under this section for a calendar year
13 shall be equal to the product of—

14 “(i) \$80,000,000, and the number of
15 applicable surcharge percentage points as
16 determined under subsection (c) up to 5
17 percentage points;

18 “(ii) \$400,000,000, and the number
19 of applicable surcharge percentage points
20 as determined under subsection (c), if such
21 percentage points are greater than 5 but
22 less than 11 percentage points; and

23 “(iii) \$500,000,000, and the number
24 of applicable surcharge percentage points
25 as determined under subsection (c), if such

1 percentage points are 11 or more percent-
2 age points; and

3 “(B) SMOKELESS TOBACCO.—With respect
4 to smokeless tobacco, the amount of any sur-
5 charge to be imposed under this section for a
6 calendar year shall be equal to the product of—

7 “(i) \$15,000,000, and the number of
8 applicable surcharge percentage points as
9 determined under subsection (c) up to 5
10 percentage points;

11 “(ii) \$30,000,000, and the number of
12 applicable surcharge percentage points as
13 determined under subsection (c), if such
14 percentage points are greater than 5 but
15 less than 11 percentage points; and

16 “(iii) \$45,000,000, and the number of
17 applicable surcharge percentage points as
18 determined under subsection (c), if such
19 percentage points are 11 or more percent-
20 age points.

21 “(2) ADJUSTMENTS.—The amount applicable
22 under paragraph (1) shall be annually adjusted by
23 the Secretary based on with respect to subparagraph
24 (A) of such paragraph—

1 “(A) the proportional percentage increase
2 or decrease, as compared to calendar year
3 1995, in the population of individuals residing
4 in the United States who are at least 13 years
5 of age but less than 18 years of age;

6 “(B) the proportional percentage increase
7 or decrease, as compared to calendar year
8 1996, in the average profit per unit (measured
9 in cents and weighted by annual sales) earned
10 by participating manufacturers for the tobacco
11 product involved (as determined by the Sec-
12 retary through a contract with a nationally rec-
13 ognized accounting firm having no connection
14 to such manufacturers).

15 “(c) DETERMINATION OF APPLICABLE SURCHARGE
16 PERCENTAGE POINTS.—

17 “(1) IN GENERAL.—With respect to a calendar
18 year, the applicable surcharge percentage points
19 shall be equal to the percentage point difference be-
20 tween—

21 “(A) the required incidence goal in the un-
22 derage use of the tobacco product involved for
23 the year (based on the national goals described
24 in section 4 of the _____ Act);
25 and

1 “(B) the number of percentage points by
2 which the average annual incidence of the daily
3 use of the tobacco products involved by individ-
4 uals who are under 18 years of age for the year
5 (as determined under section 2813) is less than
6 the underage use base percentage for such
7 products (as determined under section 2812).

8 “(2) ADJUSTMENT.—If for any calendar year
9 the Secretary determines that the average annual in-
10 cidence of the daily use of the tobacco products in-
11 volved by individuals who are under 18 years of age
12 (as determined under section 2813) is greater than
13 the underage use base percentage for such products
14 (as determined under section 2812), the applicable
15 surcharge percentage point shall be equal to—

16 “(A) the percentage point amount deter-
17 mined under paragraph (1)(A); and

18 “(B) the number of percentage points by
19 which the average annual incidence of the daily
20 use of the tobacco products involved by individ-
21 uals who are under 18 years of age (as deter-
22 mined under section 2813) is greater than the
23 underage use base percentage for such products
24 (as determined under section 2812).

1 “(3) TYPE OF PRODUCT.—Separate determina-
2 tions shall be made under this section for cigarette
3 products and smokeless tobacco products.

4 “(d) JOINT AND SEVERAL OBLIGATION.—Any sur-
5 charge imposed under this section with respect to a to-
6 bacco product (cigarette products or smokeless tobacco
7 products) shall be the joint and several obligation of all
8 participating manufacturers of such product as allocated
9 by the market share of each such manufacturer with re-
10 spect to such product. The market share of each manufac-
11 turer for each such product shall be based on the market
12 share of such product for the year preceding the year for
13 which the determination is being made.

14 “(e) ASSESSMENT.—Not later than May 1 of each
15 year in which a surcharge will be imposed under this sec-
16 tion, the Secretary shall assess, pursuant to subsection
17 (d), to each participating manufacturer the amount for
18 which such manufacturer is obligated. Not later than July
19 1 of any year in which a manufacturer receives an assess-
20 ment under this section, the manufacturer shall pay such
21 assessment in full or be subject to such interest on such
22 amount as the Secretary may by regulation prescribe.

23 “(f) USE OF AMOUNTS.—Amounts received under
24 this section shall be used to further the purposes of this
25 title.

1 “(g) PROHIBITION.—No stay or other injunctive re-
2 lief may be granted by the Secretary or any court that
3 has the effect of enjoining the imposition and collection
4 of the surcharges to be applied under this section.

5 **“SEC. 2816. ABATEMENT PROCEDURES.**

6 “(a) PETITIONS.—Upon payment by a participating
7 manufacturer of the amount assessed to the manufacturer
8 under section 2815(f), the manufacturer may submit a pe-
9 tition to the Secretary for an abatement of the assessment.
10 A notice of such abatement petition shall be submitted to
11 the attorney general of each State.

12 “(b) HEARING.—The Secretary shall provide for the
13 conduct of a hearing on an abatement petition received
14 under subsection (a) pursuant to the procedures described
15 in sections 554, 556, and 557 of title 5, United States
16 Code. The attorney general of any State shall be permitted
17 to be heard at any hearing conducted under this sub-
18 section.

19 “(c) BURDEN.—The burden at any hearing under
20 subsection (b) shall be on the participating manufacturer
21 to prove, by a preponderance of the evidence, that the
22 manufacturer should be granted the abatement.

23 “(d) BASIS OF DECISION.—Any decision regarding a
24 petition for an abatement under this section shall be based
25 on a determination as to whether—

1 “(1) the participating manufacturer has acted
2 in good faith and in full compliance with this title
3 and any regulations or State or local laws promul-
4 gated in furtherance of this title;

5 “(2) the participating manufacturer has pur-
6 sued all reasonably available measures to attain the
7 reductions;

8 “(3) there is any evidence of any direct or indi-
9 rect action by the participating manufacturer to un-
10 dermine the achievement of the reductions required
11 under section 2814 or to undermine any other provi-
12 sion of this title; and

13 “(4) the participating manufacturer has taken
14 (or failed to take) any other action as determined
15 appropriate by the Secretary.

16 “(e) AMOUNT.—Upon a determination granting an
17 abatement under this section, the Secretary shall order the
18 abatement of not more than 75 percent of the amount paid
19 by the participating manufacturer (as determined by the
20 Secretary), together with interest that may have accrued
21 on such amount during the period between the date on
22 which payment by the manufacturer was made and the
23 date on which the abatement order was granted. Such in-
24 terest shall be equal to that provided for the average 52-
25 week Treasury Bill during the period involved.

1 “(f) AGGRIEVED PARTIES.—Any participating manu-
2 facturer or attorney general of any State that is aggrieved
3 by an abatement that is granted under this section may
4 seek judicial review of the abatement decision within 30
5 days of the date of such decision in the Court of Appeals
6 for the District of Columbia Circuit. Review in such cases
7 shall be subject to the procedures described in sections
8 701 through 706 of title 5, United States Code.

9 “(g) PROHIBITION.—A participating manufacturer
10 may not file a petition under subsection (a) until such time
11 as the manufacturer has fully paid the Secretary the
12 amount assessed to the manufacturer under section
13 405(f).

14 **“SEC. 2817. INCENTIVE FOR EXCEEDING REDUCTION**
15 **GOALS.**

16 “If the Secretary determines that the percentage re-
17 duction in the underage use of tobacco products for a year
18 exceeds 60 percent for cigarettes and 45 percent for
19 smokeless tobacco products for a year as required under
20 section 2814, the Secretary shall adjust the amount of the
21 fee that a participating manufacturer shall be required to
22 pay for such year under [_____].

