

105TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. CONRAD (for himself, Mr. DASCHLE, Mr. KENNEDY, Mr. LAUTENBERG, Mr. REED, Mr. LEAHY, Mr. DODD, Mr. BINGAMAN, Mr. DURBIN, Mr. BAUCUS, Mr. DORGAN, Mr. ROCKEFELLER, Mr. KERREY, Mr. WYDEN, Mr. WELLSTONE, Mr. TORRICELLI, Mrs. BOXER, Mr. KERRY, Mr. BUMPERS, Mr. MOYNIHAN, Mr. JOHNSON, Mr. BREAUX, Mr. KOHL, Ms. LANDRIEU, Ms. MOSELEY-BRAUN, Mr. BRYAN, Mr. AKAKA, _____)

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

A BILL

To help parents keep their children from starting to use tobacco products, to expose the tobacco industry's past misconduct and to stop the tobacco industry from targeting children, to eliminate or greatly reduce the illegal use of tobacco products by children, to improve the public health by reducing the overall use of 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,*

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Healthy Kids Act”.

4 (b) TABLE OF CONTENTS.—The table of contents of
5 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purposes.
- Sec. 4. Definitions.

TITLE I—HEALTHY KIDS TRUST FUND

Subtitle A—General Provisions

- Sec. 101. Establishment of Trust Fund.
- Sec. 102. Liability of tobacco product manufacturers.
- Sec. 103. Licensing of manufacturers.
- Sec. 104. Enforcement.

Subtitle B—Payments

CHAPTER 1—TO STATES

- Sec. 111. Payments to States.

CHAPTER 2—FEDERAL HEALTH PROGRAMS

- Sec. 121. National Institutes of Health Trust Fund for Health Research.

CHAPTER 3—INVESTMENTS FOR CHILDREN

- Sec. 131. Improving child care and early childhood development.
- Sec. 132. Improving elementary education.
- Sec. 133. Increased enrollment of children with the medicaid and State children's health insurance programs.
- Sec. 134. Medicare cancer patient demonstration project; evaluation and report to Congress.

TITLE II—FDA JURISDICTION OVER TOBACCO PRODUCTS

- Sec. 201. Reference.
- Sec. 202. Statement of general authority.
- Sec. 203. Treatment of tobacco products as drugs and devices.
- Sec. 204. Safety and efficacy standard and recall authority.
- Sec. 205. General health and safety regulation of tobacco products.

SUBCHAPTER F—TOBACCO PRODUCTS

- “Sec. 571. Promulgation of regulations.
- “Sec. 572. Scientific Advisory Committee.
- “Sec. 573. Performance standards.
- “Sec. 574. Disclosure and reporting of tobacco and nontobacco ingredients and constituents.

- *Sec. 575. Tobacco product warnings, labeling and packaging.
- *Sec. 576. Preservation of State and local authority.
- *Sec. 577. Restrictions on youth access to tobacco products.
- *Sec. 578. Public disclosure of health research.
- *Sec. 579. Citizen suits.
- *Sec. 580. Agricultural producers.
- *Sec. 581. Authority of Secretary.
- Sec. 206. Repeals.
- Sec. 207. Authority of Federal Trade Commission.

TITLE III—YOUTH SMOKING REDUCTION TARGETS AND INCENTIVES TO REDUCE YOUTH SMOKING RATES

- Sec. 301. Purpose.
- Sec. 302. Child tobacco use surveys.
- Sec. 303. Reduction in underage tobacco product usage.
- Sec. 304. Noncompliance.
- Sec. 305. Rulemaking procedures.
- Sec. 306. Miscellaneous provisions.

TITLE IV—TOBACCO TRANSITION ASSISTANCE FUND

- Sec. 401. Tobacco transition assistance fund.

TITLE V—STANDARDS TO REDUCE INVOLUNTARY EXPOSURE TO TOBACCO SMOKE

- Sec. 501. Standards to reduce involuntary exposure to tobacco smoke.

TITLE VI—PUBLIC HEALTH AND OTHER PROGRAMS

Subtitle A—Research Programs

- Sec. 601. Tobacco-related research.
- Sec. 602. Research relating to patterns of smoking.
- Sec. 603. Surveillance and evaluation.

Subtitle B—Education and Prevention Programs

- Sec. 611. Grants for school- and community-based tobacco danger education programs.

Subtitle C—Miscellaneous Programs

- Sec. 621. Counter-advertising programs.
- Sec. 622. National Tobacco Cessation Program.
- Sec. 623. Assistance for those suffering from tobacco-related illnesses.
- Sec. 624. International tobacco control.
- Sec. 625. National Event Sponsorship Program.
- Sec. 626. Programs to reduce alcohol and illicit drug use by minors.

TITLE VII—LIABILITY PROTECTION; CONSENT DECREES; NATIONAL PROTOCOL

Subtitle A—Liability Protection and Attorney Fees

- Sec. 701. Dismissal of and limitations on civil actions.
- Sec. 702. Attorney's fees and expenses.

Subtitle B—Consent Decrees

- Sec. 711. Consent decrees.
- Sec. 712. Non-participating manufacturers.

Subtitle C—National Tobacco Control Protocol

CHAPTER 1—ESTABLISHMENT

- Sec. 721. National Tobacco Control Protocol.

CHAPTER 2—TERMS AND CONDITIONS

- Sec. 725. Application of chapter.
- Sec. 726. Agreement to prohibit certain advertising.
- Sec. 727. Consensual restrictions.
- Sec. 728. Agreement on format and content requirements for labeling and advertising.
- Sec. 729. Agreement to ban on nontobacco items and services, contests and games of chance, and sponsorship of events.

CHAPTER 3—ENFORCEMENT

- Sec. 731. Federal enforcement of the protocol.
- Sec. 732. State enforcement of the protocol.
- Sec. 733. Private enforcement of protocol.

TITLE VIII—MISCELLANEOUS PROVISIONS

- Sec. 801. Prohibition on use of funds to facilitate the exportation or promotion of tobacco.
- Sec. 802. Whistleblower protections.
- Sec. 803. Prohibitions relating to tobacco products and children.
- Sec. 804. Preservation of State and local authority.
- Sec. 805. Severability.

TITLE IX—PROVISIONS RELATING TO NATIVE AMERICANS

- Sec. 901. Provisions relating to Native Americans.

1 SEC. 2. FINDINGS.

2 Congress makes the following findings:

3 (1) Approximately 3,000 children begin smok-
4 ing each day. 1,000 of these children will die pre-
5 maturely from a tobacco-related illness or condition.

6 (2) The tobacco industry has targeted tobacco
7 product marketing and promotional efforts toward

1 children as a source of replacement smokers. The in-
2 dustry has also targeted minorities.

3 (3) Approximately 90 percent of smokers start
4 by the time they are 18 years old. Half of all smok-
5 ers start by age 14.

6 (4) Although most children plan to quit smok-
7 ing after experimenting, the vast majority find that
8 they have become addicted and cannot quit.

9 (5) Seventy percent of adult smokers would like
10 to quit smoking, but the tobacco industry has ma-
11 nipulated the level of nicotine in tobacco products
12 and added ingredients to enhance the addictive ef-
13 fects of nicotine to ensure that users of these prod-
14 ucts remain addicted.

15 (6) Tobacco products cause cancer, heart dis-
16 ease, lung disease, and other fatal illnesses. More
17 than 400,000 Americans die each year of these to-
18 bacco-related illnesses and conditions.

19 (7) Tobacco-related illnesses, medical conditions
20 resulting from tobacco use, and lost wages and pro-
21 ductivity cost the United States in excess of
22 \$100,000,000,000 annually.

23 (8) Federal and State taxpayers spend tens of
24 billions of dollars annually paying for the medicare,
25 medicaid, and other Federal and State health pro-

1 gram costs arising from tobacco-related illnesses and
2 conditions.

3 (9) The tobacco industry has systematically in-
4 voked and abused the attorney-client privilege to
5 hide its attempts to mislead the American public
6 about the health risks associated with tobacco use,
7 its manipulation of nicotine levels, and its efforts to
8 lure underage users and minorities to its products.

9 (10) Nicotine is an addictive drug. The market-
10 place for tobacco products is largely based on addic-
11 tion.

12 (11) Worldwide, smoking kills 3,000,000 people
13 each year. If current smoking patterns continue, to-
14 bacco use will kill 10,000,000 people a year by 2025.

15 (12) Environmental tobacco smoke is respon-
16 sible for 3,000 lung cancer deaths annually in Amer-
17 ican nonsmokers. Environmental tobacco smoke also
18 harms children's health.

19 (13) In 1995, the tobacco industry spent close
20 to \$4,900,000,000 to attract new users, retain cur-
21 rent users, increase current consumption, and gen-
22 erate favorable long-term attitudes toward smoking
23 and tobacco use.

1 (14) Tobacco product advertising misleadingly
2 portrays the use of tobacco as socially acceptable
3 and healthful.

4 (15) Tobacco product advertising is regularly
5 seen by persons under the age of 18, and persons
6 under the age of 18 are regularly exposed to tobacco
7 product promotional efforts.

8 (16) Through advertisements during and spon-
9 sorship of sporting events, tobacco has become
10 strongly associated with sports and has become por-
11 trayed as an integral part of sports and the healthy
12 lifestyle associated with rigorous sporting activity.

13 (17) Children are exposed to substantial and
14 unavoidable tobacco advertising, that leads to favor-
15 able beliefs about tobacco use, plays a role in leading
16 young people to overestimate the prevalence of to-
17 bacco use, and increases the number of young people
18 who begin to use tobacco.

19 (18) Tobacco advertising increases the size of
20 the tobacco market by increasing consumption of to-
21 bacco products including increasing tobacco sales to
22 young people.

23 (19) Children are more influenced by tobacco
24 advertising than adults, they smoke the most adver-
25 tised brands, and children as young as 3 to 6 can

1 recognize a character associated with smoking at the
2 same rate that they recognize cartoons and fast food
3 characters.

4 (20) Tobacco company documents indicate that
5 young people are an important and often crucial seg-
6 ment of the tobacco market.

7 (21) Comprehensive advertising restrictions will
8 have a positive effect on the smoking rates of young
9 people, as evidenced by the experience in Norway,
10 Finland, and other countries.

11 (22) Restrictions on advertising are necessary
12 to prevent unrestricted tobacco advertising from un-
13 dermining legislation prohibiting access to young
14 people and providing for education about tobacco
15 use.

16 (23) International experience shows that adver-
17 tising regulations that are stringent and comprehen-
18 sive have a greater impact on overall tobacco use
19 and young people's use than weaker or less com-
20 prehensive ones. Text only requirements, while not
21 as stringent as a ban, will accomplish this purpose
22 while preserving the informational function of adver-
23 tising.

24 **SEC. 3. PURPOSES.**

25 The purposes of this Act are—

1 (1) to help American families dramatically re-
2 duce the number of children illegally using tobacco
3 products by—

4 (A) increasing the price of cigarettes by at
5 least \$1.50 per pack in order to discourage
6 youth purchases;

7 (B) implementing prevention, education,
8 cessation, and counter-advertising programs;

9 (C) restricting advertisements designed to
10 encourage kids to use tobacco products;

11 (D) imposing penalties on manufacturers
12 for failing to reach youth smoking rate reduc-
13 tion targets;

14 (E) requiring retailers to comply with laws
15 forbidding sales to minors; and

16 (F) giving the Food and Drug Administra-
17 tion and State and local governments the au-
18 thority and resources to keep tobacco products
19 out of the hands of minors;

20 (2) to compensate taxpayers for their costs at-
21 tributable to tobacco-related illnesses by reimbursing
22 the medicaid and medicare programs and resolving
23 the legal claims of Federal, State and local govern-
24 ments for those costs that resulted from past mis-
25 conduct by the tobacco industry;

1 (3) to improve the public health by reducing the
2 number of adult users of tobacco products through
3 approved cessation programs and limiting public ex-
4 posure to environmental tobacco smoke;

5 (4) to provide assistance to tobacco farmers, to-
6 bacco factory workers, and rural communities;

7 (5) to affirm the full authority of the Food and
8 Drug Administration to regulate the manufacture,
9 labeling, sale, distribution, and advertising of to-
10 bacco products to the fullest extent authorized by
11 the commerce clause of the United States Constitu-
12 tion;

13 (6) to make available to the public tobacco in-
14 dustry documents regarding the health effects of to-
15 bacco products, addiction, the agricultural produc-
16 tion of tobacco, the manufacture of tobacco prod-
17 ucts, the distribution of tobacco products, and the
18 marketing of tobacco products to youths; and

19 (7) to enhance global anti-tobacco efforts to
20 minimize the adverse health effects of tobacco prod-
21 ucts.

22 **SEC. 4. DEFINITIONS.**

23 In this Act:

24 (1) **BRAND.**—The term “brand” means a vari-
25 ety of a tobacco product distinguished by the tobacco

1 used, tar content, nicotine content, flavoring used,
2 size, filtration, or packaging.

