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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Healthy Kids Act".

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

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Approximately 3,000 children begin smoking each day. 1,000 of these children will die prematurely from a tobacco-related illness or condition.

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

children as a source of replacement smokers. The industry has also targeted minorities.

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

(4) Although most children plan to quit smoking after experimenting, the vast majority find that they have become addicted and cannot quit.

(5) Seventy percent of adult smokers would like to quit smoking, but the tobacco industry has manipulated the level of nicotine in tobacco products and added ingredients to enhance the addictive effects of nicotine to ensure that users of these products remain addicted.

(6) Tobacco products cause cancer, heart disease, lung disease, and other fatal illnesses. More than 400,000 Americans die each year of these tobacco-related illnesses and conditions.

(7) Tobacco-related illnesses, medical conditions resulting from tobacco use, and lost wages and productivity cost the United States in excess of $100,000,000,000 annually.

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

gram costs arising from tobacco-related illnesses and conditions.

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

(10) Nicotine is an addictive drug. The marketplace for tobacco products is largely based on addiction.

(11) Worldwide, smoking kills 3,000,000 people each year. If current smoking patterns continue, tobacco use will kill 10,000,000 people a year by 2025.

(12) Environmental tobacco smoke is responsible for 3,000 lung cancer deaths annually in American nonsmokers. Environmental tobacco smoke also harms children's health.

(13) In 1995, the tobacco industry spent close to $4,900,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

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

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

(16) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

(17) Children are exposed to substantial and unavoidable tobacco advertising, that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

(18) Tobacco advertising increases the size of the tobacco market by increasing consumption of tobacco products including increasing tobacco sales to young people.

(19) Children are more influenced by tobacco advertising than adults, they smoke the most advertised brands, and children as young as 3 to 6 can

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

(20) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market.

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

(22) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

(23) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones. Text only requirements, while not as stringent as a ban, will accomplish this purpose while preserving the informational function of advertising.

SEC. 3. PURPOSES.

The purposes of this Act are—

(1) to help American families dramatically reduce the number of children illegally using tobacco products by—

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

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

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

(D) imposing penalties on manufacturers for failing to reach youth smoking rate reduction targets;

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

(F) giving the Food and Drug Administration and State and local governments the authority and resources to keep tobacco products out of the hands of minors;

(2) to compensate taxpayers for their costs attributable to tobacco-related illnesses by reimbursing the medicaid and medicare programs and resolving the legal claims of Federal, State and local governments for those costs that resulted from past misconduct by the tobacco industry;

(3) to improve the public health by reducing the number of adult users of tobacco products through approved cessation programs and limiting public exposure to environmental tobacco smoke;

(4) to provide assistance to tobacco farmers, tobacco factory workers, and rural communities;

(5) to affirm the full authority of the Food and Drug Administration to regulate the manufacture, labeling, sale, distribution, and advertising of tobacco products to the fullest extent authorized by the commerce clause of the United States Constitution;

(6) to make available to the public tobacco industry documents regarding the health effects of tobacco products, addiction, the agricultural production of tobacco, the manufacture of tobacco products, the distribution of tobacco products, and the marketing of tobacco products to youths; and

(7) to enhance global anti-tobacco efforts to minimize the adverse health effects of tobacco products.

SEC. 4. DEFINITIONS.

In this Act:

(1) BRAND.—The term "brand" means a variety of a tobacco product distinguished by the tobacco

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

(2) CIGAR.—The term "cigar" means any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco (other than any roll of tobacco which is a cigarette or cigarillo within the meaning of paragraph (3) or (4)).

(3) CIGARETTE.—The term "cigarette" means—

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

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

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

(5) CIGARETTE TOBACCO.—The term "cigarette tobacco" means any product that consists of loose

tobacco and is intended for use by persons in a cigarette. Unless otherwise stated, the requirements of this Act pertaining to cigarettes shall also apply to cigarette tobacco.

(6) DISTRIBUTOR.—The term "distributor" means any person who furthers the distribution of tobacco products, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Such term shall not include common carriers.

(7) LITTLE CIGAR.—The term "little cigar" means any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (1)) and as to which 1,000 units weigh not more than 3 pounds.

(8) MANUFACTURER.—The term "manufacturer" means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product.

(9) PACKAGE.—The term "package" means a pack, box, carton, or container of any kind in which tobacco products are offered for sale, sold, or otherwise distributed to consumers.