23

24

1 **“Subtitle B—Restriction on Access**
2 **to Tobacco Products**

3 **“SEC. 2821. [TO BE SUPPLIED]**

4 **“Subtitle C—State and Community**
5 **Action Program**

6 **“SEC. 2831. FUNDING FROM TOBACCO SETTLEMENT TRUST**
7 **FUND.**

8 “(a) IN GENERAL.—There shall be made available
9 from the Tobacco Settlement Trust Fund to carry out this
10 subtitle—

11 “(1) \$145,000,000 for each of the fiscal years
12 1999 and 2000;

13 “(2) \$170,000,000 for fiscal year 2001;

14 “(3) \$240,000,000 for each of the fiscal years
15 2002 and 2003;

16 “(4) \$340,000,000 for each of the fiscal years
17 2004 and 2005;

18 “(5) \$385,000,000 for each of the fiscal years
19 2006 and 2007; and

20 “(6) \$440,000,000 for fiscal year 2008.

21 “(b) SUNSET PROVISION.—This subtitle shall termi-
22 nate on September 30, 2009.

23 **“SEC. 2832. ALLOTMENTS.**

24 “(a) IN GENERAL.—From the amount made avail-
25 able under section 2831 for any fiscal year, the Secretary,

- 1 acting through the Director of the Office on Smoking and
 2 Health of the Centers for Disease Control and Prevention
 3 (referred to in this subtitle as the 'Director'), shall allot
 4 to each State the applicable percentage of such amount
 5 in accordance with the following table:

State	Applicable Percentage
Alabama	1.238619
Alaska	0.500000
Arizona	1.134776
Arkansas	0.732229
California	8.585426
Colorado	1.027658
Connecticut	1.557000
Delaware	0.500000
District of Columbia	0.521120
Florida	3.500870
Georgia	1.956917
Hawaii	0.626458
Idaho	0.500000
Illinois	4.166040
Indiana	1.671714
Iowa	0.739712
Kansas	0.743167
Kentucky	1.828537
Louisiana	1.868947
Maine	0.848964
Maryland	2.000535
Massachusetts	3.607905
Michigan	4.320991
Minnesota	2.412484
Mississippi	0.830156
Missouri	1.617624
Montana	0.500000
Nebraska	0.500000
Nevada	0.500000
New Hampshire	0.538242
New Jersey	3.406803
New Mexico	0.500000
New York	14.166024
North Carolina	2.045166
North Dakota	0.500000
Ohio	4.572863
Oklahoma	0.820915
Oregon	1.065587
Pennsylvania	5.102394
Rhode Island	0.801176
South Carolina	0.861529
South Dakota	0.500000
Tennessee	2.417855
Texas	4.340060

Utah	0.500000
Vermont	0.500000
Virginia	1.339502
Washington	1.749731
West Virginia	0.978560
Wisconsin	2.046211
Wyoming	0.500000
American Samoa	0.008463
N. Mariana Islands	0.001481
Guam	0.006343
U.S. Virgin Islands	0.004683
Puerto Rico	0.188344

1 “(b) REALLOTMENT.—To the extent that amounts
2 made available under section 2831 for a fiscal year are
3 not otherwise allotted to States because—

4 “(1) 1 or more States have not submitted an
5 application or description of activities in accordance
6 with section 2835 for the fiscal year;

7 “(2) 1 or more States have notified the Sec-
8 retary that they do not intend to use the full amount
9 of their allotment; or

10 “(3) the Secretary has determined that the
11 State is not in compliance with this title, and there-
12 fore is subject to penalties under section 2837;
13 such excess amount shall be reallocated among each of the
14 remaining States in proportion to the amount otherwise
15 allotted to such States for the fiscal year involved without
16 regard to this subsection.

17 “(c) REGULATIONS.—Not later than 18 months after
18 the date of enactment of this title, the Secretary shall pro-
19 mulgate regulations to implement this subtitle. This sub-

1 title shall take effect regardless of the date on which such
2 regulations are promulgated.

3 **"SEC. 2833. PAYMENTS UNDER ALLOTMENTS TO STATES.**

4 “(a) IN GENERAL.—

5 “(1) METHOD OF PAYMENT.—The Secretary
6 shall make payments to States under allotments
7 under this subtitle as provided for under section 203
8 of the Intergovernmental Cooperation Act of 1968.

9 “(2) AVAILABILITY OF FUNDS.—Any amount
10 paid to a State for a fiscal year under this subtitle
11 and remaining unobligated at the end of such year
12 shall remain available to such State for the next fis-
13 cal year for the purposes for which such payment
14 was made.

15 “(b) REDUCTIONS.—The Secretary, at the request of
16 a State, may reduce the amount of payments to the State
17 under subsection (a) by—

18 “(1) the fair market value of any supplies or
19 equipment furnished by the Secretary to the State;
20 and

21 “(2) the amount of the pay, allowances, and
22 travel expenses of any officer or employee of the
23 Federal Government when detailed to the State and
24 the amount of any other costs incurred in connection
25 with the detail of such officer or employee;

1 when the furnishing of such supplies or equipment or the
2 detail of such an officer or employee is for the convenience
3 of and at the request of the State and for the purpose
4 of conducting activities described in section 2834. The
5 amount by which any payment is so reduced shall be avail-
6 able for payment by the Secretary of the costs incurred
7 in furnishing the supplies or equipment or in detailing the
8 personnel, on which reduction of the payment is based,
9 and the amount shall be deemed to be part of the payment
10 and shall be deemed to have been paid to the State.

11 **"SEC. 2834. USE OF ALLOTMENTS.**

12 “(a) STATE AND COMMUNITY ACTION ACTIVITIES.—

13 “(1) IN GENERAL.—Except as provided in sub-
14 sections (b) and (c), amounts paid to a State under
15 section 2833 may be used for the following:

16 “(A) Activities described in the plan of the
17 State, submitted in accordance with section
18 2835, including—

19 “(i) evidence-based State and commu-
20 nity initiatives for tobacco use prevention
21 and control;

22 “(ii) infrastructure development mod-
23 eled after the National Cancer Society’s
24 ASSIST program, or another evidence-
25 based model approved by the Director;

1 “(iii)

2 ~~to~~ to develop effective counter advertis-
3 ing;

4 “(iv) the development and implemen-
5 tation of anti-tobacco education programs
6 and public policy initiatives; and

7 “(v) school-based efforts to prevent
8 tobacco use and addiction, developed sci-
9 entifically and approved by the Director.

10 “(B) Planning, administration, and educational
11 activities related to the activities described in sub-
12 paragraph (A).

13 “(C) The monitoring and evaluation of activi-
14 ties carried out under subparagraphs (A) and (B).

15 “(2) COORDINATION.—State and community
16 action activities permitted under paragraph (1) may
17 be conducted in coordination with the following pro-
18 grams:

19 “(A) The special supplemental food pro-
20 gram under section 17 of the Child Nutrition
21 Act of 1966 (42 U.S.C. 1786)

22 “(B) The Maternal and Child Health Serv-
23 ices Block Grant program under title V of the
24 Social Security Act (42 U.S.C. 701 et seq.).

~~“(K) The medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).~~

~~“(L) Programs administered by the Department of Veterans Affairs.~~

“(3) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States in planning and operating activities to be carried out under this subtitle.

“(b) LIMITATION.—A State may not use amounts paid to the State under section 2833 to—

“(1) purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

“(2) satisfy any requirement for the expenditure of non-Federal funds as a condition of the receipt of Federal funds;

“(3) provide financial assistance to any entity other than a public or nonprofit private entity; or

“(4) fund educational, recreational, or health activities not scientifically proven to prevent youth smoking or lead to success of cessation efforts among youths.

1 “(c) ADMINISTRATION.—Not more than 10 percent
2 of the allotment of a State for a the fiscal year under this
3 subtitle may be used by the State to administer the funds
4 paid to the State under section 2833. The State shall pay
5 from non-Federal sources the remaining costs of admin-
6 istering such funds.

7 **“SEC. 2835. APPLICATION FOR PAYMENTS; STATE PLAN.**

8 “(a) IN GENERAL.—The Secretary may make pay-
9 ments under section 2833 to a State for a fiscal year only
10 if—

11 “(1) the State submits to the Secretary an ap-
12 plication for such payments;

13 “(2) the application contains a State plan in ac-
14 cordance with subsection (b);

15 “(3) the application contains the certification
16 described in subsection (c);

17 “(4) the application contains such assurances
18 as the Secretary may require regarding the compli-
19 ance of the State with the requirements of this sub-
20 title (including assurances regarding compliance
21 with the agreements described in subsection (c));
22 and

23 “(5) the application is in such form and is sub-
24 mitted by such date as the Secretary may require.