3 (2) CIGAR.—The term “cigar” means any roll
4 of tobacco wrapped in leaf tobacco or in any sub-
5 stance containing tobacco (other than any roll of to-
6 bacco which is a cigarette or cigarillo within the
7 meaning of paragraph (3) or (4)).

8 (3) CIGARETTE.—The term “cigarette”
9 means—

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

12 (B) any roll of tobacco wrapped in any
13 substance containing tobacco which, because of
14 its appearance, the type of tobacco used in the
15 filler, or its packaging and labeling, is likely to
16 be offered to, or purchased by, consumers as a
17 cigarette described in subparagraph (A).

18 (4) CIGARILLOS.—The term “cigarillos” means
19 any roll of tobacco wrapped in leaf tobacco or any
20 substance containing tobacco (other than any roll of
21 tobacco which is a cigarette within the meaning of
22 paragraph (3)) and as to which 1,000 units weigh
23 not more than 3 pounds.

24 (5) CIGARETTE TOBACCO.—The term “cigarette
25 tobacco” means any product that consists of loose

1 tobacco and is intended for use by persons in a ciga-
2 rette. Unless otherwise stated, the requirements of
3 this Act pertaining to cigarettes shall also apply to
4 cigarette tobacco.

5 (6) DISTRIBUTOR.—The term “distributor”
6 means any person who furthers the distribution of
7 tobacco products, whether domestic or imported, at
8 any point from the original place of manufacture to
9 the person who sells or distributes the product to in-
10 dividuals for personal consumption. Such term shall
11 not include common carriers.

12 (7) LITTLE CIGAR.—The term “little cigar”
13 means any roll of tobacco wrapped in leaf tobacco or
14 any substance containing tobacco (other than any
15 roll of tobacco which is a cigarette within the mean-
16 ing of subsection (1)) and as to which 1,000 units
17 weigh not more than 3 pounds.

18 (8) MANUFACTURER.—The term “manufac-
19 turer” means any person, including any repacker or
20 relabeler, who manufactures, fabricates, assembles,
21 processes, or labels a tobacco product.

22 (9) PACKAGE.—The term “package” means a
23 pack, box, carton, or container of any kind in which
24 tobacco products are offered for sale, sold, or other-
25 wise distributed to consumers.

1 (10) PERSON.—The term “person” means an
2 individual, partnership, corporation, parent corpora-
3 tion, or any other business or legal entity or succes-
4 sor in interest of any such person.

5 (11) PIPE TOBACCO.—The term “pipe tobacco”
6 means any loose tobacco that, because of its appear-
7 ance, type, packaging, or labeling, is likely to be of-
8 fered to, or purchased by, consumers as a tobacco
9 product to be smoked in a pipe.

10 (12) POINT OF SALE.—The term “point of
11 sale” means any location at which an individual can
12 purchase or otherwise obtain tobacco products for
13 personal consumption.

14 (13) RETAILER.—The term “retailer” means
15 any person who sells tobacco products to individuals
16 for personal consumption, or who operates a facility
17 where vending machines or self-service displays are
18 permitted under this Act.

19 (14) ROLL-YOUR-OWN TOBACCO.—The term
20 “roll-your-own tobacco” means any tobacco which,
21 because of its appearance, type, packaging, or label-
22 ing, is suitable for use and likely to be offered to,
23 or purchased by, consumers as tobacco for making
24 cigarettes.

1 (15) SALE.—The term “sale” includes the sell-
2 ing, providing samples of, or otherwise making to-
3 bacco products available for personal consumption in
4 any place within the scope of this Act.

5 (16) SECRETARY.—Except as provided in title
6 IV, the term “Secretary” means the Secretary of
7 Health and Human Services.

8 (17) SMOKELESS TOBACCO.—The term “smoke-
9 less tobacco” means any product that consists of
10 cut, ground, powdered, or leaf tobacco that is in-
11 tended to be placed in the oral or nasal cavity.

12 (18) STATE.—The term “State” includes the
13 several States, the District of Columbia, the Com-
14 monwealth of Puerto Rico, Guam, the Virgin Is-
15 lands, American Samoa, the Northern Mariana Is-
16 lands, and any other territory or possession of the
17 United States. Such term includes any political divi-
18 sion of any State.

19 (19) TOBACCO.—The term “tobacco” means to-
20 bacco in its unmanufactured form.

21 (20) TOBACCO PRODUCT.—The term “tobacco
22 product” means any product made of or derived
23 from tobacco leaf for human consumption, including,
24 but not limited to, cigarettes, cigarillos, cigarette to-

1 bacco, cigars, little cigars, pipe tobacco, and smoke-
2 less tobacco, and roll-your-own tobacco.

(21) TRUST FUND.—Except as provided in section 121 and title IV, the term “Trust Fund” means the Health Enhancement and Lowered Tobacco Hazards for Young Kids Trust Fund established under section 101.

8 **TITLE I—HEALTHY KIDS TRUST**
9 **FUND**

10 **Subtitle A—General Provisions**

11 SEC. 101. ESTABLISHMENT OF TRUST FUND.

12 (a) CREATION.—

13 (1) IN GENERAL.—There is established in the
14 Treasury of the United States a trust fund to be
15 known as the “Health Enhancement and Lowered
16 Tobacco Hazards for Young Kids Trust Fund” (re-
17 ferred to as the “HEALTHY Kids Trust Fund”),
18 consisting of such amounts as may be appropriated
19 or credited to the Trust Fund.

(2) TRUSTEES.—The trustees of the Trust Fund shall be the Secretary of the Treasury and the Secretary of Health and Human Services.

23 (b) TRANSFERS.—There are hereby appropriated and
24 transferred to the Trust Fund an amount equal to the
25 initial payment under section 102 and 75 percent of the—

1 (1) amounts received under the annual assess-
2 ments made under section 102;

3 (2) amounts paid as fines or penalties, includ-
4 ing interest thereon, under section 103; and

5 (3) amounts repaid or recovered under title III,
6 including interest thereon.

7 (c) REPAYABLE ADVANCES.—

8 (1) AUTHORIZATION.—There are authorized to
9 be appropriated to the Trust Fund, as repayable ad-
10 vances, such sums as may from time to time be nec-
11 essary to make the expenditures described in sub-
12 section (d).

13 (2) REPAYMENT WITH INTEREST.—Repayable
14 advances made to the Trust Fund shall be repaid,
15 and interest on such advances shall be paid, to the
16 general fund of the Treasury when the Secretary of
17 the Treasury determines that moneys are available
18 in the Trust Fund for such purposes.

19 (3) RATE OF INTEREST.—Interest on advances
20 made pursuant to this subsection shall be at a rate
21 determined by the Secretary of the Treasury (as of
22 the close of the calendar month preceding the month
23 in which the advance is made) to be equal to the
24 current average market yield on outstanding market-
25 able obligations of the United States with remaining

1 period to maturity comparable to the anticipated pe-
2 riod during which the advance will be outstanding.

3 (d) EXPENDITURES FROM TRUST FUND.—Amounts
4 in the Trust Fund shall be made available in each fiscal
5 year, without further appropriation as follows:

6 (1) 14.5 percent of such amounts shall be made
7 available for payments to States as provided for
8 under section 111.

9 (2) 17 percent of such amounts shall be made
10 available for grants to the States for child care and
11 early childhood development as provided for in sec-
12 tion 131.

13 (3) 6 percent of such amounts shall be made
14 available for grants to States for education as pro-
15 vided for in section 132.

16 (4) 4 percent of such amounts shall be made
17 available to carry out the outreach and increased en-
18 rollment provisions under the amendments made by
19 section 133 to the medicaid program under title XIX
20 of the Social Security Act (42 U.S.C. 1396 et seq.)
21 and the children's health insurance program under
22 title XXI of such Act (42 U.S.C. 1397aa et seq.).

23 (5) 15.5 percent of such amounts shall be made
24 available for public health programs, of which—

1 (A) \$300,000,000 shall be made available
2 to the Secretary to carry out chapter IX of the
3 Food Drug and Cosmetic Act (as added by sec-
4 tion 204):

5 (B) \$200,000,000 shall be made available
6 to the Indian Health Service to be used as pro-
7 vided for in title IX; and

8 (C) the remainder shall be made available
9 for public health programs as provided for in
10 title VI.

11 (6) 21 percent of such amounts shall be made
12 available to the National Institutes of Health Trust
13 Fund for Health Research for the conduct of health
14 research as provided for in section 121.

15 (7) For agricultural programs as provided for
16 in title IV—

17 (A) 12 percent of such amounts shall be
18 made available to the Tobacco Community Re-
19 vivalization Trust Fund for each of the first 10
20 fiscal years after the date of enactment of this
21 Act;

22 (B) 4 percent of such amounts shall be
23 made available to the Tobacco Community Re-
24 vivalization Trust Fund for each of the 11th

1 through 15th fiscal years after the date of en-
2 actment of this Act; and

3 (C) 2 percent of such amounts shall be
4 made available to the Tobacco Community Re-
5 vivalization Trust Fund for each of the 16th
6 through 25th fiscal years after the date of en-
7 actment of this Act.

8 (8) For the Hospital Insurance Trust Fund—

9 (A) 4 percent of such amounts shall be
10 made available to such Trust Fund for each of
11 the first 10 fiscal years after the date of enact-
12 ment of this Act (less amounts made available
13 under paragraph (9) for the first 3 such fiscal
14 years);

15 (B) 8 percent of such amounts shall be
16 made available to such Trust Fund for each of
17 the 11th through 15th fiscal years after the
18 date of enactment of this Act;

19 (C) 9 percent of such amounts shall be
20 made available to such Trust Fund for each of
21 the 16th through 25th fiscal years after the
22 date of enactment of this Act; and

23 (D) 10 percent of such amounts shall be
24 made available to such Trust Fund for each
25 subsequent fiscal year.

1 (9) For carrying out section 134, \$250,000,000
2 shall be made available in each of the 3 fiscal years
3 described in such section:

4 (10) For reducing the debt—

5 (A) 6 percent of such amounts shall be
6 made available for such reduction in each of the
7 first 10 fiscal years after the date of enactment
8 of this Act;

9 (B) 10 percent of such amounts shall be
10 made available for such reduction in each of the
11 11th through 15th fiscal years after the date of
12 enactment of this Act;

13 (C) 11 percent of such amounts shall be
14 made available for such reduction in each of the
15 16th through 25th fiscal years after the date of
16 enactment of this Act; and

17 (D) 12 percent of such amounts shall be
18 made available for such reduction in each sub-
19 sequent fiscal year.

20 (e) BUDGETARY TREATMENT AND DEFINITION.—

21 (1) TREATMENT.—Amounts made available
22 under paragraphs (8) and (10) of subsection (d)
23 shall not be included—

24 (A) by the Office of Management and
25 Budget in the estimates and reports required by

1 sections 252(b) and 254 of the Balanced Budg-
2 et and Emergency Deficit Control Act of 1985;
3 and

4 (B) by the Committee on the Budget of
5 the House of Representatives and the Commit-
6 tee on the Budget of the Senate for purposes of
7 congressional enforcement under section 302(f)
8 and 311(2)(B) of the Congressional Budget Act
9 of 1974 and section 202 of House Concurrent
10 Resolution 67 (104th Congress).

11 (2) DEFINITION.—In subsection (d)109), the
12 term “debt” means any obligation of the Federal
13 Government included in the debt subject to limit.

14 **SEC. 102. LIABILITY OF TOBACCO PRODUCT MANUFACTUR-**
15 **ERS.**

16 (a) PAYMENTS.—

17 (1) INITIAL PAYMENT --Not later than 90 days
18 after the date of enactment of this Act, each manu-
19 facturer shall pay to the Trust Fund an amount
20 that bears the same ratio to \$15,000,000,000 as the
21 average stock market capitalization of the tobacco
22 manufacturer (as defined in paragraph (3)) bears to
23 the average stock market capitalization of all to-
24 bacco manufacturers for 1996.

1 (2) ANNUAL ASSESSMENTS AND COLLECTION.—

2 For each calendar year beginning with the first full
3 calendar year following the year in which this Act is
4 enacted, the Secretary shall assess each manufac-
5 turer an amount determined under subsection (b).
6 Such assessments shall be collected in a manner
7 similar to the manner in which excise taxes are col-
8 lected under chapter 52 of the Internal Revenue
9 Code of 1986.

10 (3) AVERAGE STOCK MARKET CAPITALIZA-
11 TION.—For purposes of this subsection, the average
12 stock market capitalization of a manufacturer for a
13 year shall be determined by the Secretary of the
14 Treasury based on data submitted by manufacturers
15 and other appropriate data. Such determinations
16 shall be made regardless of whether the manufac-
17 turer issues stock.