(10) PERSON.—The term "person" means an individual, partnership, corporation, parent corporation, or any other business or legal entity or successor in interest of any such person.

(11) PIPE TOBACCO.—The term "pipe tobacco" means any loose tobacco that, because of its appearance, type, packaging, or labeling, is likely to be offered to, or purchased by, consumers as a tobacco product to be smoked in a pipe.

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

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

(14) ROLL-YOUR-OWN TOBACCO.—The term "roll-your-own tobacco" means any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

(15) SALE.—The term "sale" includes the selling, providing samples of, or otherwise making tobacco products available for personal consumption in any place within the scope of this Act.

(16) SECRETARY.—Except as provided in title IV, the term "Secretary" means the Secretary of Health and Human Services.

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

(18) STATE.—The term "State" includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States. Such term includes any political division of any State.

(19) TOBACCO.—The term "tobacco" means tobacco in its unmanufactured form.

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

bacco, cigars, little cigars, pipe tobacco, and smokeless 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.

TITLE I—HEALTHY KIDS TRUST FUND

Subtitle A—General Provisions

SEC. 101. ESTABLISHMENT OF TRUST FUND.

(a) CREATION.—

(1) IN GENERAL.—There is established in the Treasury of the United States a trust fund to be known as the "Health Enhancement and Lowered Tobacco Hazards for Young Kids Trust Fund" (referred to as the "HEALTHY Kids Trust Fund"), consisting of such amounts as may be appropriated 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.

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

(1) amounts received under the annual assessments made under section 102;

(2) amounts paid as fines or penalties, including interest thereon, under section 103; and

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

(c) REPAYABLE ADVANCES.—

(1) AUTHORIZATION.—There are authorized to be appropriated to the Trust Fund, as repayable advances, such sums as may from time to time be necessary to make the expenditures described in subsection (d).

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

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

period to maturity comparable to the anticipated period during which the advance will be outstanding.

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

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

(2) 17 percent of such amounts shall be made available for grants to the States for child care and early childhood development as provided for in section 131.

(3) 6 percent of such amounts shall be made available for grants to States for education as provided for in section 132.

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

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

(A) $300,000,000 shall be made available to the Secretary to carry out chapter IX of the Food Drug and Cosmetic Act (as added by section 204);

(B) $200,000,000 shall be made available to the Indian Health Service to be used as provided for in title IX; and

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

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

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

(A) 12 percent of such amounts shall be made available to the Tobacco Community Revitalization Trust Fund for each of the first 10 fiscal years after the date of enactment of this Act;

(B) 4 percent of such amounts shall be made available to the Tobacco Community Revitalization Trust Fund for each of the 11th

through 15th fiscal years after the date of enactment of this Act; and

(C) 2 percent of such amounts shall be made available to the Tobacco Community Revitalization Trust Fund for each of the 16th through 25th fiscal years after the date of enactment of this Act.

(8) For the Hospital Insurance Trust Fund—

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

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

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

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

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

(10) For reducing the debt—

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

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

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

(D) 12 percent of such amounts shall be made available for such reduction in each subsequent fiscal year.

(e) BUDGETARY TREATMENT AND DEFINITION.—

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

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

sections 252(b) and 254 of the Balanced Budget and Emergency Deficit Control Act of 1985; and

(B) by the Committee on the Budget of the House of Representatives and the Committee on the Budget of the Senate for purposes of congressional enforcement under section 302(f) and 311(2)(B) of the Congressional Budget Act of 1974 and section 202 of House Concurrent Resolution 67 (104th Congress).

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

SEC. 102. LIABILITY OF TOBACCO PRODUCT MANUFACTURERS.

(a) PAYMENTS.—

(1) INITIAL PAYMENT.—Not later than 90 days after the date of enactment of this Act, each manufacturer shall pay to the Trust Fund an amount that bears the same ratio to $15,000,000,000 as the average stock market capitalization of the tobacco manufacturer (as defined in paragraph (3)) bears to the average stock market capitalization of all tobacco manufacturers for 1996.

(2) ANNUAL ASSESSMENTS AND COLLECTION.—For each calendar year beginning with the first full calendar year following the year in which this Act is enacted, the Secretary shall assess each manufacturer an amount determined under subsection (b). Such assessments shall be collected in a manner similar to the manner in which excise taxes are collected under chapter 52 of the Internal Revenue Code of 1986.