1 “(b) STATE PLAN.—A State plan required under
2 subsection (a)(2) for a fiscal year is in accordance with
3 this subsection if the plan meets the following conditions:

4 “(1) The plan is developed by the State agency
5 with principal responsibility for public health pro-
6 grams, in consultation with the advisory committee
7 established pursuant to subsection (c)(2).

8 “(2) The plan specifies the activities authorized
9 under section 2834 that are to be carried out with
10 payments made to the State under section 2833.

11 “(3) The plan specifies the amount of such pay-
12 ments to be expended for each of such activities and
13 includes a description of the programs and projects
14 to be carried out.

15 “(4) The plan describes the measurable objec-
16 tives, developed in consultation with the Secretary,
17 that will be used to evaluate program outcomes.

18 “(c) STATE CERTIFICATION.—The certification re-
19 ferred to in subsection (a)(3) for a fiscal year is a certifi-
20 cation to the Secretary by the chief executive officer of
21 the State involved as follows:

22 “(1)(A) In the development of the State plan
23 required in subsection (a)(2)—

24 “(i) the chief health officer of the State
25 held public hearings on the plan; and

1 “(ii) proposals for the plan were made
2 public in a manner that facilitated comments
3 from public and private entities (including Fed-
4 eral and other public agencies).

5 “(B) The State agrees that, if any revisions are
6 made in such plan during the fiscal year, the State
7 will, with respect to the revisions, hold hearings and
8 make proposals public in accordance with subpara-
9 graph (A), and will submit to the Secretary a de-
10 scription of the revisions.

11 “(2) The State has established an advisory
12 committee in accordance with subsection (d).

13 “(3) The State agrees to expend payments
14 under section 2833 only for the activities authorized
15 in section 2834.

16 “(4) The State agrees to expend such payments
17 in accordance with the State plan submitted under
18 subsection (a)(2) (with any revisions submitted to
19 the Secretary under paragraph (1)(B)), including
20 making expenditures to carry out the strategy con-
21 tained in the plan pursuant to subsection (b)(5).

22 “(5)(A) The State agrees that, in the case of
23 each population for which such strategy is carried
24 out, the State will measure the extent of progress

1 being made toward improving the health status of
2 the population.

3 “(B) The State agrees that—

4 “(i) the State will collect and report data
5 in accordance with section 2836(a);

6 “(ii) for purposes of subparagraph (A),
7 progress will be measured through the use of
8 the applicable uniform data items developed by
9 the Secretary under section 2836(a)(2), or if no
10 such items are applicable, through use of the
11 uniform criteria developed by the Secretary
12 under section 2836(a)(3).

13 “(6) With respect to the activities authorized in
14 section 2834, the State agrees to maintain State ex-
15 penditures for such activities at a level that is not
16 less than the average level of such expenditures
17 maintained by the State for the 2-year period pre-
18 ceding the fiscal year for which the State is applying
19 to receive payments under section 2833.

20 “(7) The State agrees to establish reasonable
21 criteria to evaluate the effective performance of enti-
22 ties that receive funds from such payments and pro-
23 cedures for procedural and substantive independent
24 State review of the failure by the State to provide
25 funds for any such entity.

1 “(8) The State agrees to permit and cooperate
2 with Federal investigations undertaken in accord-
3 ance with section 2837.

4 “(d) STATE ADVISORY COMMITTEE.—

5 “(1) IN GENERAL.—For purposes of subsection
6 (c)(2), an advisory committee is in accordance with
7 this subsection if such committee meets the condi-
8 tions described in this subsection.

9 “(2) DUTIES.—A condition under paragraph
10 (1) for a State is that the duties of the committee
11 are—

12 “(A) to hold public hearings on the State
13 plan required under subsection (a)(2); and

14 “(B) to make recommendations pursuant
15 to subsection (b)(1) regarding the development
16 and implementation of such plan, including rec-
17 ommendations on—

18 “(i) the conduct of assessments of [to
19 be supplied];

20 “(ii) which of the activities authorized
21 in section 2834 should be carried out in
22 the State;

23 “(iii) the allocation of payments made
24 to the State under section 2833;

1 “(iv) the coordination of activities car-
2 ried out under such plan with relevant pro-
3 grams of other entities; and

4 “(v) the collection and reporting of
5 data in accordance with section 2836(a).

6 “(3) COMPOSITION.—

7 “(A) IN GENERAL.—A condition under
8 paragraph (1) for a State is that the advisory
9 committee be composed of such members of the
10 general public, and such officials of the health
11 departments of political subdivisions of the
12 State, as may be necessary to provide adequate
13 representation of the general public and of such
14 health departments.

15 “(B) REPRESENTATIVES.—With respect to
16 compliance with subparagraph (A), the mem-
17 bership of the advisory committee established
18 pursuant to subsection (c)(2) may include rep-
19 resentatives of community-based organizations
20 (including minority community-based organiza-
21 tions), schools of public health, and entities to
22 which the State involved awards grants or con-
23 tracts to carry out activities authorized under
24 section 2834.

1 “(4) CHAIRPERSON; MEETINGS.—A condition
2 under paragraph (1) for a State is that the State
3 public health officer shall serve as the chairperson of
4 the advisory committee, and that the committee
5 meet not less than twice each fiscal year.

6 **“SEC. 2836. REPORTS, DATA, AND AUDITS.**

7 “(a) DATA.—

8 “(1) COLLECTION AND REPORTING.—For pur-
9 poses of section 2835(c)(5)(B)(i), a State is collect-
10 ing and reporting data for a fiscal year in accord-
11 ance with this subsection if the State submits to the
12 Secretary, not later than February 1 of the succeed-
13 ing fiscal year year, a report that—

14 “(A) describes the purposes for which the
15 State expended payments made to the State
16 under section 2833;

17 “(B) pursuant to section 2835(c)(5)(A),
18 describes the extent of progress made by the
19 State for purposes of such section;

20 “(C) meets the conditions described para-
21 graph (2); and

22 “(D) contains such additional information
23 regarding activities authorized under section
24 2834, and is submitted in such form, as the
25 Secretary may require.

1 “(2) UNIFORM DATA SETS.—

2 “(A) IN GENERAL.—The Secretary, in con-
3 sultation with the States, shall develop sets of
4 data for uniformly defining levels of youth and
5 adult use of tobacco products (referred to as
6 ‘uniform tobacco product use data items’). The
7 Secretary shall develop formats for the uniform
8 collecting and reporting of information on such
9 items.

10 “(B) LATER FISCAL YEARS.—In the case of fis-
11 cal year 2000 and each subsequent fiscal year, a
12 condition under paragraph (1) for a State is that the
13 State will, in accordance with the applicable format
14 under subparagraph (A), collect during such year,
15 and include in the report under paragraph (1), the
16 necessary information for each of the tobacco prod-
17 uct use data items.

18 “(3) UNIFORM CRITERIA.—The Secretary, in
19 consultation with the States, shall establish criteria
20 for the uniform collection and reporting of data on
21 activities authorized in section 2844 with respect to
22 which no uniform tobacco product use data items
23 under paragraph (2) exist.

24 “(4) PUBLIC INSPECTION OF REPORTS.—A con-
25 dition under paragraph (1) for a fiscal year is that

1 the State involved will make copies of the report
2 submitted under such paragraph for the fiscal year
3 available for public inspection, and will upon request
4 provide a copy of the report to any individual for a
5 charge not exceeding the cost of providing the copy.

6 “(b) AUDITS.—

7 “(1) FISCAL CONTROL AND ACCOUNTING PRO-
8 CEDURES.—Each State shall establish fiscal control
9 and fund accounting procedures as may be necessary
10 to ensure the proper disbursement of and accounting for
11 Federal funds paid to the State under section 2833,
12 ~~and funds transferred under section 4(e) for use~~
13 ~~under this subtitle.~~

14 “(2) ANNUAL SUBMISSION.—Each State shall
15 annually audit its expenditures from payments re-
16 ceived under section 2833. Such State audits shall
17 be conducted by an entity independent of any agency
18 administering a program funded under this subtitle,
19 and, in so far as practical, in accordance with the
20 Comptroller General’s standards for auditing govern-
21 mental organizations, programs, activities, and func-
22 tions. Within 30 days following the date on which
23 each audit is completed, the chief executive officer of
24 the State shall transmit a copy of that audit to the
25 Secretary.