18 (b) ANNUAL ASSESSMENTS.—The Secretary shall as-
19 sess each manufacturer (in accordance with regulations,
20 relating to the timing and method of payment of assess-
21 ments, to be promulgated by the Secretary of the Treas-
22 ury) an amount in accordance with the following:

23 (1) SMALL CIGARETTES.—With respect to a
24 manufacturer of cigarettes weighing not more than
25 3 pounds per thousand, the assessment shall equal—

1 (A) for cigarettes removed during calendar
2 year 1999, \$25 per thousand;

3 (B) for cigarettes removed during calendar
4 year 2000, \$50 per thousand; and

5 (C) for cigarettes removed during calendar
6 year 2001, \$75 per thousand.

7 (2) LARGE CIGARETTES.—

8 (A) IN GENERAL.—With respect to a man-
9 ufacturer of cigarettes weighing more than 3
10 pounds per thousand, the assessment shall
11 equal—

12 (i) for cigarettes removed during cal-
13 endar year 1999, \$52.50 per thousand;

14 (ii) for cigarettes removed during cal-
15 endar year 2000, \$105 per thousand; and

16 (iii) for cigarettes removed during cal-
17 endar year 2001, \$157.50 per thousand.

18 (B) EXCEPTION.—On cigarettes more than
19 6½ inches in length, at the rate prescribed for
20 cigarettes weighing not more than 3 pounds per
21 thousand, counting each 2¾ inches, or fraction
22 thereof, of the length of each as one cigarette.

23 (3) SMALL CIGARS.—With respect to a manu-
24 facturer of cigars weighing not more than 3 pounds
25 per thousand, the assessment shall equal—

1 (A) for cigars removed during calendar
2 year 1999, \$25 per thousand;

3 (B) for cigars removed during calendar
4 year 2000, \$50 per thousand; and

5 (C) for cigars removed during calendar
6 year 2001, \$75 per thousand.

7 (4) LARGE CIGARS.—With respect to a manu-
8 facturer of cigars weighing more than 3 pounds per
9 thousand, the assessment shall equal—

10 (A) for cigars removed during calendar
11 year 1999, 25 percent of the price for which
12 such cigars are sold but not more than \$500
13 per thousand;

14 (B) for cigars removed during calendar
15 year 2000, 50 percent of the price for which
16 such cigars are sold but not more than \$1,000
17 per thousand; and

18 (C) for cigars removed during calendar
19 year 2001, 75 percent of the price for which
20 such cigars are sold but not more than \$1,500
21 per thousand.

22 (5) SNUFF.—With respect to a manufacturer of
23 snuff (as such term is defined for purposes of chap-
24 ter 52 of the Internal Revenue Code of 1986) the
25 assessment shall equal—

1 (A) for snuff removed during calendar year
2 1999, \$6.67 per pound (and a proportionate as-
3 sessment at the like rate on all fractional parts
4 of a pound);

5 (B) for snuff removed during calendar year
6 2000, \$13.33 per pound (and a proportionate
7 assessment at the like rate on all fractional
8 parts of a pound); and

9 (C) for snuff removed during calendar year
10 2001, \$20 per pound (and a proportionate as-
11 sessment at the like rate on all fractional parts
12 of a pound).

13 (6) CHEWING TOBACCO.—With respect to a
14 manufacturer of chewing tobacco (as such term is
15 defined for purposes of chapter 52 of the Internal
16 Revenue Code of 1986) the assessment shall equal—

17 (A) for chewing tobacco removed during
18 calendar year 1999, \$2.67 per pound (and a
19 proportionate assessment at the like rate on all
20 fractional parts of a pound);

21 (B) for chewing tobacco removed during
22 calendar year 2000, \$5.33 per pound (and a
23 proportionate assessment at the like rate on all
24 fractional parts of a pound); and

1 (C) for chewing tobacco removed during
2 calendar year 2001, \$8 per pound (and a pro-
3 portionate assessment at the like rate on all
4 fractional parts of a pound).

5 (7) PIPE TOBACCO.—With respect to a manu-
6 facturer of pipe tobacco (as such term is defined for
7 purposes of chapter 52 of the Internal Revenue Code
8 of 1986) the assessment shall equal—

9 (A) for pipe tobacco removed during cal-
10 endar year 1999, \$5.33 per pound (and a pro-
11 portionate assessment at the like rate on all
12 fractional parts of a pound);

13 (B) for pipe tobacco removed during cal-
14 endar year 2000, \$10.67 per pound (and a pro-
15 portionate assessment at the like rate on all
16 fractional parts of a pound); and

17 (C) for pipe tobacco removed during cal-
18 endar year 2001, \$16.00 per pound (and a pro-
19 portionate assessment at the like rate on all
20 fractional parts of a pound).

21 (8) ROLL-YOUR-OWN TOBACCO.—With respect
22 to a manufacturer of roll-your-own tobacco the as-
23 sessment shall equal—

24 (A) for roll-your-own tobacco removed dur-
25 ing calendar year 1999, \$5.71 per pound (and

1 a proportionate assessment at the like rate on
2 all fractional parts of a pound);

3 (B) for roll-your-own tobacco removed dur-
4 ing calendar year 2000, \$11.43 per pound (and
5 a proportionate assessment at the like rate on
6 all fractional parts of a pound); and

7 (C) for roll-your-own tobacco removed dur-
8 ing calendar year 2001, \$17.14 per pound (and
9 a proportionate assessment at the like rate on
10 all fractional parts of a pound).

11 (c) INFLATION ADJUSTMENT.—In the case of a cal-
12 endar year after 2001, the dollar amount described in sub-
13 paragraph (C) of paragraphs (1), (2), (3), (4), (5), (6),
14 (7), and (8), and the percentage in subparagraph (C) of
15 paragraph (4), applicable to the preceding calendar year
16 shall be increased by an amount equal to—

17 (1) such dollar amount (or percentage), multi-
18 plied by

19 (2) the greater of—

20 (A) the medical consumer price percentage
21 increase for such calendar year as determined
22 in the same manner as the adjustment is deter-
23 mined under section 1(f)(3) of the Internal
24 Revenue Code of 1986 for such calendar year
25 by substituting “the second preceding calendar

1 year" for "calendar year 1992" in subpara-
2 graph (B) thereof; or

3 (B) 3 percent.

4 (d) ASSESSMENTS APPLICABLE TO FLOOR
5 STOCKS.—

6 (1) IN GENERAL.—Tobacco products manufac-
7 tured in or imported into the United States which
8 are removed before any assessment date, and held
9 on such date for sale by any person, shall be subject
10 to an assessment in an amount equal to the excess
11 of—

12 (A) the assessment which would be im-
13 posed under subsection (b) on the product if the
14 product had been removed on such date, over

15 (B) the prior assessment (if any) imposed
16 under such subsection on such product.

17 (2) LIABILITY FOR ASSESSMENT AND METHOD
18 OF PAYMENT.—

19 (A) LIABILITY FOR ASSESSMENT.—A per-
20 son holding tobacco products on any assessment
21 date, to which any assessment imposed under
22 paragraph (1) applies shall be liable for such
23 assessment.

24 (B) METHOD OF PAYMENT.—The assess-
25 ment imposed under paragraph (1) shall be

1 paid in such manner as the Secretary of the
2 Treasury shall prescribe by regulations.

3 (C) TIME FOR PAYMENT.—The assessment
4 imposed under paragraph (1) shall be paid on
5 or before April 1 following any assessment date.

6 (3) ARTICLES IN FOREIGN TRADE ZONES.—
7 Notwithstanding the Act of June 18, 1934 (48 Stat.
8 998, 19 U.S.C. 81a) and any other provision of law,
9 any product which is located in a foreign trade zone
10 on any assessment date, shall be subject to the as-
11 sessment imposed by paragraph (1) if—

12 (A) internal revenue taxes have been deter-
13 mined, or customs duties liquidated, with re-
14 spect to such product before such date; or

15 (B) such article is held on such date under
16 the supervision of a customs officer.

17 (4) ASSESSMENT DATE.—The term “assess-
18 ment date” means January 1.

19 (e) NO TAX BENEFIT.—

20 (1) IN GENERAL.—The initial payment de-
21 scribed in subsection (a)(1) shall not be considered
22 to be an ordinary and necessary expense in carrying
23 on a trade or business for purposes of the Internal
24 Revenue Code of 1986 and shall not be tax deduct-
25 ible.

1 (2) LOOK-BACK PENALTIES.—The payment of
2 penalties under title III shall not be considered to be
3 an ordinary and necessary expense in carrying on a
4 trade or business for purposes of the Internal Revenue
5 Code of 1986 and shall not be deductible.

6 (f) EFFECT OF BANKRUPTCY.—Section 507(a)(8) of
7 title 11, United States Code, is amended—

8 (1) in subparagraph (F)(iii), by striking “or” at
9 the end;

10 (2) in subparagraph (G), by striking the period
11 and inserting “; or”; and

12 (3) by adding at the end the following:

13 “(H) a payment, an assessment, or a penalty
14 to be paid into the Health Enhancement
15 and Lowered Tobacco Hazards for Young Kids
16 Trust Fund under section 102 (or any other
17 section) of the Healthy Kids Act.”.

18 (g) LIMITATION.—A manufacturer may not utilize
19 any proceeds from liability insurance coverage to make
20 payments or pay assessments under this section.

21 (h) HEALTHY KIDS STAMP.—The Secretary shall
22 promulgate regulations to provide that a Healthy Kids
23 Stamp be affixed to each package of a tobacco product
24 for which an assessment has been paid under this section.

1 (i) NONAPPLICATION TO CERTAIN MANUFACTUR-
2 ERS.—

3 (1) EXEMPTION.—

4 (A) IN GENERAL.—A manufacturer de-
5 scribed in paragraph (2) shall be exempt from
6 the requirements of this section relating to—

7 (i) the payment of an initial payment
8 under subsection (a)(1); and

9 (ii) the payment of that portion of the
10 annual assessments under this section that
11 will be provided under paragraphs (1)
12 through (4) of section 101(d) to States
13 with which such manufacturer has settled
14 tobacco-related civil actions as of the date
15 of enactment of this Act as determined by
16 the Secretary under subparagraph (B).

17 (B) DETERMINATION.—For purposes of
18 subparagraph (A)(ii), the Secretary shall deter-
19 mine the amount of the assessments involved
20 that will be provided under paragraphs (1)
21 through (4) of section 101(d) to States de-
22 scribed in such subparagraph based on the ratio
23 described in section 111(b)(2)(A) with respect
24 to such States. Such amount shall be deducted

1 from the aggregate assessment due from the
2 manufacturer involved.

3 (2) MANUFACTURER.—A manufacturer de-
4 scribed in this section is a manufacturer that has re-
5 solved tobacco-related civil actions with more than
6 25 States prior to January 1, 1998 through judicial
7 consent decrees.

8 (3) LIMITATION.—The provisions of paragraph
9 (1) shall apply only to assessments on cigarettes to
10 the extent that such cigarettes constitute less than
11 3 percent of all cigarettes manufactured and distrib-
12 uted for consumer use in any year.

13 **SEC. 103. LICENSING OF MANUFACTURERS.**

14 (a) IN GENERAL.—The Secretary, acting through the
15 Food and Drug Administration, shall establish a tobacco
16 manufacturer licensing program.

17 (b) REQUIREMENT.—A manufacturer or importer
18 shall have in effect a license issued under the program
19 under subsection (a) in order—

20 (1) to be eligible to manufacture and distribute
21 tobacco products in the United States, or, in the
22 case of an importer, to be eligible to import tobacco
23 products; and

24 (2) to be eligible to receive the protections pro-
25 vided under subtitle A of title VII.

1 (c) NONPAYMENT OF ASSESSMENTS.—A manufac-
2 turer or importer shall not be eligible to receive a license
3 under this section if such manufacturer or importer has
4 failed to pay the payment of assessment required under
5 section 102.

6 (d) REVOCATION AND SUSPENSION.—The Secretary
7 shall promulgate regulations to provide for the enforce-
8 ment of the program established under section (a). Such
9 regulations shall provide for the revocation or suspension
10 of a license for nonpayment of required assessments.

11 **SEC. 104. ENFORCEMENT.**

12 (a) IN GENERAL.—The Secretary of the Treasury, in
13 consultation with the Secretary of Health and Human
14 Services, shall enforce the provisions of section 102 with
15 respect to any manufacturer that fails to pay any amount
16 assessed under section 102.

17 (b) AMOUNT OF PENALTY.—The amount of the pen-
18 alty imposed by subsection (a) on any failure with respect
19 to a manufacturer shall be established by the Secretary
20 of the Treasury for each day during the noncompliance
21 period, except that no such penalty shall be less than
22 \$25,000 plus interest.

23 (c) NONCOMPLIANCE PERIOD.—For purposes of this
24 section, the term “noncompliance period” means, with re-

1 spect to any failure to pay an assessment under section
2 102, the period—

3 (1) beginning on the due date for such pay-
4 ment; and

5 (2) ending on the date on which such payment
6 is paid in full.

7 Subtitle B—Payments

8 CHAPTER 1—TO STATES

9 SEC. 111. PAYMENTS TO STATES.

10 (a) AVAILABILITY OF FUNDS.—

11 (1) IN GENERAL.—The amounts made available
12 for a fiscal year under section 101(d)(1) shall be
13 made available to carry out subsections (b) and (d).

14 (2) NO OVERPAYMENT.—With respect to the
15 amount provided to a State under paragraph (1) for
16 a fiscal year, the Secretary shall not treat such
17 amount as an overpayment under any joint Federal-
18 State health program.

19 (3) FISCAL YEAR LIMITATION.—Amounts made
20 available for a fiscal year under subsection (b) shall
21 not exceed the amount available for such fiscal year
22 under section 101(d)(1).

23 (b) REIMBURSEMENT.—

24 (1) IN GENERAL.—The Secretary shall use
25 amounts made available under subsection (a)(1) in

1 each fiscal year to provide funds to each State that
2 is eligible under subsection (c) to reimburse such
3 State for amounts expended by the State under the
4 State program under title XIX of the Social Security
5 Act (42 U.S.C. 1396 et seq.) or any other State
6 health program for the treatment of individuals with
7 tobacco-related illnesses or conditions.

8 (2) AMOUNT.—

9 (A) IN GENERAL.—Except as provided in
10 subparagraph (B), the amount for which a
11 State is eligible under paragraph (1) shall be
12 based on the ratio of the total Federal pay-
13 ments to the State under title XIX of the Social
14 Security Act (42 U.S.C. 1396 et seq.) for the
15 fiscal year involved to the total Federal pay-
16 ments to all States under such title for such fis-
17 cal year.

18 (B) SPECIAL PAYMENT RULE.—In the case
19 of a State that, as of the date of the enactment
20 of this Act, has resolved tobacco-related civil ac-
21 tions through judicial consent decrees with a
22 manufacturer described in section 102(i), the
23 amount determined under subparagraph (A)
24 shall be reduced by an amount equal to the
25 amount by which such manufacturer's payment

1 under section 102(a)(2) is reduced under sec-
2 tion 102(i) as a result of such settlement.

3 (3) ADJUSTMENT.—With respect to a fiscal
4 year in which the amount determined under para-
5 graphs (1) and (2) of subsection (a) exceeds the lim-
6 itation under subsection (a)(3), the Secretary shall
7 make pro rata reductions in the amounts provided to
8 States under this subsection.

9 (4) REALLOTMENT.—The amount for which a
10 State is eligible under this subsection that is not
11 made available to the State as a result of the failure
12 of the State to meet the requirements of subsection
13 (c) shall be made available to other States on a pro
14 rata basis.

15 (5) USE OF FUNDS.—Amounts provided to a
16 State under this subsection shall be used—

17 (A) to reimburse the State for expenses in-
18 curred by the State under the State program
19 under title XIX of the Social Security Act (42
20 U.S.C. 1396 et seq.) relating to the treatment
21 of tobacco-related illnesses or conditions;

22 (B) to reimburse the State for other ex-
23 penses incurred by the State in providing di-
24 rectly, or reimbursing others for the provision

1 of. treatment for tobacco-related illnesses or
2 conditions; and

3 (C) to provide funds to local governmental
4 entities as provided for in subsection (d).

5 (c) ELIGIBILITY.—To be eligible to receive funds
6 under this section a State shall—

7 (1) agree to resolve in accordance with section
8 701 any civil action that has been commenced by the
9 State against a tobacco manufacturer, distributor, or
10 retailer of a tobacco product seeking recovery for ex-
11 penditures attributable to the treatment of tobacco
12 induced illnesses and conditions or other damages;

13 (2) prepare and submit to the Secretary for ap-
14 proval a plan describing the manner in which the
15 State will comply with the requirements of sub-
16 section (d) and a certification that all actions de-
17 scribed in paragraph (1) have been resolved; and

18 (3) comply with the provisions of subsection (d)
19 with respect to State and local governments.

20 (d) FUNDS FOR LOCAL GOVERNMENTAL ENTI-
21 TIES.—To be eligible to receive funds under subsection
22 (b), a State shall have adopted procedures to provide an
23 equitable portion of such funds to local governmental enti-
24 ties within the State that can demonstrate that such enti-
25 ties incurred tobacco-related health costs through—

1 (1) contributions to the program under title
2 XIX of the Social Security Act (42 U.S.C. 1396 et
3 seq.);

4 (2) the provision of indigent care;

5 (3) the provision of health care coverage to gov-
6 ernmental employees; or

7 (4) the implementation of tobacco product en-
8 forcement or tobacco product regulatory require-
9 ments in accordance with this Act.

10 **CHAPTER 2—FEDERAL HEALTH** 11 **PROGRAMS**

12 **SEC. 121. NATIONAL INSTITUTES OF HEALTH TRUST FUND** 13 **FOR HEALTH RESEARCH.**

14 (a) **CREATION OF TRUST FUND.**—There is estab-
15 lished in the Treasury of the United States a trust fund
16 to be known as the “National Institutes of Health Trust
17 Fund for Health Research” (hereafter referred to in this
18 section as the “Trust Fund”), consisting of such amounts
19 as may be appropriated or transferred to the Trust Fund
20 as provided in this section.

21 (b) **FUNDING.**—There shall be transferred to the
22 Trust Fund an amount equal to the amount made avail-
23 able for a fiscal year under section 101(d)(6) to carry out
24 this section in such fiscal year.

25 (c) **OBLIGATIONS FROM TRUST FUND.**—

1 (1) IN GENERAL.—Subject to the provisions of
2 paragraph (4), with respect to the amounts made
3 available in the Trust Fund in a fiscal year, the Sec-
4 retary shall distribute during any fiscal year—

5 (A) 2 percent of such amounts to the Of-
6 fice of the Director of the National Institutes of
7 Health to be allocated at the Director's discre-
8 tion—

9 (i) for carrying out the responsibilities
10 of the Office of the Director, including the
11 Office of Research on Women's Health and
12 the Office of Research on Minority Health,
13 the Office of Alternative Medicine, the Of-
14 fice of Rare Disease Research, the Office
15 of Behavioral and Social Sciences Research
16 (for use for efforts to reduce tobacco use),
17 the Office of Dietary Supplements, and the
18 Office for Disease Prevention; and

19 (ii) for construction and acquisition of
20 equipment for or facilities of or used by
21 the National Institutes of Health;

22 (B) 2 percent of such amounts for transfer
23 to the National Center for Research Resources
24 to carry out section 1502 of the National Insti-
25 tutes of Health Revitalization Act of 1993 con-

1. cerning Biomedical and Behavioral Research
2. Facilities:

3. (C) 7.5 percent of such amounts to be used
4. for research into the prevention and cure of
5. cancer;

6. (D) 7.5 percent of such amounts to be
7. used as provided for in section 601;

8. (E) 1 percent of such amounts to be used
9. for prevention research programs at the Centers
10. for Disease Control and Prevention;

11. (F) 1 percent of such amounts to be used
12. for quality and health outcomes research at the
13. Agency for Health Care Policy and Research;
14. and

15. (G) the remainder of such amounts to
16. member institutes and centers, including the
17. Office of AIDS Research, of the National Insti-
18. tutes of Health in the same proportion to such
19. remainder, as the amount of annual appropria-
20. tions under appropriations Acts for each mem-
21. ber institute and center for the fiscal year bears
22. to the total amount of appropriations under ap-
23. propriations Acts for all member institutes and
24. centers of the National Institutes of Health for
25. the fiscal year.

1 (2) PLANS OF ALLOCATION.—The amounts
2 transferred under paragraph (1)(G) shall be allo-
3 cated by the Director of the National Institutes of
4 Health or the various directors of the institutes and
5 centers, as the case may be, pursuant to allocation
6 plans developed by the various advisory councils to
7 such directors, after consultation with such
8 directors.

9 (3) GRANTS AND CONTRACTS FULLY FUNDED
10 IN FIRST YEAR.—With respect to any grant or con-
11 tract funded by amounts distributed under para-
12 graph (1), the full amount of the total obligation of
13 such grant or contract shall be funded in the first
14 year of such grant or contract, and shall remain
15 available until expended.

16 (4) TRIGGER AND RELEASE OF MONIES AND
17 PHASE-IN.—

18 (A) TRIGGER AND RELEASE.—No expendi-
19 ture shall be made under paragraph (1) during
20 any fiscal year in which the annual amount ap-
21 propriated for the National Institutes of Health
22 is less than the amount so appropriated for fis-
23 cal year 1999.

1 (B) PHASE-IN.—The Secretary shall phase
2 in the distributions required under paragraph
3 (1) so that—

4 (i) 25 percent of the amount in the
5 Trust Fund is distributed in the first fiscal
6 year for which funds are available;

7 (ii) 50 percent of the amount in the
8 Trust Fund is distributed in the second
9 fiscal year for which funds are available;

10 (iii) 75 percent of the amount in the
11 Trust Fund is distributed in the third fis-
12 cal year for which funds are available; and

13 (iv) 100 percent of the amount in the
14 Trust Fund is distributed in the fourth
15 and each succeeding fiscal year for which
16 funds are available.

17 **CHAPTER 3—INVESTMENTS FOR**
18 **CHILDREN**

19 **SEC. 131. IMPROVING CHILD CARE AND EARLY CHILDHOOD**
20 **DEVELOPMENT.**

21 (a) IN GENERAL.—The Secretary shall use amounts
22 made available under section 101(d)(2) for a fiscal year
23 for the following purposes:

24 (1) Improving the affordability of child care
25 through increased appropriations for child care

1 under the Child Care and Development Block Grant
2 Act of 1990 (42 U.S.C. 9858 et seq.).

3 (2) Enhancing the quality of child care and
4 early childhood development through the provision of
5 grants to States under the Child Care and Develop-
6 ment Block Grant Act of 1990 (42 U.S.C. 9858 et
7 seq.).

8 (3) Expanding the availability and quality of
9 school-age care through the provision of grants to
10 States under the Child Care and Development Block
11 Grant Act of 1990 (42 U.S.C. 9858 et seq.).

12 (4) Assisting young children by providing
13 grants to local collaboratives under the Child Care
14 and Development Block Grant Act of 1990 (42
15 U.S.C. 9858 et seq.) for the purpose of improving
16 parent education and supportive services, strength-
17 ening the quality of child care, improving health
18 services, and improving services for children with
19 disabilities.

20 (b) SUPPLEMENT NOT SUPPLANT.—Amounts made
21 available to a State under this section shall be used to
22 supplement and not supplant other Federal, State and
23 local funds provided for programs that serve the health
24 and developmental needs of children. Amounts provided
25 to the State under any of the provisions of law referred

1 to in this section shall not be reduced solely as a result
2 of the availability of funds under this section.

3 **SEC. 132. IMPROVING ELEMENTARY EDUCATION.**

4 (a) GRANTS AUTHORIZED.—The Secretary of Edu-
5 cation shall use amounts made available under section
6 101(d)(3) for a fiscal year to award grants to States and
7 local educational agencies to train, recruit and hire ele-
8 mentary school teachers for the purpose of reducing the
9 average class size for students in grades 1 through 3 to
10 not more than 18 students per teacher.

11 (b) REGULATIONS REQUIRED.—The Secretary of
12 Education, not later than March 1, 1999, shall promulgate
13 regulations as the Secretary determines necessary to assist
14 States and school districts in providing smaller class sizes
15 with qualified teachers in early grades. Such regulations
16 may include provisions relating to—

- 17 (1) the use of funds by the State, including the
18 awarding of grants to local educational agencies;
19 (2) teacher preparation and certification; and
20 (3) accountability for improved student achieve-
21 ment.

22 (c) STATE PLAN.—

23 (1) IN GENERAL.—Each State desiring a grant
24 under this section shall submit to the Secretary of
25 Education a State plan at such time, in such man-

1 ner, and accompanied by such information as the
2 Secretary may require.

3 (2) CONTENTS.—Each State plan shall dem-
4 onstrate to the satisfaction of the Secretary of Edu-
5 cation that—

6 (A) the activities assisted by the State with
7 funds made available under this section will be
8 conducted in compliance with any regulations
9 promulgated under subsection (a);

10 (B) the State will use the funds made
11 available under this section to reduce class size
12 for students in grades 1 through 3 in elemen-
13 tary schools throughout the State, focusing on
14 using the funds to train, recruit, and hire
15 teachers for elementary schools serving commu-
16 nities with the least available resources for such
17 activities and the largest class sizes in those
18 grades; and

19 (C) of the funds that are made available to
20 the State under this section, the State will
21 make available to each local educational agency
22 that serves children in grades 1 through 3 and
23 in which at least 30 percent of the children are
24 from families below the Federal poverty level, at
25 least as great a percentage of such funds as the

1 percentage of funds provided to that local edu-
2 cational agency as compared to other local edu-
3 cational agencies in the State under part A of
4 title I of the Elementary and Secondary Edu-
5 cation Act of 1965.