1 “(3) REPAYMENTS.—Each State shall, after
2 being provided by the Secretary with adequate notice
3 and an opportunity for a hearing within the State,
4 repay to the United States amounts found not to
5 have been expended in accordance with the require-
6 ments of this subtitle or the certification provided by
7 the State under section 2835. If such repayment is
8 not made, the Secretary shall, after providing the
9 State with adequate notice and opportunity for a
10 hearing within the State, offset such amounts
11 against the amount of any allotment to which the
12 State is or may become entitled under this subtitle.

13 “(4) AVAILABILITY.—The State shall make cop-
14 ies of the reports and audits required by this sub-
15 section available for public inspection within the
16 State.

17 “(5) EVALUATION.—The Comptroller General
18 of the United States shall, from time to time, evalu-
19 ate the expenditures by the States of payments
20 under this subtitle in order to ensure that expendi-
21 tures are consistent with the provisions of this sub-
22 title and the certification provide by the State under
23 section 2835.

24 “(6) REPORT BY SECRETARY.—Not later than
25 October 1, 2000, the Secretary shall prepare and

1 submit to the appropriate committees of Congress a
2 report concerning the activities of the States that
3 have received funds under this subtitle and may in-
4 clude in the report any recommendations for appro-
5 priate changes in legislation.

6 “(c) NONAPPLICATION OF CERTAIN PROVISIONS.—

7 Title XVII of the Omnibus budget Reconciliation Act of
8 1981 shall not apply with respect to audits of funds allot-
9 ted under this subtitle.

10 **“SEC. 2837. WITHHOLDING.**

11 “(a) WITHHOLDING FOR MISUSE.—

12 “(1) IN GENERAL.—The Secretary shall, after
13 adequate notice and opportunity for a hearing con-
14 ducted within the affected State, withhold funds
15 from any State which does not use its allotment in
16 accordance with the requirements of this subtitle or
17 the certifications otherwise provided by States under
18 this subtitle. The Secretary shall withhold such
19 funds until the Secretary finds that the reason for
20 the withholding has been removed and there is rea-
21 sonable assurance that it will not recur.

22 “(2) INVESTIGATION.—The Secretary may not
23 institute proceedings to withhold funds under para-
24 graph (1) unless the Secretary has conducted an in-
25 vestigation concerning whether the State has used

1 its allotment in accordance with the requirements of
2 this subtitle or the certifications otherwise provided
3 under this subtitle. Investigations required by this
4 paragraph shall be conducted within the affected
5 State by qualified investigators.

6 “(3) RESPONSE TO COMPLAINTS.—The Sec-
7 retary shall respond in an expeditious manner to
8 complaints of a substantial or serious nature that a
9 State has failed to use funds in accordance with the
10 requirements of this subtitle or the certifications
11 otherwise provided under this subtitle.

12 “(4) MINOR FAILURES.—The Secretary may
13 not withhold funds under paragraph (1) from a
14 State for a minor failure to comply with the require-
15 ments of this subtitle or certifications otherwise pro-
16 vided under this subtitle.

17 “(b) INVESTIGATIONS.—

18 “(1) BY SECRETARY.—The Secretary shall con-
19 duct in several States in each fiscal year investiga-
20 tions of the use of funds received by the States
21 under this subtitle in order to evaluate compliance
22 with the requirements of this subtitle and certifi-
23 cations otherwise provided under this subtitle.

24 “(2) BY COMPTROLLER GENERAL.—The Comp-
25 troller General of the United States may conduct in-

1 vestigations of the use of funds received under this
2 subtitle by a State in order to insure compliance
3 with the requirements of this subtitle and certifi-
4 cations otherwise provided under this subtitle.

5 “(c) AVAILABILITY OF RECORDS.—Each State, and
6 each entity which has received funds from an allotment
7 made to a State under this subtitle, shall make appro-
8 priate books, documents, papers, and records available to
9 the Secretary or the Comptroller General of the United
10 States, or any of their duly authorized representatives, for
11 examination, copying, or mechanical reproduction on or
12 off the premises of the appropriate entity upon a reason-
13 able request therefor.

14 “(d) LIMITATION.—

15 “(1) IN GENERAL.—In conducting any inves-
16 tigation in a State, the Secretary or the Comptroller
17 General of the United States may not make a re-
18 quest for any information not readily available to
19 such State or an entity which has received funds
20 from an allotment made to the State under this sub-
21 title or make an unreasonable request for informa-
22 tion to be compiled, collected, or transmitted in any
23 form not readily available.

24 “(2) NONAPPLICATION TO JUDICIAL PROCEED-
25 INGS.—Paragraph (1) does not apply to the collec-

1 tion, compilation, or transmittal of data in the
2 course of a judicial proceeding.

3 **"SEC. 2838. NONDISCRIMINATION.**

4 “(a) PROGRAMS AND ACTIVITIES.—

5 “(1) IN GENERAL.—For the purpose of apply-
6 ing the prohibitions against discrimination on the
7 basis of age under the Age Discrimination Act of
8 1975, on the basis of handicap under section 504 of
9 the Rehabilitation Act of 1973, on the basis of sex
10 under title IX of the Education Amendments of
11 1972, or on the basis of race, color, or national ori-
12 gin under title VI of the Civil Rights Act of 1964,
13 programs and activities funded in whole or in part
14 with funds made available under this subtitle are
15 considered to be programs and activities receiving
16 Federal financial assistance.

17 “(2) GENDER OR RELIGION.—No person shall
18 on the ground of gender or religion be excluded from
19 participation in, be denied the benefits of, or be sub-
20 jected to discrimination under, any program or ac-
21 tivity funded in whole or in part with funds made
22 available under this subtitle.

23 “(b) FAILURE TO COMPLY.—Whenever the Secretary
24 finds that a State, or an entity that has received a pay-
25 ment from an allotment to a State under this subtitle, has

1 failed to comply with a provision of law referred to in sub-
2 section (a)(1), with subsection (a)(2), or with an applica-
3 ble regulation (including one prescribed to carry out sub-
4 section (a)(2)), the Secretary shall notify the chief execu-
5 tive officer of the State and shall request such officer to
6 secure compliance. If within a reasonable period of time,
7 not to exceed 60 days, the chief executive officer fails or
8 refuses to secure compliance, the Secretary may—

9 “(1) refer the matter to the Attorney General
10 with a recommendation that an appropriate civil ac-
11 tion be instituted;

12 “(2) exercise the powers and functions provided
13 by title VI of the Civil Rights Act of 1964, the Age
14 Discrimination Act of 1975, or section 504 of the
15 Rehabilitation Act of 1973, as may be applicable; or

16 “(3) take such other action as may be provided
17 by law.

18 “(c) ACTION BY ATTORNEY GENERAL.—When a
19 matter is referred to the Attorney General pursuant to
20 subsection (b)(1), or whenever he has reason to believe
21 that a State or an entity is engaged in a pattern or prac-
22 tice in violation of a provision of law referred to in sub-
23 section (a)(1) or in violation of subsection (a)(2), the At-
24 torney General may bring a civil action in any appropriate

1 district court of the United States for such relief as may
2 be appropriate, including injunctive relief.

3 **"SEC. 2839. CRIMINAL PENALTY FOR FALSE STATEMENTS.**

4 "Whoever—

5 "(1) knowingly and willfully makes or causes to
6 be made any false statement or representation of a
7 material fact in connection with the furnishing of
8 items or services for which payment may be made by
9 a State from funds allotted to the State under this
10 subtitle; or

11 "(2) having knowledge of the occurrence of any
12 event affecting his or her initial or continued right
13 to any such payment conceals or fails to disclose
14 such event with an intent fraudulently to secure
15 such payment either in a greater amount than is due
16 or when no such payment is authorized;

17 shall be fined not more than \$25,000 or imprisoned for
18 not more than 5 years, or both.