6 (3) APPROVAL.—The Secretary shall approve a
7 State plan submitted under paragraph (1) if the
8 State plan meets the requirements of this sub-
9 section.

10 (d) SUPPLEMENT NOT SUPPLANT.—Amounts made
11 available to a State under this section shall be used to
12 supplement and not supplant other Federal, State and
13 local funds provided for programs that improve elementary
14 education as provided for in this section. Amounts pro-
15 vided to the State under this section shall not be reduced
16 solely as a result of the availability of funds under this
17 section.

18 **SEC. 133. INCREASED ENROLLMENT OF CHILDREN WITH**
19 **THE MEDICAID AND STATE CHILDREN'S**
20 **HEALTH INSURANCE PROGRAMS.**

21 (a) TRANSITIONAL INCREASED FEDERAL MATCHING
22 RATE FOR INCREASED MEDICAID ADMINISTRATIVE
23 COSTS.—Section 1931(h) of the Social Security Act (42
24 U.S.C. 1396u-1(h)) is amended—

1 (1) in paragraph (2), by striking "attributable
2 to" and all that follows and inserting "attributable
3 to—

4 "(A) administrative costs of eligibility de-
5 terminations that (but for the enactment of this
6 section) would not be incurred; and

7 "(B) outreach activities to enroll uninsured
8 children in a State plan approved under this
9 title or title XXI."; and

10 (2) by striking paragraphs (3) and (4) and in-
11 serting the following:

12 "(3) LIMITATION.—

13 "(A) IN GENERAL.—Beginning with fiscal
14 year 1998, the total amount of additional Fed-
15 eral funds that are expended as a result of the
16 application of this subsection shall not exceed
17 \$525,000,000.

18 "(B) AVAILABILITY OF APPROPRIATION.—

19 Any amount appropriated in accordance with
20 this paragraph shall remain available until ex-
21 pended.

22 "(C) EQUITABLE DISTRIBUTION OF
23 FUNDS.—In applying this paragraph, the Sec-
24 retary shall ensure the equitable distribution of
25 additional funds among the States."

1 (b) MEDICAID PRESUMPTIVE ELIGIBILITY FOR LOW-
2 INCOME CHILDREN.—

3 (1) IN GENERAL.—Section 1920A(b)(3) of the
4 Social Security Act (42 U.S.C. 1396r-1a(b)(3)) is
5 amended—

6 (A) in subparagraph (A)(i)—

7 (i) by striking “or (II)” and inserting
8 “, (II)”; and

9 (ii) by inserting “, or (III) is an ele-
10 mentary school or secondary school, as
11 such terms are defined in section 14101 of
12 the Elementary and Secondary Education
13 Act of 1965 (20 U.S.C. 8801), is a child
14 care resource and referral agency, a child
15 support enforcement agency, or is author-
16 ized to determine the eligibility of a child
17 for obtaining child health assistance under
18 title XXI that is in the form of coverage
19 that meets the requirements of section
20 2103” before the semicolon; and

21 (B) in subparagraph (C), by striking “lim-
22 iting the classes of” and inserting “imposing
23 limitations on”.

24 (2) RETROACTIVITY.—The amendments made
25 by paragraph (1) take effect as if included in the en-

1 actment of section 4912 of the Balanced Budget Act
2 of 1997 (Public Law 105-33; 111 Stat. 571)..

3 (c) MEDICAID EXPENDITURES COUNTED AGAINST
4 STATE ALLOTMENTS UNDER TITLE XXI.—

5 (1) IN GENERAL.—Section 2104(d) of the So-
6 cial Security Act (42 U.S.C. 1397dd(d)) is amended
7 to read as follows:

8 “(d) CERTAIN MEDICAID EXPENDITURES COUNTED
9 AGAINST INDIVIDUAL STATE ALLOTMENTS.—The amount
10 of the allotment otherwise provided to a State under sub-
11 section (b) or (c) for a fiscal year shall be reduced by the
12 amount (if any) of the payments made to that State under
13 section 1903(a) for expenditures claimed by the State dur-
14 ing such fiscal year that is attributable to the provision
15 of medical assistance to a child for which payment is made
16 under section 1903(a)(1) on the basis of an enhanced
17 FMAP under the fourth sentence of section 1905(b).”.

18 (2) RETROACTIVITY.—The amendment made by
19 paragraph (1) takes effect as if included in the en-
20 actment of section 4901 of the Balanced Budget Act
21 of 1997 (Public Law 105-33; 111 Stat. 552).

22 (d) MEDICAID AND STATE CHILDREN'S HEALTH IN-
23 SURANCE PROGRAM ELIGIBILITY FOR LEGAL IMMIGRANT
24 CHILDREN WHO ENTERED THE UNITED STATES AFTER
25 AUGUST 1996.—

1 (1) EXEMPTION FROM 5-YEAR BAN.—Section
2 403 of the Personal Responsibility and Work Oppor-
3 tunity Reconciliation Act of 1996 (8 U.S.C. 1613),
4 as amended by sections 5302(c)(1)(B) and 5303(c)
5 of the Balanced Budget Act of 1997 (Public Law
6 105-33; 111 Stat. 599, 600), is amended by adding
7 at the end the following:

8 “(e) MEDICAID AND SCHIP BENEFITS FOR CERTAIN
9 CHILDREN.—Notwithstanding any other provision of law,
10 the limitations under section 401(a) and subsection (a)
11 shall not apply to an individual who is under 19 years of
12 age and who lawfully entered the United States after Au-
13 gust 22, 1996, but only with respect to the eligibility of
14 that individual for—

15 “(1) child health assistance under title XXI of
16 the Social Security Act (42 U.S.C. 1397aa et seq.);
17 and

18 “(2) medical assistance under title XIX of such
19 Act (42 U.S.C. 1396 et seq.), if the individual is an
20 optional targeted low-income child described in sec-
21 tion 1905(u)(2)(B) of such Act (42 U.S.C.
22 1396d(u)(2)(B)).”.

23 (2) NONAPPLICATION OF STATE AUTHORITY TO
24 DETERMINE ELIGIBILITY FOR MEDICAID.—Section
25 402(b)(2) of the Personal Responsibility and Work

1 Opportunity Reconciliation Act of 1996 (8 U.S.C.
2 1612(b)(2)), as amended by sections 5303(b) and
3 5305(b) of the Balanced Budget Act of 1997 (Public
4 Law 105-33; 111 Stat. 600, 601), is amended—

5 (A) in the matter preceding subparagraph
6 (A), by striking “Qualified” and inserting “Ex-
7 cept as provided in subparagraphs (A), (E),
8 (F), and (G), qualified”; and

9 (B) by adding at the end the following:

10 “(G) MEDICAID EXCEPTION FOR CERTAIN
11 CHILDREN.—With respect to eligibility for bene-
12 fits for the program described in section
13 403(e)(2), paragraph (1) shall not apply to any
14 individual described in that section.”.

15 (3) RETROACTIVITY.—The amendments made
16 by paragraphs (1) and (2) take effect as if included
17 in the enactment of the Balanced Budget Act of
18 1997 (Public Law 105-33; 111 Stat. 251).

19 (e) ANNUAL PERFORMANCE BONUS FOR REDUCTION
20 IN MEDICAID ELIGIBLE BUT UNENROLLED CHILDREN.—
21 Section 1903 of the Social Security Act (42 U.S.C. 1396b)
22 is amended by adding at the end the following:

23 “(x) PERFORMANCE BONUS FOR REDUCTION IN ELI-
24 GIBLE BUT UNENROLLED CHILDREN.—

1 “(1) PERFORMANCE BONUS.—Beginning with
2 fiscal year 1999, in addition to the amounts paid to
3 a State under subsection (a), the Secretary shall pay
4 to each State that has an approved plan under this
5 title an amount equal to the performance bonus de-
6 termined under paragraph (2).

7 “(2) PERFORMANCE BONUS.—

8 “(A) FORMULA.—The performance bonus
9 for a State for a fiscal year is equal to the
10 product of—

11 “(i) the excess baseline enrollment for
12 the State for the fiscal year;

13 “(ii) the average per child expendi-
14 tures by the State under this title for the
15 fiscal year; and

16 “(iii) the difference between the en-
17 hanced FMAP and the Federal medical as-
18 sistance percentage (as defined in the first
19 sentence of section 1905(b)) of the State
20 for the fiscal year described in section
21 2105(b).

22 “(B) DETERMINATION OF THE EXCESS
23 BASELINE ENROLLMENT.—

24 “(i) IN GENERAL.—For purposes of
25 subparagraph (A)(i), the excess baseline

1 enrollment for a State for a fiscal year is
2 the difference between (I) the actual num-
3 ber of full year equivalent children enrolled
4 under the State plan and (II) the baseline
5 number of full year equivalent children
6 that would be enrolled under the State
7 plan in the absence of the performance
8 bonus outreach efforts of the State.

9 “(ii) DETERMINATION OF THE BASE-
10 LINE NUMBER OF FULL YEAR EQUIVALENT
11 CHILDREN.—For purposes of clause (i)(II),
12 the baseline number of full year equivalent
13 children that would be enrolled under the
14 State plan in the absence of the perform-
15 ance bonus outreach efforts of the State
16 is—

17 “(I) in the case of fiscal year
18 1999, the actual number of full year
19 equivalent children enrolled under the
20 State plan in fiscal year 1998, in-
21 creased by the national percentage in-
22 crease for fiscal year 1999 in the
23 number of full year equivalent chil-
24 dren enrolled in all State plans under
25 this title, as projected by the Congress-

1 sional Budget Office in January 1998;
2 and

3 “(II) in the case of any succeed-
4 ing fiscal year, the baseline number of
5 full year equivalent children that
6 would be enrolled under the State
7 plan in the absence of the perform-
8 ance bonus outreach efforts of the
9 State determined for the preceding
10 fiscal year, increased by the national
11 percentage increase for that succeed-
12 ing fiscal year in the number of full
13 year equivalent children enrolled in all
14 State plans under this title, as pro-
15 jected by the Congressional Budget
16 Office in January 1998.

17 “(C) DETERMINATION OF AVERAGE PER
18 CHILD EXPENDITURES.—For purposes of sub-
19 paragraph (A)(ii), the average per child expend-
20 itures by a State under this title for a fiscal
21 year is—

22 “(i) the total amount paid to the
23 State under subsection (a)(1) that is at-
24 tributable to medical assistance provided to
25 children under the State plan; divided by

1 “(ii) the actual number of full year
2 equivalent children enrolled under the
3 State plan in that fiscal year.

4 “(3) DATA REQUIREMENTS.—Each State shall
5 submit to the Secretary such data, at such time and
6 in such manner, as the Secretary determines is nec-
7 essary to make the payments required under this
8 subsection. The Secretary shall ensure that data is
9 provided under this subsection in a manner that is
10 consistent with other data reporting requirements
11 for information required to be submitted by a State
12 under this title and title XXI, and that avoids dupli-
13 cation of reporting requirements.

14 “(4) STATES WITH SIGNIFICANTLY HIGHER IN-
15 CREASED ACTUAL ENROLLMENT THAN THE EX-
16 PECTED NATIONAL INCREASE.—For any fiscal year,
17 if a State’s actual full year equivalent children en-
18 rollment percentage increase over the preceding fis-
19 cal year is at least twice the estimated national per-
20 centage increase in such enrollment for that fiscal
21 year, as projected by the Congressional Budget Of-
22 fice in January 1998, the State shall submit such
23 additional information as the Secretary determines
24 is necessary to verify that the increase is the result
25 of the State reducing the number of unenrolled chil-

1 dren who are eligible for medical assistance under
2 this title in the State.

3 “(5) TIMING OF PERFORMANCE BONUS PAY-
4 MENTS; RECONCILIATION.—The Secretary shall pay
5 the performance bonuses required under this sub-
6 section for a fiscal year not later than September 30
7 of the succeeding fiscal year based on reporting data
8 that reflects each State’s actual number of full year
9 equivalent children enrolled under the State plan
10 and average per child expenditures. A State shall
11 provide the Secretary with access to any records or
12 information relevant to the payment of a perform-
13 ance bonus under this subsection for the purposes of
14 review or audit.

15 “(6) WAIVERS.—The provisions of this sub-
16 section apply to a State providing medical assistance
17 under this title under waiver authority in the same
18 manner as they apply to a State with an approved
19 plan under this title.

20 “(7) LIMITATION.—Amounts paid to States for
21 a fiscal year under this subsection shall not exceed
22 the amount made available under section 101(d)(4)
23 of the Healthy Kids Act for such fiscal year (less
24 amounts paid to States under the amendments made

1 by subsections (a) through (d) of section 133 of such
2 Act).”.