19 **"Subtitle D—Smoking Cessation**
20 **Programs**

21 **"SEC. 2841. FUNDING FROM TOBACCO SETTLEMENT TRUST**
22 **FUND.**

23 "(a) FUNDING.—There shall be made available from
24 the Tobacco Settlement Trust Fund to carry out this sec-
25 tion—

1 “(1) \$1,000,000,000 for each of the fiscal years
2 1999 through 2002; and

3 “(2) \$1,500,000,000 for each of the fiscal years
4 2003 through 2008.

5 “(b) LIMITATION.—Not more than 2 percent of the
6 amount available for any fiscal year under subsection (a)
7 shall be made available to the Secretary to carry out the
8 activity described in section 2842(c).

9 “(c) SUNSET PROVISION.—This subtitle shall termi-
10 nate on September 30, 2009.

11 **“SEC. 2842. ALLOTMENTS.**

12 “(a) IN GENERAL.—From the amount made avail-
13 able under section 2841 for any fiscal year, the Secretary
14 shall allot to each State the applicable percentage of such
15 amount in accordance with the following table:

State	Applicable Percentage
Alabama	1.238619
Alaska	0.500000
Arizona	1.134776
Arkansas	0.732229
California	8.585426
Colorado	1.027658
Connecticut	1.557000
Delaware	0.500000
District of Columbia	0.521120
Florida	3.500870
Georgia	1.956917
Hawaii	0.626458
Idaho	0.500000
Illinois	4.166040
Indiana	1.671714
Iowa	0.739712
Kansas	0.743167
Kentucky	1.828537
Louisiana	1.868947
Maine	0.848964
Maryland	2.000535
Massachusetts	3.607905

Michigan	4.320991
Minnesota	2.412484
Mississippi	0.830156
Missouri	1.617624
Montana	0.500000
Nebraska	0.500000
Nevada	0.500000
New Hampshire	0.538242
New Jersey	3.406803
New Mexico	0.500000
New York	14.166024
North Carolina	2.045166
North Dakota	0.500000
Ohio	4.572863
Oklahoma	0.820915
Oregon	1.065587
Pennsylvania	5.102394
Rhode Island	0.801176
South Carolina	0.861529
South Dakota	0.500000
Tennessee	2.417855
Texas	4.340060
Utah	0.500000
Vermont	0.500000
Virginia	1.339502
Washington	1.749731
West Virginia	0.978560
Wisconsin	2.046211
Wyoming	0.500000
American Samoa	0.008463
N. Mariana Islands	0.001481
Guam	0.006343
U.S. Virgin Islands	0.004683
Puerto Rico	0.188344

1 “(b) REALLOTMENT.—To the extent that amounts
2 made available under section 2831 for a fiscal year are
3 not otherwise allotted to States because—

4 “(1) 1 or more States have not submitted an
5 application or description of activities in accordance
6 with section 2845 for the fiscal year;

7 “(2) 1 or more States have notified the Sec-
8 retary that they do not intend to use the full amount
9 of their allotment; or

1 “(3) the Secretary has determined that the
2 State is not in compliance with this title, and there-
3 fore is subject to penalties under section 2847;
4 such excess amount shall be reallocated among each of the
5 remaining States in proportion to the amount otherwise
6 allotted to such States for the fiscal year involved without
7 regard to this subsection.

8 “(c) ANALYSES.—The Secretary, acting through the
9 Administrator of the Agency Health Care Policy and Re-
10 search, shall conduct periodic analyses of the best avail-
11 able scientific information in the area of smoking and to-
12 bacco product use cessation.

13 “(d) REGULATIONS.—Not later than 9 months after
14 the date of enactment of this title, the Secretary shall pro-
15 mulgate regulations to implement this subtitle. This sub-
16 title shall take effect regardless of the date on which such
17 regulations are promulgated.

18 **“SEC. 2843. PAYMENTS UNDER ALLOTMENTS TO STATES.**

19 “(a) IN GENERAL.—

20 “(1) METHOD OF PAYMENT.—The Secretary
21 shall make payments to States under allotments
22 under this subtitle as provided for under section 203
23 of the Intergovernmental Cooperation Act of 1968.

24 “(2) AVAILABILITY OF FUNDS.—Any amount
25 paid to a State for a fiscal year under this subtitle

1 and remaining unobligated at the end of such year
2 shall remain available to such State for the next fis-
3 cal year for the purposes for which such payment
4 was made.

5 “(b) REDUCTIONS.—The Secretary, at the request of
6 a State, may reduce the amount of payments to the State
7 under subsection (a) by—

8 “(1) the fair market value of any supplies or
9 equipment furnished by the Secretary to the State;
10 and

11 “(2) the amount of the pay, allowances, and
12 travel expenses of any officer or employee of the
13 Federal Government when detailed to the State and
14 the amount of any other costs incurred in connection
15 with the detail of such officer or employee;
16 when the furnishing of such supplies or equipment or the
17 detail of such an officer or employee is for the convenience
18 of and at the request of the State and for the purpose
19 of conducting activities described in section 2844. The
20 amount by which any payment is so reduced shall be avail-
21 able for payment by the Secretary of the costs incurred
22 in furnishing the supplies or equipment or in detailing the
23 personnel, on which reduction of the payment is based,
24 and the amount shall be deemed to be part of the payment
25 and shall be deemed to have been paid to the State.

1 **"SEC. 2844. USE OF ALLOTMENTS.**

2 “(a) STATE AND COMMUNITY ACTION ACTIVITIES.—

3 “(1) IN GENERAL.—Except as provided in sub-
4 sections (b) and (c), amounts paid to a State under
5 section 2843 may be used for the following:

6 “(A) Activities described in the plan of the
7 State, submitted in accordance with section
8 2845, including—

9 “(i) science-based programs designed
10 to assist individuals who to quit their use
11 of tobacco products;

12 “(ii) training in cessation intervention
13 methods for health plans and health pro-
14 fessionals, including physicians, nurses,
15 dentists, and other health care providers;
16 and

17 “(iii) programs to encourage health
18 insurers and health plans to provide cov-
19 erage for science-based tobacco use ces-
20 sation treatment.

21 “(B) Planning, administration, and educational
22 activities related to the activities described in sub-
23 paragraph (A).

24 “(C) The monitoring and evaluation of ac-
25 tivities carried out under subparagraphs (A)
26 and (B).

1 “(2) COORDINATION.—Tobacco use cessation
2 activities permitted under paragraph (1) may be
3 conducted in coordination with the following pro-
4 grams:

5 “(A) The special supplemental food pro-
6 gram under section 17 of the Child Nutrition
7 Act of 1966 (42 U.S.C. 1786)

8 “(B) The Maternal and Child Health Serv-
9 ices Block Grant program under title V of the
10 Social Security Act (42 U.S.C. 701 et seq.).

11 “(C) The State Children’s Health Insur-
12 ance Program of the State under title XXXI of
13 the Social Security Act (42 U.S.C. 13397aa et
14 seq.).

15 “(D) A Head Start program under the
16 Head Start Act (42 U.S.C. 9801 et seq.).

17 “(E) The school lunch program uknder the
18 National School Lunch Act (42 U.S.C. 1751 et
19 seq.).

20 “(F) An Indian Health Service Program.

21 “(G) The community health center pro-
22 gram under section 330 of the Public Health
23 Service Act (42 U.S.C. 254b).

24 “(H) Programs under title X of the Public
25 Health Service Act (42 U.S.C. 300 et seq.).

1 “(I) State-initiated smoking cessation pro-
2 grams that include provisions for reimbursing
3 individuals for medications or other therapeutic
4 techniques.

5 “(J) The substance abuse and mental health
6 services block grant program, and the preven-
7 tive health services block grant program, under
8 title XIX of the Public Health Service Act (42
9 U.S.C. 300w et seq.).

10 “(K) The medicaid program under title
11 XIX of the Social Security Act (42 U.S.C. 1396
12 et seq.).

13 “(L) Programs administered by the De-
14 partment of Veterans Affairs.

15 “(3) TECHNICAL ASSISTANCE.—The Secretary
16 may provide technical assistance to States in plan-
17 ning and operating activities to be carried out under
18 this subtitle.