3 **SEC. 134. MEDICARE CANCER PATIENT DEMONSTRATION**
4 **PROJECT; EVALUATION AND REPORT TO**
5 **CONGRESS.**

6 (a) **ESTABLISHMENT.**—The Secretary shall establish
7 a 3-year demonstration project which provides for pay-
8 ment under the medicare program under title XVIII of
9 the Social Security Act (42 U.S.C. 1395 et seq.) of routine
10 patient care costs—

11 (1) which are provided to an individual diag-
12 nosed with cancer and enrolled in the medicare pro-
13 gram under such title as part of the individual's par-
14 ticipation in an approved clinical trial program; and
15 (2) which are not otherwise eligible for payment
16 under such title for individuals who are entitled to
17 benefits under such title.

18 (b) **APPLICATION.**—The beneficiary cost sharing pro-
19 visions under the medicare program, such as deductibles,
20 coinsurance, and copayment amounts, shall apply to any
21 individual participating in a demonstration project con-
22 ducted under this section.

23 (c) **APPROVED CLINICAL TRIAL PROGRAM.**—

1 (1) IN GENERAL.—For purposes of this section,
2 the term “approved clinical trial program” means a
3 clinical trial program which is approved by—

4 (A) the National Institutes of Health;

5 (B) a National Institutes of Health cooper-
6 ative group or a National Institutes of Health
7 center; and

8 (C) the National Cancer Institute, with re-
9 spect to programs that oversee and coordinate
10 extramural clinical cancer research, trials spon-
11 sored by such Institute and conducted at des-
12 ignated cancer centers, clinical trials, and Insti-
13 tute grants that support clinical investigators.

14 (2) MODIFICATIONS IN APPROVED TRAILS.—
15 Beginning 1 year after the date of enactment of this
16 Act, the Secretary, in consultation with the Cancer
17 Policy Board of the Institute of Medicine, may mod-
18 ify or add to the requirements of paragraph (1) with
19 respect to an approved clinical trial program.

20 (d) ROUTINE PATIENT CARE COSTS.—

21 (1) IN GENERAL.—For purposes of this section,
22 “routine patient care costs” shall include the costs
23 associated with the provision of items and services
24 that—

1 (A) would otherwise be covered under the
2 medicare program if such items and services
3 were not provided in connection with an ap-
4 proved clinical trial program; and

5 (B) are furnished according to the design
6 of an approved clinical trial program.

7 (2) EXCLUSION.—For purposes of this section,
8 “routine patient care costs” shall not include the
9 costs associated with the provision of—

10 (A) an investigational drug or device, un-
11 less the Secretary has authorized the manufac-
12 turer of such drug or device to charge for such
13 drug or device; or

14 (B) any item or service supplied without
15 charge by the sponsor of the approved clinical
16 trial program.

17 (e) STUDY.—The Secretary shall study the impact on
18 the medicare program under title XVIII of the Social Se-
19 curity Act of covering routine patient care costs for indi-
20 viduals with a diagnosis of cancer and other diagnoses,
21 who are entitled to benefits under such title and who are
22 enrolled in an approved clinical trial program.

23 (f) REPORT TO CONGRESS.—Not later than 30
24 months after the date of enactment of this Act, the Sec-
25 retary shall submit a report to Congress that contains a

1 detailed description of the results of the study conducted
2 under subsection (e) including recommendations regarding
3 the extension and expansion of the demonstration project
4 conducted under this section.

5 (g) FUNDING.—The Secretary shall use amounts
6 made available under section 101(d)(9)(A) for a fiscal
7 year to carry out this section.

1 **TITLE II—FDA JURISDICTION**
2 **OVER TOBACCO PRODUCTS**

3 **SEC. 201. REFERENCE.**

4 Whenever in this title an amendment or repeal is ex-
5 pressed in terms of an amendment to, or repeal of, a sec-
6 tion or other provision, the reference shall be considered
7 to be made to a section or other provision of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

9 **SEC. 202. STATEMENT OF GENERAL AUTHORITY.**

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

15 **SEC. 203. TREATMENT OF TOBACCO PRODUCTS AS DRUGS**
16 **AND DEVICES.**

17 (a) **DEFINITIONS.—**

18 (1) **DRUG.**—Section 201(g)(1) (21 U.S.C.
19 321(g)(1)) is amended by striking “; and (D)” and
20 inserting “; (D) nicotine in tobacco products; and
21 (E)”.

22 (2) **DEVICES.**—Section 201(h) (21 U.S.C.
23 321(h)). is amended—

24 (A) in paragraph (2), by striking “or” at
25 the end;

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

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

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

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

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

15 (b) REGULATORY AUTHORITY.—Section 503(g) (21
16 U.S.C. 353(g)) is amended by adding at the end the fol-
17 lowing:

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

22 (c) DEVICES.—Section 520(e)(1) (21 U.S.C.
23 360j(e)(1)) is amended by striking "or use—" and insert-
24 ing "or use, including restrictions on the access to, and
25 the advertising and promotion of, tobacco products—".

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

3 “(u) In the case of a tobacco product, it is sold, dis-
4 tributed, advertised, or labeled in violation of this Act or
5 the regulations promulgated under this Act.

6 “(v) The regulations promulgated in accordance with
7 subchapter E shall, at a minimum, require that a tobacco
8 product be deemed to be misbranded if the labeling of the
9 package of the product, or any claim of the manufacturer
10 in connection with the product, states or implies (as deter-
11 mined by the Secretary) that the product presents a re-
12 duced health risk unless it is demonstrated to the satisfac-
13 tion of the Secretary that the product will achieve the best
14 public health result, taking into account all relevant fac-
15 tors including, but not limited to, the probability of the
16 increased number of new users of tobacco products and
17 the reduced probability that existing users of tobacco
18 products will quit.”.

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

21 “(aa) The failure to comply with the requirements of
22 section 581.

23 “(bb) The failure or refusal to comply with any of
24 the requirements of subsections (a), (b) or (e) of section
25 578.”.

1 (f) STATE AND LOCAL REQUIREMENTS.—Section
2 521 (21 U.S.C. 360k) is amended—

3 (1) in subsection (a), by striking “subsection
4 (b)” and inserting “subsections (b) and (c)”; and

5 (2) by adding at the end the following:

6 “(c) This section shall not apply to devices that are
7 tobacco products.”.

8 **SEC. 204. SAFETY AND EFFICACY STANDARD AND RECALL**
9 **AUTHORITY.**

10 (a) SAFETY AND EFFICACY STANDARD.—Section
11 513(a) (21 U.S.C. 360c(a)) is amended—

12 (1) in paragraph (1)(B), by inserting after the
13 first sentence the following: “For a device which is
14 a tobacco product, the assurance in the previous sen-
15 tence need not be found if the Secretary finds that
16 special controls achieve the best public health re-
17 sult.”; and

18 (2) in paragraph (2)—

19 (A) by redesignating subparagraphs (A),
20 (B) and (C) as clauses (i), (ii) and (iii), respec-
21 tively;

22 (B) by striking “(2) For” and inserting
23 “(2)(A) For”; and

24 (C) by adding at the end the following:

1 “(B) For purposes of paragraph (1)(B), subsections
2 (c)(2)(C), (d)(2)(B), (e)(2)(A), (f)(3)(B)(i), and
3 (f)(3)(C)(i), and sections 514, 519(a), 520(e), and 520(f),
4 the safety and effectiveness of a device that is a tobacco
5 product need not be found if the Secretary finds that the
6 action to be taken under any such provision would achieve
7 the best public health result. The finding as to whether
8 the best public health result has been achieved shall be
9 determined with respect to the risks and benefits to the
10 population as a whole, including users and non-users of
11 the tobacco product, and taking into account—

12 “(i) the increased or decreased likelihood that
13 existing consumers of tobacco products will stop
14 using such products; and

15 “(ii) the increased or decreased likelihood that
16 those who do not use tobacco products will start
17 using such products.”.

18 (b) RECALL AUTHORITY.—Section 518(e)(1) (21
19 U.S.C. 360h(e)(1)) is amended by inserting after “adverse
20 health consequences or death,” the following: “and for to-
21 bacco products that the best public health result would
22 be achieved,”.

1 **SEC. 205. GENERAL HEALTH AND SAFETY REGULATION OF**
2 **TOBACCO PRODUCTS.**

3 Chapter V (21 U.S.C. 351 et seq.) is amended by
4 adding at the end the following:

5 **SUBCHAPTER F—TOBACCO PRODUCTS**

6 **“SEC. 571. PROMULGATION OF REGULATIONS.**

7 “Any regulations necessary to implement this sub-
8 chapter shall be promulgated not later than 12 months
9 after the date of enactment of this subchapter using notice
10 and comment rulemaking (in accordance with chapter 5
11 of title 5, United States Code). Such regulations may be
12 revised thereafter as determined necessary by the Sec-
13 retary.

14 **“SEC. 572. SCIENTIFIC ADVISORY COMMITTEE.**

15 “(a) **ESTABLISHMENT.**—Not later than 1 year after
16 the date of enactment of this subchapter, the Secretary
17 shall establish an advisory committee, to be known as the
18 ‘Scientific Advisory Committee’, to assist the Secretary.

19 **“(b) MEMBERSHIP.—**

20 **“(1) IN GENERAL.**—The Secretary shall appoint
21 as members of the Scientific Advisory Committee
22 any individuals with expertise in the medical, sci-
23 entific, or other technological data involving the
24 manufacture and use of tobacco products, and of ap-
25 propriately diversified professional backgrounds.

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

5 “(A) is in the regular full-time employ of
6 the Federal Government;

7 “(B) is, or is in the employ of, a manufac-
8 turer, distributor, or retailer of a tobacco prod-
9 uct, or organization substantially funded by
10 manufacturers, distributors, or retailers of to-
11 bacco products;

12 “(C) is, or is in the employ of, an attorney
13 representing an entity described in subpara-
14 graph (B); or

15 “(D) is, or is in the employ of, a consult-
16 ant employed by or under retainer to an entity
17 described in subparagraph (B).

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

21 “(c) COMPENSATION AND EXPENSES.—Members of
22 the Scientific Advisory Committee shall be entitled to the
23 same compensation and expenses as the compensation and
24 expenses provided to members of the advisory committees
25 established under section 514(b)(5)(B).

1 “(d) DUTIES.—The Scientific Advisory Committee
2 shall—

3 “(1) provide assistance to the Secretary;

4 “(2) examine the effects of the alteration of the
5 nicotine yield levels in tobacco products;

6 “(3) examine whether there is a threshold level
7 below which nicotine yields do not produce depend-
8 ence on the tobacco product involved, and, if so,
9 what that level is; and

10 “(4) review other safety, dependence or health
11 issues relating to tobacco products as determined ap-
12 propriate by the Secretary.

13 **“SEC. 573. PERFORMANCE STANDARDS.**

14 “(a) GENERAL RULE.—The Secretary may adopt a
15 performance standard under section 514(a)(2) for a to-
16 bacco product regardless of whether the product has been
17 classified under section 513. Such standards may in-
18 clude—

19 “(1) the reduction or elimination of nicotine
20 yields of the product;

21 “(2) the reduction or elimination of other con-
22 stituents or harmful components of the product; or

23 “(3) standards relating to any other require-
24 ment pursuant to section 512(a)(2).

1 “(b) TOBACCO CONSTITUENTS.—The Secretary may
2 require that a manufacturer test, report and disclose to-
3 bacco and tobacco smoke constituents, including labeling
4 and advertising disclosures relating to such constituents,
5 including, but not limited to, tar and nicotine.

6 **“SEC. 574. DISCLOSURE AND REPORTING OF TOBACCO AND**
7 **NONTOBACCO INGREDIENTS AND CONSTITU-**
8 **ENTS.**

9 “(a) DISCLOSURE OF ALL INGREDIENTS.—

10 “(1) IMMEDIATE AND ANNUAL DISCLOSURE.—

11 Not later than 30 days after the date of enactment
12 of this subchapter, and annually thereafter, each
13 manufacturer of a tobacco product shall submit to
14 the Secretary an ingredient list for each brand of to-
15 bacco product it manufactures that contains the in-
16 formation described in paragraph (2).