19 “(b) LIMITATION.—A State may not use amounts
20 paid to the State under section 2843 to—

21 “(1) make cash payments to intended recipients
22 of tobacco use cessation services;

23 “(2) purchase or improve land, purchase, con-
24 struct, or permanently improve (other than minor

1 remodeling) any building or other facility, or pur-
2 chase major medical equipment;

3 “(3) satisfy any requirement for the expendi-
4 ture of non-Federal funds as a condition of the re-
5 ceipt of Federal funds; or

6 “(4) provide financial assistance to any entity
7 other than a public or nonprofit private entity.

8 “(c) ADMINISTRATION.—Not more than 8 percent of
9 the allotment of a State for a the fiscal year under this
10 subtitle may be used by the State to administer the funds
11 paid to the State under section 2843. The State shall pay
12 from non-Federal sources the remaining costs of admin-
13 istering such funds.

14 **“SEC. 2845. APPLICATION FOR PAYMENTS; STATE PLAN.**

15 “(a) IN GENERAL.—The Secretary may make pay-
16 ments under section 2843 to a State for a fiscal year only
17 if—

18 “(1) the State submits to the Secretary an ap-
19 plication for such payments;

20 “(2) the application contains a State plan in ac-
21 cordance with subsection (b);

22 “(3) the application contains the certification
23 described in subsection (c);

24 “(4) the application contains such assurances
25 as the Secretary may require regarding the compli-

1 ance of the State with the requirements of this sub-
2 title (including assurances regarding compliance
3 with the agreements described in subsection (c));
4 and

5 “(5) the application is in such form and is sub-
6 mitted by such date as the Secretary may require.

7 “(b) STATE PLAN.—A State plan required in sub-
8 section (a)(2) for a fiscal year is in accordance with this
9 subsection if the plan meets the following conditions:

10 “(1) The plan is developed by the State agency
11 with principal responsibility for public health pro-
12 grams, in consultation with the advisory committee
13 established pursuant to subsection (c)(2).

14 “(2) The plan provides for tobacco use ces-
15 sation treatment consistent with the smoking ces-
16 sation guidelines issued by the Agency for Health
17 Care Policy and Research, or another evidence-based
18 guideline approved by the Secretary.

19 “(3) The plan specifies the populations in the
20 State for which such activities are to be carried out,
21 and specifies the populations in the State that have
22 a disparate need for such activities.

23 “(4) With respect to each population specified
24 under paragraph (3), the plan contains a strategy

1 for expending such payments to carry out such ac-
2 tivities. Such strategy shall include—

3 “(A) a description of the programs and
4 projects to be carried out;

5 “(B) an estimate of the number of individ-
6 uals to be served by the programs and projects;
7 and

8 “(C) an estimate of the number of public
9 health personnel needed to carry out the strat-
10 egy.

11 “(5) The plan specifies the amount of such pay-
12 ments to be expended for each of such activities and,
13 with respect to the activity involved, the amount to
14 be expended for each population specified under
15 paragraph (3).

16 “(6) The plan provides for training in tobacco
17 use cessation intervention methods for health plans
18 and health professionals, including physicians,
19 nurses, dentists, and other health care providers.

20 “(7) The plan ensures access to smoking ces-
21 sation programs for rural and underserved popu-
22 lations.

23 “(8) The plan describes the measurable objec-
24 tives, developed in consultation with the Secretary,
25 that will be used to evaluate program outcomes.

1 “(c) STATE CERTIFICATION.—The certification re-
2 ferred to in subsection (a)(3) for a fiscal year is a certifi-
3 cation to the Secretary by the chief executive officer of
4 the State involved as follows:

5 “(1)(A) In the development of the State plan
6 required in subsection (a)(2)—

7 “(i) the chief health officer of the State
8 held public hearings on the plan; and

9 “(ii) proposals for the plan were made
10 public in a manner that facilitated comments
11 from public and private entities (including Fed-
12 eral and other public agencies).

13 “(B) The State agrees that, if any revisions are
14 made in such plan during the fiscal year, the State
15 will, with respect to the revisions, hold hearings and
16 make proposals public in accordance with subpara-
17 graph (A), and will submit to the Secretary a de-
18 scription of the revisions.

19 “(2) The State has established an advisory
20 committee in accordance with subsection (d).

21 “(3) The State agrees to expend payments
22 under section 2843 only for the activities authorized
23 in section 2844.

24 “(4) The State agrees to expend such payments
25 in accordance with the State plan submitted under

1 subsection (a)(2) (with any revisions submitted to
2 the Secretary under paragraph (1)(B)), including
3 making expenditures to carry out the strategy con-
4 tained in the plan pursuant to subsection (b)(5).

5 “(5)(A) The State agrees that, in the case of
6 each population for which such strategy is carried
7 out, the State will measure the extent of progress
8 being made toward improving the health status of
9 the population.

10 “(B) The State agrees that—

11 “(i) the State will collect and report data
12 in accordance with section 2846(a)

13 “(ii) for purposes of subparagraph (A),
14 progress will be measured through the use of
15 the applicable uniform data items developed by
16 the Secretary under section 2846(a)(2), or if no
17 such items are applicable, through use of the
18 uniform criteria developed by the Secretary
19 under section 2846(a)(3).

20 “(6) With respect to the activities authorized in
21 section 2844, the State agrees to maintain State ex-
22 penditures for such activities at a level that is not
23 less than the average level of such expenditures
24 maintained by the State for the 2-year period pre-

1 ceding the fiscal year for which the State is applying
2 to receive payments under section 2843.

3 “(7) The State agrees to establish reasonable
4 criteria to evaluate the effective performance of enti-
5 ties that receive funds from such payments and pro-
6 cedures for procedural and substantive independent
7 State review of the failure by the State to provide
8 funds for any such entity.

9 “(8) The State agrees to permit and cooperate
10 with Federal investigations undertaken in accord-
11 ance with section 2847.

12 “(d) STATE ADVISORY COMMITTEE.—

13 “(1) IN GENERAL.—For purposes of subsection
14 (c)(2), an Advisory Committee is in accordance with
15 this subsection if such committee meets the condi-
16 tions described in this subsection.

17 “(2) DUTIES.—A condition under paragraph
18 (1) for a State is that the duties of the committee
19 are—

20 “(A) to hold public hearings on the State
21 plan required under subsection (a)(2); and

22 “(B) to make recommendations pursuant
23 to subsection (b)(1) regarding the development
24 and implementation of such plan, including rec-
25 ommendations on—

1 “(i) the conduct of assessments of the
2 public health;

3 “(ii) which of the activities authorized
4 in section 2844 should be carried out in
5 the State;

6 “(iii) the allocation of payments made
7 to the State under section 2843;

8 “(iv) the coordination of activities car-
9 ried out under such plan with relevant pro-
10 grams of other entities; and

11 “(v) the collection and reporting of
12 data in accordance with section 2846(a).

13 “(3) COMPOSITION.—

14 “(A) IN GENERAL.—A condition under
15 paragraph (1) for a State is that the Advisory
16 Committee be composed of such members of the
17 general public, and such officials of the health
18 departments of political subdivisions of the
19 State, as may be necessary to provide adequate
20 representation of the general public and of such
21 health departments.

22 “(B) REPRESENTATIVES.—With respect to
23 compliance with subparagraph (A), the mem-
24 bership of the advisory committee established
25 pursuant to subsection (c)(2) may include rep-

1 representatives of community-based organizations
2 (including minority community-based organiza-
3 tions), schools of public health, and entities to
4 which the State involved awards grants or con-
5 tracts to carry out activities authorized under
6 section 2844.

7 “(4) CHAIRPERSON; MEETINGS.—A condition
8 under paragraph (1) for a State is that the State
9 public health officer serves as the chairperson of the
10 committee, and that the committee meets not less
11 than twice each fiscal year.

12 **“SEC. 2846. REPORTS, DATA, AND AUDITS.**

13 “(a) DATA.—

14 “(1) COLLECTION AND REPORTING.—For pur-
15 poses of section 2845(c)(5)(B)(i), a State is collect-
16 ing and reporting data for a fiscal year in accord-
17 ance with this subsection if the State submits to the
18 Secretary, not later than February 1 of the succeed-
19 ing fiscal year year, a report that—

20 “(A) describes the purposes for which the
21 State expended payments made to the State
22 under section 2843;

23 “(B) pursuant to section 2845(c)(5)(A),
24 describes the extent of progress made by the
25 State for purposes of such section;

1 “(C) meets the conditions described para-
2 graph (2); and

3 “(D) contains such additional information
4 regarding activities authorized under section
5 2844, and is submitted in such form, as the
6 Secretary may require.