17 “(2) REQUIREMENTS.—The list described in
18 paragraph (1) shall, with respect to each brand or
19 variety of tobacco product of a manufacturer, in-
20 clude—

21 “(A) a list of all ingredients, constituents,
22 substances, and compounds that are found in or
23 added to the tobacco or tobacco product (in-
24 cluding the paper, filter, or packaging of the
25 product if applicable) in the manufacture of the

1 tobacco product, for each brand or variety of to-
2 bacco product so manufactured, including, if
3 determined necessary by the Secretary, any ma-
4 terial added to the tobacco used in the product
5 prior to harvesting;

6 “(B) the quantity of the ingredients, con-
7 stituents, substances, and compounds that are
8 listed under subparagraph (A) in each brand or
9 variety of tobacco product;

10 “(C) the nicotine content of the product,
11 measured in milligrams of nicotine;

12 “(D) for each brand or variety of ciga-
13 rettes—

14 “(i) the filter ventilation percentage
15 (the level of air dilution in the cigarette as
16 provided by the ventilation holes in the fil-
17 ter, described as a percentage);

18 “(ii) the pH level of the smoke of the
19 cigarette; and

20 “(iii) the tar, nicotine, and carbon
21 monoxide delivery level under Federal
22 Trade Commission parameters and any
23 other smoking conditions established by
24 the Secretary, reported in milligrams of

1 tar, nicotine, and carbon monoxide per cig-
2 arette;

3 “(E) for each brand or variety of smoke-
4 less tobacco products—

5 “(i) the pH level of the tobacco;

6 “(ii) the moisture content of the to-
7 bacco expressed as a percentage of the
8 weight of the tobacco; and

9 “(iii) the nicotine content—

10 “(I) for each gram of the prod-
11 uct, measured in milligrams of nico-
12 tine;

13 “(II) expressed as a percentage
14 of the dry weight of the tobacco; and

15 “(III) with respect to unionized
16 (free) nicotine, expressed as a percent-
17 age per gram of the tobacco and ex-
18 pressed in milligrams per gram of the
19 tobacco; and

20 “(F) any other information determined ap-
21 propriate by the Secretary.

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

1 “(b) SAFETY ASSESSMENTS.—

2 “(1) APPLICATION TO NEW INGREDIENTS.—

3 “(A) IN GENERAL.—Not later than 1 year
4 after the date of enactment of this subchapter,
5 and annually thereafter, each manufacturer
6 shall submit to the Secretary a safety assess-
7 ment for each new ingredient, constituent, sub-
8 stance, or compound that such manufacturer
9 desires to make a part of a tobacco product.
10 Such new ingredient, constituent, substance, or
11 compound shall not be included in a tobacco
12 product prior to approval by the Secretary of
13 such a safety assessment.

14 “(B) METHOD OF FILING.—A safety as-
15 sessment submitted under subparagraph (A)
16 shall be signed by an officer of the manufac-
17 turer who is acting on behalf of the manufac-
18 turer and who has the authority to bind the
19 manufacturer, and contain a statement that en-
20 sures that the information contained in the as-
21 sessment is true, complete and accurate.

22 “(C) DEFINITION OF NEW INGREDIENT.—

23 For purposes of subparagraph (A), the term
24 ‘new ingredient, constituent, substance, or
25 compound’ means an ingredient, constituent

1 substance, or compound listed under subsection
2 (a)(1) that was not used in the brand or variety
3 of tobacco product involved prior to January 1,
4 1998.

5 “(2) APPLICATION TO OTHER INGREDIENTS.—

6 With respect to the application of this section to in-
7 gredients, constituents substances, or compounds
8 listed under subsection (a) to which paragraph (1)
9 does not apply, all such ingredients, constituents,
10 substances, or compounds shall be reviewed through
11 the safety assessment process within the 5-year pe-
12 riod beginning on the date of enactment of this sub-
13 chapter. The Secretary shall develop a procedure for
14 the submission of safety assessments of such ingre-
15 dients, constituents, substances, or compounds that
16 staggers such safety assessments within the 5-year
17 period.

18 “(3) BASIS OF ASSESSMENT.—The safety as-
19 sessment of an ingredient, constituents, substance,
20 or compound described in paragraphs (1) and (2)
21 shall—

22 “(A) be based on the best scientific evi-
23 dence available at the time of the submission of
24 the assessment; and

1 “(B) demonstrate that there is a reason-
2 able certainty among experts qualified by sci-
3 entific training and experience who are con-
4 sulted, that the ingredient, constituents, sub-
5 stance, or compound will not present any risk
6 to consumers or the public in the quantities
7 used under the intended conditions of use.

8 “(c) PROHIBITION.—

9 “(1) REGULATIONS.—Not later than 12 months
10 after the date of enactment of this subchapter, the
11 Secretary shall promulgate regulations to prohibit
12 the use of any ingredient, constituent, substance, or
13 compound in the tobacco product of a manufac-
14 turer—

15 “(A) if no safety assessment has been sub-
16 mitted by the manufacturer for the ingredient,
17 constituent, substance, or compound as other-
18 wise required under this section; or

19 “(B) if the Secretary finds that the manu-
20 facturer has failed to demonstrate the safety of
21 the ingredient, constituent, substance, or
22 compound that was the subject of the assess-
23 ment under paragraph (2).

24 “(2) REVIEW OF ASSESSMENTS.—

1 “(A) GENERAL REVIEW.—Not later than
2 180 days after the receipt of a safety assess-
3 ment under subsection (b), the Secretary shall
4 review the findings contained in such assess-
5 ment and approve or disapprove of the safety of
6 the ingredient, constituents, substance, or
7 compound that was the subject of the assess-
8 ment. The Secretary may, for good cause, ex-
9 tend the period for such review. The Secretary
10 shall provide notice to the manufacturer of an
11 action under this subparagraph.

12 “(B) INACTION BY SECRETARY.—If the
13 Secretary fails to act with respect to an assess-
14 ment of an existing ingredient, constituent, sub-
15 stance, or additive during the period referred to
16 in subparagraph (A), the manufacturer of the
17 tobacco product involved may continue to use
18 the ingredient, constituents, substance, or
19 compound involved until such time as the Sec-
20 retary makes a determination with respect to
21 the assessment.

22 “(d) RIGHT TO KNOW; FULL DISCLOSURE OF INGRE-
23 DIENTS TO THE PUBLIC.—

24 “(1) IN GENERAL.—Except as provided in para-
25 graph (3), a package of a tobacco product shall dis-

1 close all ingredients, constituents, substances, or
2 compounds contained in the product in accordance
3 with regulations promulgated under section 701(a)
4 by the Secretary.

5 “(2) DISCLOSURE OF PERCENTAGE OF DOMES-
6 TIC AND FOREIGN TOBACCO.—The regulations re-
7 ferred to in paragraph (1) shall require that the
8 package of a tobacco product disclose, with respect
9 to the tobacco contained in the product—

10 “(A) the percentage that is domestic to-
11 bacco; and

12 “(B) the percentage that is foreign to-
13 bacco.

14 “(3) HEALTH DISCLOSURE.—Notwithstanding
15 section 301(j), the Secretary may require the public
16 disclosure of any ingredient, constituent, substance,
17 or compound contained in a tobacco product that re-
18 lates to a trade secret or other matter referred to in
19 section 1905 of title 18, United States Code, if the
20 Secretary determines that such disclosure will pro-
21 mote the public health.

22 **“SEC. 575. TOBACCO PRODUCT WARNINGS, LABELING AND**
23 **PACKAGING.**

24 “(a) CIGARETTE WARNINGS.—

25 “(1) IN GENERAL.—

1 “(A) PACKAGING.—It shall be unlawful for
2 any person to manufacture, package, or import
3 for sale or distribution any cigarettes the pack-
4 age of which fails to bear, in accordance with
5 the requirements of this subsection, one of the
6 following labels:

7 “WARNING: Cigarettes Are Addictive.

8 “WARNING: Tobacco Smoke Can Harm
9 Your Children.

10 “WARNING: Cigarettes Cause Fatal Lung
11 Disease.

12 “WARNING: Cigarettes Cause Cancer.

13 “WARNING: Cigarettes Cause Strokes
14 And Heart Disease.

15 “WARNING: Smoking During Pregnancy
16 Can Harm Your Baby.

17 “WARNING: Smoking Can Kill You.

18 “WARNING: Tobacco Smoke Causes
19 Fatal Lung Disease In Nonsmokers.

20 “WARNING: Quitting Smoking Now
21 Greatly Reduces Serious Risks To Your
22 Health.

23 “(B) ADVERTISING.—It shall be unlawful
24 for any manufacturer, importer, distributor or
25 retailer of cigarettes to advertise or cause to be

1 advertised any cigarette unless the advertising
2 bears, in accordance with the requirements of
3 this subsection, one of the following labels:

4 "WARNING: Cigarettes Are Addictive.

5 "WARNING: Tobacco Smoke Can Harm
6 Your Children.

7 "WARNING: Cigarettes Cause Fatal Lung
8 Disease.

9 "WARNING: Cigarettes Cause Cancer.

10 "WARNING: Cigarettes Cause Strokes
11 And Heart Disease.

12 "WARNING: Smoking During Pregnancy
13 Can Harm Your Baby.

14 "WARNING: Smoking Can Kill You.

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

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

20 "(C) ADDITIONAL WARNINGS.—Beginning
21 on the date that is 18 months after the date of
22 enactment of this subchapter, the Secretary
23 may substitute for, or require warnings in addi-
24 tion to, those otherwise required under subpara-
25 graphs (A) and (B) if the Secretary determines

1 that such warnings would be more effective in
2 detering the use of cigarettes.

3 “(2) REQUIREMENTS FOR LABELING.—

4 “(A) LOCATION.—Each label statement re-
5 quired by subparagraph (A) of paragraph (1)
6 shall be located on the upper portion of the
7 front and rear panels of the cigarette package
8 (or carton) directly on the package underneath
9 the cellophane or other clear wrapping and oc-
10 cupy not less than 25 percent of such panels.

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

1 “(C) EXCEPTION.—With respect to ciga-
2 rettes manufactured and distributed prior to
3 January 1, 2000, the provisions of subpara-
4 graph (A) shall not apply with respect to the
5 front panel in the case of a flip-top cigarette
6 package (offered for sale on June 1, 1997)
7 where the front portion of the flip-top does not
8 comprise at least 25 percent of the front panel.
9 In the case of such a package, the label state-
10 ment required by subparagraph (A) of para-
11 graph (1) shall occupy the entire front portion
12 of the flip-top.

13 “(3) REQUIREMENTS FOR ADVERTISING.—

14 “(A) LOCATION.—Each label statement re-
15 quired by subparagraph (B) of paragraph (1)
16 shall appear in a conspicuous and prominent
17 format and location at the top of each adver-
18 tisement within the trim area and shall occupy
19 not less than 20 percent of the area of the ad-
20 vertisement involved.

21 “(B) TYPE, COLOR AND FORMAT.—

22 “(i) TYPE.—With respect to each
23 label statement required by subparagraph
24 (B) of paragraph (1), the phrase ‘WARN-
25 ING’ shall appear in capital letters and the

1 label statement shall be printed in the fol-
2 lowing types:

3 “(I) With respect to whole page
4 advertisements on broadsheet news-
5 paper—45 point type.

6 “(II) With respect to half page
7 advertisements on broadsheet news-
8 paper—39 point type.

9 “(III) With respect to whole page
10 advertisements on tabloid news-
11 paper—39 point type.

12 “(IV) With respect to half page
13 advertisements on tabloid news-
14 paper—27 point type.

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

17 “(VI) With respect to whole page
18 magazine advertisements—31.5 point
19 type.

20 “(VII) With respect to 28cm x 3
21 column advertisements—22.5 point
22 type.

23 “(VIII) With respect to 20cm x 2
24 column advertisements—15 point
25 type.

1 Within the 20 percent requirement de-
2 scribed in subparagraph (A), the Secretary
3 may revise the required type sizes if the
4 Secretary determines that such revisions
5 will enhance public health protections.

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

14 “(iii) FORMAT.—The label statements
15 under subparagraph (B) of paragraph (1)
16 shall be black when the background is
17 white and white when the background is
18 black, and shall be in the point size re-
19 quired under this subparagraph. The label
20 statements shall be enclosed by a rectangu-
21 lar border that is the same color as the let-
22 ters of the statements and that is the
23 width of the first down stroke of the cap-
24 ital ‘W’ of the word ‘WARNING’ in the
25 label statements.

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

4 “(i) in the case of an advertisement
5 that appears in a newspaper, magazine, pe-
6 riodical or other publication that is not in
7 English, such statements shall appear in
8 the predominant language of the publica-
9 tion; or

10 “(ii) in the case of any other adver-
11 tisement that is not in English, such state-
12 ments shall appear in the same language
13 as that principally used in the advertise-
14 ment.

15 “(4) ROTATION OF LABEL STATEMENTS.—

16 “(A) LABELING.—The label statements
17 specified in subparagraph (A) of paragraph (1)
18 shall be randomly displayed in each 12 month
19 period, in as equal a number of times as is pos-
20 sible on each brand of the product and be ran-
21 domly distributed in all areas of the United
22 States in which such product is marketed in ac-
23 cordance with a plan submitted by the manu-
24 facturer, importer, distributor or retailer and
25 approved by the Secretary.

1 “(B) ADVERTISING.—The label statements
2 specified in subparagraph (B) of paragraph (1)
3 shall be rotated quarterly in alternating se-
4 quence in advertisements for each such brand
5 of cigarettes in accordance with a plan submit-
6 ted by the manufacturer, importer, distributor
7 or retailer and approved by the Secretary.

8 “(C) APPROVAL OF PLANS.—The Sec-
9 retary shall review each plan submitted by a
10 manufacturer, importer, distributor or retailer
11 of cigarettes under this paragraph and approve
12 such plan if the plan will provide for the equal
13 distribution and display on packaging and the
14 rotation required in advertising under this para-
15 graph and if such plan assures that all of the
16 labels required under subparagraphs (A) and
17 (B) will be displayed by the manufacturer, im-
18 porter, distributor or retailer at the same time.

19 “(b) SMOKELESS TOBACCO PRODUCTS.—

20 “(1) IN GENERAL.—

21 “(A) PACKAGING.—It shall be unlawful for
22 any person to manufacture, package, or import
23 for sale or distribution any smokeless tobacco
24 product the package of which fails to bear, in

1 accordance with the requirements of this sub-
2 section, one of the following labels:

3 "WARNING: This Product Can Cause
4 Mouth Cancer.

5 "WARNING: This Product Can Kill You.

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

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

10 "WARNING: This Product Contains Can-
11 cer-Causing Chemicals.

12 "WARNING: Smokeless Tobacco Is Ad-
13 dictive.

14 "(B) ADVERTISING.—It shall be unlawful
15 for any manufacturer, importer, distributor or
16 retailer of smokeless tobacco products to adver-
17 tise or cause to be advertised any smokeless to-
18 bacco product unless the advertising bears, in
19 accordance with the requirements of this sub-
20 section, one of the following labels:

21 "WARNING: This Product Can Cause
22 Mouth Cancer.

23 "WARNING: This Product Can Kill You.

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

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

3 “WARNING: This Product Contains Can-
4 cer-Causing Chemicals.

5 “WARNING: Smokeless Tobacco Is Ad-
6 dictive.

7 “(C) ADDITIONAL WARNINGS.—Beginning
8 on the date that is 18 months after the date of
9 enactment of this subchapter, the Secretary
10 may substitute for, or require warnings in addi-
11 tion to, those otherwise required under subpara-
12 graphs (A) and (B) if the Secretary determines
13 that such warnings would be more effective in
14 deterring the use of smokeless tobacco products.

15 “(2) REQUIREMENTS FOR LABELING.—

16 “(A) LOCATION.—Each label statement re-
17 quired by subparagraph (A) of paragraph (1)
18 shall be located on the 2 most prominent dis-
19 play panels of the product and occupy not less
20 than 25 percent of such panels.

21 “(B) TYPE AND COLOR.—With respect to
22 each label statement required by subparagraph
23 (A) of paragraph (1), the phrase ‘WARNING’
24 shall appear in capital letters and the label
25 statement shall be printed in 17 point type with

1 adjustments as determined appropriate by the
2 Secretary to reflect the length of the required
3 statement and the size of the package. All the
4 letters in the label shall appear in conspicuous
5 and legible type in contrast by typography, lay-
6 out, or color with all other printed material on
7 the package and be printed in an alternating
8 black-on-white and white-on-black format as de-
9 termined appropriate by the Secretary.

10 “(3) ADVERTISING AND ROTATION.—The provi-
11 sions of paragraph (3) and (4) of subsection (a)
12 shall apply to advertisements for smokeless tobacco
13 products and the rotation of the label statements re-
14 quired under paragraph (1)(A) on such products.

15 “(c) OTHER TOBACCO PRODUCTS.—The Secretary
16 may prescribe such regulations as may be necessary to es-
17 tablish warning labels for other tobacco product packag-
18 ing, labeling and advertising.

19 “(d) CONSTRUCTION.—

20 “(1) IN GENERAL.—Noting in this section shall
21 be construed to limit the ability of the Secretary to
22 change the text or layout of any of the warning
23 statements, or any of the labeling provisions, under
24 subsections (a) and (b) and other provisions of this
25 Act, if determined necessary by the Secretary in

1 order to make such statements or labels larger, more
2 prominent, more conspicuous, or more effective.

3 “(2) UNFAIR ACTS.—Nothing in this section
4 (other than the requirements of subsections (a), (b)
5 and (c)) shall be construed to limit or restrict the
6 authority of the Federal Trade Commission with re-
7 spect to unfair or deceptive acts or practices in the
8 advertising of cigarettes or smokeless tobacco prod-
9 ucts.

10 “(e) LIMITED PREEMPTION.—

11 “(1) STATE AND LOCAL ACTION.—No warning
12 label with respect to cigarettes or smokeless tobacco
13 products, or any other tobacco product for which
14 warning labels have been required under this section,
15 other than the warning labels required under this
16 Act, shall be required by any State or local statute
17 or regulation to be included on any package of ciga-
18 rettes or a smokeless tobacco product.

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

23 “(f) ELECTRONIC MEDIUM ADVERTISING.—It shall
24 be unlawful to advertise tobacco products on any medium

1 of electronic communications subject to the jurisdiction of
2 the Federal Communications Commission.

3 **"SEC. 576. PRESERVATION OF STATE AND LOCAL AUTHOR-**
4 **ITY.**

5 "Except as otherwise provided for in section 575(e),
6 nothing in this subchapter shall be construed as prohibit-
7 ing a State or locality from imposing requirements, prohi-
8 bitions, penalties or other measures to further the pur-
9 poses of this subchapter that are in addition to the re-
10 quirements, prohibitions, or penalties required under this
11 subchapter: State and local governments may impose addi-
12 tional tobacco product control measures to further restrict
13 or limit the use of such products.

14 **"SEC. 577. RESTRICTIONS ON YOUTH ACCESS TO TOBACCO**
15 **PRODUCTS.**

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

18 "(b) STATE LICENSING.—

19 "(1) IN GENERAL.—Except as provided in para-
20 graph (2), in order to receive any amounts under
21 section 111 of the Healthy Kids Act, a State shall
22 have in place a program that meets or exceeds (as
23 determined by the Secretary) the requirements of
24 the model State program described in paragraph (3)
25 under which a retailer would be required to obtain

1 a State or local license to sell or otherwise distribute
2 tobacco products directly to consumers in such
3 State.

4 "(2) START-UP PERIOD.—

5 "(A) IN GENERAL.—The Secretary may
6 waive the requirement of paragraph (1) for
7 such time as the Secretary determines is nec-
8 essary, after promulgation of the model pro-
9 gram described in paragraph (3), to permit the
10 legislature of a State to meet and enact laws to
11 comply with paragraph (1) and to permit the
12 State to implement the program described in
13 paragraph (1).

14 "(B) ELIGIBILITY.—To be eligible for a
15 waiver under subparagraph (A), the Governor
16 of the State involved shall certify to the Sec-
17 retary in writing that the State intends to im-
18 plement a program that meets the requirements
19 of this section at the earliest possible oppor-
20 tunity. If, subsequent to such notification, the
21 Secretary determines that the State has failed
22 to implement such a program, the Secretary
23 may recover any funds distributed to the State
24 under section 111 of the Healthy Kids Act.

1 “(3) MODEL PROGRAM.—Not later than 12
2 months after the date of enactment of this sub-
3 chapter, the Secretary shall promulgate a model
4 State program. Such model State program shall at
5 a minimum—

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

9 “(B) prohibit retailers from selling or oth-
10 erwise distributing tobacco products directly to
11 consumers in a State unless such retailers have
12 in effect tobacco licenses issued or renewed in
13 accordance with State or local laws;

14 “(C) provide for the notification of every
15 person in the State who is engaged in the dis-
16 tribution at retail of tobacco products of the li-
17 cense requirement and of the date by which
18 such person shall have obtained a license in
19 order to continue to distribute such products;

20 “(D) prohibit licensed retailers from selling
21 or otherwise distributing tobacco products to
22 minors;

23 “(E) provide for penalties of up to \$50,000
24 for each violation of the requirements under
25 such program relating to the sale or distribu-

1 tion of tobacco products without a license and
2 for appropriate penalties for other violations of
3 laws relating to youth access to tobacco prod-
4 ucts;

5 “(F) require retailers to comply with the
6 applicable requirements of this section and any
7 regulations relating to this section; and

8 “(G) provide for the suspension or revoca-
9 tion of a license in the case of a retailer that
10 repeatedly sells or distributes tobacco products
11 to individuals in violation of subsection (a) or
12 State or local law.

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

18 “(1) EMPLOYEES OF RETAILERS.—In the case
19 of an employee of a retailer who distributes a to-
20 bacco product to a minor in violation of subsection
21 (a), the regulations shall provide for the application
22 of a civil money penalty of—

23 “(A) \$25 for the 1st violation;

24 “(B) \$50 for the 2nd violation; and

1 “(C) \$150 for the 3rd and subsequent vio-
2 lations.

3 “(2) MINORS.—In the case of a minor who pur-
4 chases or attempts to purchase a tobacco product in
5 violation of subsection (a) (other than a minor en-
6 gaged in an authorized sting or a law enforcement
7 operation), the regulations may provide for civil
8 money penalties, loss of driving privileges, or other
9 penalties.

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

14 “(A) \$250 for the 1st violation;

15 “(B) \$500 for the 2nd violation;

16 “(C) \$1,500 for the 3rd violation;

17 “(D) \$5,000 for the 4th violation; and

18 “(E) \$10,000 for the 5th and subsequent
19 violations.

20 “(d) ENFORCEMENT.—

21 “(1) IN GENERAL.—The Secretary may enter
22 into agreements with, and provide grants to, States
23 to enforce this section. Any State that elects to en-
24 force the provisions of this section within the State
25 shall conduct sting operations and other compliance

1 checks and enforce State laws under this section
2 through the use of penalties described in subsection
3 (c) so as to ensure that minors are successful in pur-
4 chasing tobacco products less than 5 percent of the
5 time.

6 “(2) REQUIREMENTS.—The Secretary may by
7 regulation implement such requirements as the Sec-
8 retary determines necessary to ensure that any com-
9 pliance checks performed by the State under para-
10 graph (1) are accurate.

11 “(3) VIOLATIONS.—If the Secretary determines
12 that the provisions of subsection (a) are being vio-
13 lated within a State, the Secretary shall have the au-
14 thority to enforce such provisions in the State.

15 “(e) STATE COMPLIANCE.—Beginning with the 3rd
16 full calendar year following the date of enactment of this
17 subchapter, if, with respect to a State, the Secretary deter-
18 mines that minors are successful in purchasing tobacco
19 products more than 5 percent of the time, the Secretary
20 shall notify the State and reduce payments to the State
21 under section 111 of the Healthy Kids Act by 1 percent
22 for each percentage point by which the State is not in com-
23 pliance with this subsection.

24 “(f) PREEMPTION.—The provisions of this section
25 shall not preempt any provision of State or local law that

1 provides greater restrictions than those required in this
2 section.

3 “(g) FEDERAL LICENSING OF ENTITIES.—

4 “(1) IN GENERAL.—The Secretary, in consulta-
5 tion with the Secretary of Defense, Secretary of
6 State, and other appropriate Federal officials, shall
7 establish and implement a Federal tobacco licensing
8 program to be applied to entities that sell or distrib-
9 ute tobacco products—

10 “(A) on any military installation (as de-
11 fined in section 2801(c)(2) of title X, United
12 States Code);

13 “(B) in any United States embassy;

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

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

19 “(E) through any other Federal entity or
20 on any other Federal property as determined
21 appropriate by the Secretary.

22 “(2) REQUIREMENTS.—The program estab-
23 lished under paragraph (1) shall apply requirements
24 (including those for penalties, suspensions, and rev-

1 locations) similar to those required to be imple-
2 mented by States under this section.

3 “(3) INDIAN TRIBES AND TRIBAL LANDS.—For
4 purposes of applying and enforcing the provisions of
5 this section to entities that sell or otherwise distrib-
6 ute tobacco products on Indian reservations (as de-
7 fined in section 403(9) of the Indian Child Protec-
8 tion and Family Violence Prevention Act (25 U.S.C.
9 3202(9))), an Indian tribe or tribal organization (as
10 such terms are defined in section 4 of the Indian
11 Self Determination and Education Assistance Act
12 (25 U.S.C. 450b)) shall be treated as a State.

13 **“SEC. 578. PUBLIC DISCLOSURE OF HEALTH RESEARCH.**

14 “(a) SUBMISSION BY MANUFACTURERS.—Not later
15 than 3 months after the date of the enactment of this sub-
16 chapter and thereafter as required by the Secretary, each
17 manufacturer of a tobacco product shall submit to the Sec-
18 retary a copy of each document in the manufacturer’s pos-
19 session—

20 “(1) relating, referring, or pertaining to—

21 “(A) any health effects in humans or ani-
22 mals, including addiction, caused by the use of
23 tobacco products or components of tobacco
24 products;