7 “(2) UNIFORM DATA SETS.—

8 “(A) IN GENERAL.—The Secretary, in con-
9 sultation with the States, shall develop sets of
10 data for uniformly defining levels of youth and
11 adult use of tobacco products (referred to as
12 ‘uniform tobacco product use data items’). The
13 Secretary shall develop formats for the uniform
14 collecting and reporting of information on such
15 items.

16 “(B) LATER FISCAL YEARS.—In the case of fis-
17 cal year 2000 and each subsequent fiscal year, a
18 condition under paragraph (1) for a State is that the
19 State will, in accordance with the applicable format
20 under subparagraph (A), collect during such year,
21 and include in the report under paragraph (1), the
22 necessary information for each of the tobacco prod-
23 uct use data items.

24 “(3) UNIFORM CRITERIA.—The Secretary, in
25 consultation with the States, shall establish criteria

1 for the uniform collection and reporting of data on
2 activities authorized in section 2844 with respect to
3 which no uniform tobacco product use data items
4 under paragraph (2) exist.

5 “(4) PUBLIC INSPECTION OF REPORTS.—A con-
6 dition under paragraph (1) for a fiscal year is that
7 the State involved will make copies of the report
8 submitted under such paragraph for the fiscal year
9 available for public inspection, and will upon request
10 provide a copy of the report to any individual for a
11 charge not exceeding the cost of providing the copy.

12 “(b) AUDITS.—

13 “(1) FISCAL CONTROL AND ACCOUNTING PRO-
14 CEDURES.—Each State shall establish fiscal control
15 and fund accounting procedures as may be necessary
16 to ensure the proper disbursement of and accounting for
17 Federal funds paid to the State under section 2843
18 and funds transferred under section [4(c)] for use
19 under this subtitle.

20 “(2) ANNUAL SUBMISSION.—Each State shall
21 annually audit its expenditures from payments re-
22 ceived under section 2843. Such State audits shall
23 be conducted by an entity independent of any agency
24 administering a program funded under this subtitle,
25 and, in so far as practical, in accordance with the

1 Comptroller General's standards for auditing govern-
2 mental organizations, programs, activities, and func-
3 tions. Within 30 days following the date on which
4 each audit is completed, the chief executive officer of
5 the State shall transmit a copy of that audit to the
6 Secretary.

7 “(3) REPAYMENTS.—Each State shall, after
8 being provided by the Secretary with adequate notice
9 and an opportunity for a hearing within the State,
10 repay to the United States amounts found not to
11 have been expended in accordance with the require-
12 ments of this subtitle or the certification provided by
13 the State under section 2845. If such repayment is
14 not made, the Secretary shall, after providing the
15 State with adequate notice and opportunity for a
16 hearing within the State, offset such amounts
17 against the amount of any allotment to which the
18 State is or may become entitled under this subtitle.

19 “(4) AVAILABILITY.—The State shall make cop-
20 ies of the reports and audits required by this sub-
21 section available for public inspection within the
22 State.

23 “(5) EVALUATION.—The Comptroller General
24 of the United States shall, from time to time, evalu-
25 ate the expenditures by the States of payments

1 under this subtitle in order to ensure that expendi-
2 tures are consistent with the provisions of this sub-
3 title and the certification provide by the State under
4 section 2845.

5 “(6) REPORT BY SECRETARY.—Not later than
6 October 1, 2000, the Secretary shall prepare and
7 submit to the appropriate committees of Congress a
8 report concerning the activities of the States that
9 have received funds under this subtitle and may in-
10 clude in the report any recommendations for appro-
11 priate changes in legislation.

12 “(c) NONAPPLICATION OF CERTAIN PROVISIONS.—
13 Title XVII of the Omnibus budget Reconciliation Act of
14 1981 shall not apply with respect to audits of funds allot-
15 ted under this subtitle.

16 **“SEC. 2847. WITHHOLDING.**

17 “(a) WITHHOLDING FOR MISUSE.—

18 “(1) IN GENERAL.—The Secretary shall, after
19 adequate notice and opportunity for a hearing con-
20 ducted within the affected State, withhold funds
21 from any State which does not use its allotment in
22 accordance with the requirements of this subtitle or
23 the certifications otherwise provided by States under
24 this subtitle. The Secretary shall withhold such
25 funds until the Secretary finds that the reason for

1 the withholding has been removed and there is rea-
2 sonable assurance that it will not recur.

3 “(2) INVESTIGATION.—The Secretary may not
4 institute proceedings to withhold funds under para-
5 graph (1) unless the Secretary has conducted an in-
6 vestigation concerning whether the State has used
7 its allotment in accordance with the requirements of
8 this subtitle or the certifications otherwise provided
9 under this subtitle. Investigations required by this
10 paragraph shall be conducted within the affected
11 State by qualified investigators.

12 “(3) RESPONSE TO COMPLAINTS.—The Sec-
13 retary shall respond in an expeditious manner to
14 complaints of a substantial or serious nature that a
15 State has failed to use funds in accordance with the
16 requirements of this subtitle or the certifications
17 otherwise provided under this subtitle.

18 “(4) MINOR FAILURES.—The Secretary may
19 not withhold funds under paragraph (1) from a
20 State for a minor failure to comply with the require-
21 ments of this subtitle or certifications otherwise pro-
22 vided under this subtitle.

23 “(b) INVESTIGATIONS.—

24 “(1) BY SECRETARY.—The Secretary shall con-
25 duct in several States in each fiscal year investiga-

1 tions of the use of funds received by the States
2 under this subtitle in order to evaluate compliance
3 with the requirements of this subtitle and certifi-
4 cations otherwise provided under this subtitle.

5 “(2) BY COMPTROLLER GENERAL.—The Comp-
6 troller General of the United States may conduct in-
7 vestigations of the use of funds received under this
8 subtitle by a State in order to insure compliance
9 with the requirements of this subtitle and certifi-
10 cations otherwise provided under this subtitle.

11 “(c) AVAILABILITY OF RECORDS.—Each State, and
12 each entity which has received funds from an allotment
13 made to a State under this subtitle, shall make appro-
14 priate books, documents, papers, and records available to
15 the Secretary or the Comptroller General of the United
16 States, or any of their duly authorized representatives, for
17 examination, copying, or mechanical reproduction on or
18 off the premises of the appropriate entity upon a reason-
19 able request therefor.

20 “(d) LIMITATION.—

21 “(1) IN GENERAL.—In conducting any inves-
22 tigation in a State, the Secretary or the Comptroller
23 General of the United States may not make a re-
24 quest for any information not readily available to
25 such State or an entity which has received funds

1 from an allotment made to the State under this sub-
2 title or make an unreasonable request for informa-
3 tion to be compiled, collected, or transmitted in any
4 form not readily available.

5 “(2) NONAPPLICATION TO JUDICIAL PROCEED-
6 INGS.—Paragraph (1) does not apply to the collec-
7 tion, compilation, or transmittal of data in the
8 course of a judicial proceeding.

9 **“SEC. 2848. NONDISCRIMINATION.**

10 “(a) PROGRAMS AND ACTIVITIES.—

11 “(1) IN GENERAL.—For the purpose of apply-
12 ing the prohibitions against discrimination on the
13 basis of age under the Age Discrimination Act of
14 1975, on the basis of handicap under section 504 of
15 the Rehabilitation Act of 1973, on the basis of sex
16 under title IX of the Education Amendments of
17 1972, or on the basis of race, color, or national ori-
18 gin under title VI of the Civil Rights Act of 1964,
19 programs and activities funded in whole or in part
20 with funds made available under this subtitle are
21 considered to be programs and activities receiving
22 Federal financial assistance.

23 “(2) GENDER OR RELIGION.—No person shall
24 on the ground of gender or religion be excluded from
25 participation in, be denied the benefits of, or be sub-

1 jected to discrimination under, any program or ac-
2 tivity funded in whole or in part with funds made
3 available under this subtitle.

4 “(b) FAILURE TO COMPLY.—Whenever the Secretary
5 finds that a State, or an entity that has received a pay-
6 ment from an allotment to a State under this subtitle, has
7 failed to comply with a provision of law referred to in sub-
8 section (a)(1), with subsection (a)(2), or with an applica-
9 ble regulation (including one prescribed to carry out sub-
10 section (a)(2)), the Secretary shall notify the chief execu-
11 tive officer of the State and shall request such officer to
12 secure compliance. If within a reasonable period of time,
13 not to exceed 60 days, the chief executive officer fails or
14 refuses to secure compliance, the Secretary may—

15 “(1) refer the matter to the Attorney General
16 with a recommendation that an appropriate civil ac-
17 tion be instituted;

18 “(2) exercise the powers and functions provided
19 by title VI of the Civil Rights Act of 1964, the Age
20 Discrimination Act of 1975, or section 504 of the
21 Rehabilitation Act of 1973, as may be applicable; or

22 “(3) take such other action as may be provided
23 by law.

24 “(c) ACTION BY ATTORNEY GENERAL.—When a
25 matter is referred to the Attorney General pursuant to

1 subsection (b)(1), or whenever he has reason to believe
2 that a State or an entity is engaged in a pattern or prac-
3 tice in violation of a provision of law referred to in sub-
4 section (a)(1) or in violation of subsection (a)(2), the At-
5 torney General may bring a civil action in any appropriate
6 district court of the United States for such relief as may
7 be appropriate, including injunctive relief.

8 **"SEC. 2849. CRIMINAL PENALTY FOR FALSE STATEMENTS.**

9 "Whoever—

10 "(1) knowingly and willfully makes or causes to
11 be made any false statement or representation of a
12 material fact in connection with the furnishing of
13 items or services for which payment may be made by
14 a State from funds allotted to the State under this
15 subtitle; or

16 "(2) having knowledge of the occurrence of any
17 event affecting his or her initial or continued right
18 to any such payment conceals or fails to disclose
19 such event with an intent fraudulently to secure
20 such payment either in a greater amount than is due
21 or when no such payment is authorized;

22 shall be fined not more than \$25,000 or imprisoned for
23 not more than 5 years, or both.

1 **“Subtitle E—Tobacco-Related**
2 **Research Initiatives**

3 **“SEC. 2851. INTERAGENCY COUNCIL FOR REDUCING SMOK-**
4 **ING AND USE OF TOBACCO PRODUCTS FOR**
5 **THE LONG TERM. [TO BE SUPPLIED]**

6 **“SEC. 2852. STUDY BY THE INSTITUTE OF MEDICINE. [TO BE**
7 **SUPPLIED]**

8 **“SEC. 2853. DEMONSTRATION GRANTS FOR REDUCING**
9 **SMOKING AND USE OF TOBACCO PRODUCTS**
10 **FOR THE LONG TERM. [TO BE SUPPLIED]**

11 **“Subtitle F—National Public**
12 **Education Campaign**

13 **“SEC. 2861. [TO BE SUPPLIED]**

14 **TITLE III—STANDARDS TO RE-**
15 **DUCE INVOLUNTARY EXPO-**
16 **SURE TO TOBACCO SMOKE**

17 **SEC. 301. [TO BE SUPPLIED]**

Title II, Subtitle B

Restrictions on Access to Tobacco Products

- \$65 million annually from Tobacco Settlement Trust Fund -- distributed to states along same formula as other public health provisions
- oversight from CDC Office on Smoking and Health
- states required to enact law on youth access; bill will outline a model law
- states penalized for noncompliance, including failure to reach 80% retailer compliance; incentive for states to reach 95% retailer compliance
 - penalty for noncompliance is loss of enforcement dollars; after 3d year of noncompliance state loses funding entirely, can negotiate with Secretary to reinstate. Nondisbursed funds distributed to other states.
- state law must include:
 - licensing of tobacco retailers
 - prohibition on sale of tobacco products to persons under 18
 - penalties for clerks/employees
 - penalties for retailers/licensees (phased in over 10 years, emphasis on license suspension)
 - penalties against minors for purchase, possession, use
 - requirement that retailer to post signs
 - defense against penalties if minor used a fake ID and retailer has complied with other provisions
 - random unannounced inspections to assess level of compliance
 - designation of a state agency with law enforcement authority to enforce the law
- states must report annually to the Secretary on methods, success, etc.

Title II, Subtitle E

Tobacco-Related Research Initiatives

- Secretary must contract with Institute of Medicine to do independent study and recommendations outlining a strategy for tobacco-related research to include:
 - prevention (public education, media, community strategies)
 - science of addiction
 - cessation treatment methodologies
 - surveillance and epidemiology
 - prevention and treatment of tobacco-related diseases
- allocates research dollars to NIH, CDC, and AHCPR to carry out research strategy, and includes a trigger to ensure that tobacco research dollars do not supplant current baselines
- provides for an interagency council to ensure adherence to research strategy, and to ensure that science-based developments are disseminated to states and communities for incorporation into local efforts



10/11/00 - FDA

FDA's authority to regulate tobacco products as contemplated in S. 1648

The President has stated that the Administration will support proposed tobacco legislation only if it affirms the FDA's full authority to regulate tobacco products. That means the authority must be as effective as FDA's authority over other drugs and devices, and must be sufficiently flexible to meet changing circumstances. S. 1648, if enacted, does not meet that standard. The bill has two problems. First, the bill deprives the FDA of needed elements of regulatory authority. Second, by creating a separate Chapter for tobacco products, the bill unnecessarily impinges on FDA's ability to exercise, in the most effective and efficient manner, its authority over tobacco products..

I. The separate Chapter created by S. 1648 to regulate tobacco product suffers from the following specific deficiencies:

A. Access. The bill deprives FDA or any other HHS agency of the ability to modify access requirements if the current access restrictions in the FDA rule are inadequate or require redirection (such as limiting the types of stores where tobacco products can be sold). The bill also bifurcates access and advertising regulatory authority, the former going to the Centers for Disease Control; the latter to FDA. That division of responsibility weakens both authorities.

B. Advertising. The bill deprives FDA of the authority to modify advertising restrictions if the ones in the current rule require amendment or supplementation.

C. Flexibility. The bill requires that both Houses of Congress act affirmatively -- by enacting a law --to eliminate nicotine or to eliminate tobacco products (even if, in the distant future, a safer alternative to nicotine or the product is developed).

D. Product Safety. The bill limits FDA's authority to set standards pertaining to nicotine and other ingredients in tobacco products, and deprives FDA of the authority to require safer products through regulation of, for example, the filter, paper or tobacco leaf. In addition, the bill eliminates FDA's ability to require premarket approval and rigorous testing for new tobacco products.

E. Enforcement. The bill does not contain the following enforcement authorities that are in current law: civil money penalties; recall authority; authority to detain illegal products without a court order; and authority to seize products pursuant to a court order. Additionally, the bill eliminates FDA's current adulteration and misbranding authority for tobacco products -- which is the authority to bring individual enforcement actions without issuing a regulation.

II. Even if all of the above elements of FDA authority were added to S. 1648, the creation of a separate Chapter for regulation of tobacco products creates unnecessary obstacles to the effective exercise of FDA authority. Three points illustrate this.

A. The inference that would be drawn from enactment of a new Chapter is that Congress intended to create a tobacco jurisdiction in FDA not only separate from but different than that

exercised over all other FDA-regulated products. The current statutory scheme that FDA has used to regulate tobacco has been interpreted in more than 20 years of regulations, guidances and judicial cases. Enactment of a new Chapter would replace all of that with a stand-alone, uninterpreted and unexplicated new jurisdiction, the full scope and extent of which would have to be re-built through agency action and judicial rulings.

By contrast, clarification in the Food Drug and Cosmetic Act of the definitions of "drug" and "device" to explicitly include tobacco products -- and clarification of FDA's statutory authority to place restrictions on medical device products to explicitly include tobacco advertising -- leaves in place this entire regulatory context. Should Congress so choose, the standard for safety and efficacy of new products could be amended to one that achieves an enhanced public health outcome.

B. New statutes require years to implement. A new Chapter will almost certainly require new rules, which will take years to implement, especially given the virtual certainty of legal challenges.

C. Finally, a new Chapter will almost certainly generate litigation over whether the FDA must scrap entirely its current regulation and re-start the regulatory process after new legislation is adopted.

3/5

1 p.m.