(3) AVERAGE STOCK MARKET CAPITALIZATION.—For purposes of this subsection, the average stock market capitalization of a manufacturer for a year shall be determined by the Secretary of the Treasury based on data submitted by manufacturers and other appropriate data. Such determinations shall be made regardless of whether the manufacturer issues stock.

(b) ANNUAL ASSESSMENTS.—The Secretary shall assess each manufacturer (in accordance with regulations, relating to the timing and method of payment of assessments, to be promulgated by the Secretary of the Treasury) an amount in accordance with the following:

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

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

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

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

(2) LARGE CIGARETTES.—

(A) IN GENERAL.—With respect to a manufacturer of cigarettes weighing more than 3 pounds per thousand, the assessment shall equal—

(i) for cigarettes removed during calendar year 1999, $52.50 per thousand;

(ii) for cigarettes removed during calendar year 2000, $105 per thousand; and

(iii) for cigarettes removed during calendar year 2001, $157.50 per thousand.

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

(3) SMALL CIGARS.—With respect to a manufacturer of cigars weighing not more than 3 pounds per thousand, the assessment shall equal—

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

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

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

(4) LARGE CIGARS.—With respect to a manufacturer of cigars weighing more than 3 pounds per thousand, the assessment shall equal—

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

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

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

(5) SNUFF.—With respect to a manufacturer of snuff (as such term is defined for purposes of chapter 52 of the Internal Revenue Code of 1986) the assessment shall equal—

(A) for snuff removed during calendar year 1999, $6.67 per pound (and a proportionate assessment at the like rate on all fractional parts of a pound);

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

(C) for snuff removed during calendar year 2001, $20 per pound (and a proportionate assessment at the like rate on all fractional parts of a pound).

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

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

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

(C) for chewing tobacco removed during calendar year 2001, $8 per pound (and a proportionate assessment at the like rate on all fractional parts of a pound).

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

(A) for pipe tobacco removed during calendar year 1999, $5.33 per pound (and a proportionate assessment at the like rate on all fractional parts of a pound);

(B) for pipe tobacco removed during calendar year 2000, $10.67 per pound (and a proportionate assessment at the like rate on all fractional parts of a pound); and

(C) for pipe tobacco removed during calendar year 2001, $16.00 per pound (and a proportionate assessment at the like rate on all fractional parts of a pound).

(8) ROLL-YOUR-OWN TOBACCO.—With respect to a manufacturer of roll-your-own tobacco the assessment shall equal—

(A) for roll-your-own tobacco removed during calendar year 1999, $5.71 per pound (and

a proportionate assessment at the like rate on all fractional parts of a pound):

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

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

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

(1) such dollar amount (or percentage), multiplied by

(2) the greater of—

(A) the medical consumer price percentage increase for such calendar year as determined in the same manner as the adjustment is determined under section 1(f)(3) of the Internal Revenue Code of 1986 for such calendar year by substituting "the second preceding calendar

year" for "calendar year 1992" in subparagraph (B) thereof; or

(B) 3 percent.

(d) ASSESSMENTS APPLICABLE TO FLOOR STOCKS.—

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

(A) the assessment which would be imposed under subsection (b) on the product if the product had been removed on such date, over

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

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

(A) LIABILITY FOR ASSESSMENT.—A person holding tobacco products on any assessment date, to which any assessment imposed under paragraph (1) applies shall be liable for such assessment.

(B) METHOD OF PAYMENT.—The assessment imposed under paragraph (1) shall be

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

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

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

(A) internal revenue taxes have been determined, or customs duties liquidated, with respect to such product before such date; or

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

(4) ASSESSMENT DATE.—The term "assessment date" means January 1.

(e) NO TAX BENEFIT.—

(1) IN GENERAL.—The initial payment described in subsection (a)(1) shall not be considered to be an ordinary and necessary expense in carrying on a trade or business for purposes of the Internal Revenue Code of 1986 and shall not be tax deductible.

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

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

(1) in subparagraph (F)(iii), by striking "or" at the end;

(2) in subparagraph (G), by striking the period and inserting "; or"; and

(3) by adding at the end the following:

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

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

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

(i) NONAPPLICATION TO CERTAIN MANUFACTURERS.—

(1) EXEMPTION.—

(A) IN GENERAL.—A manufacturer described in paragraph (2) shall be exempt from the requirements of this section relating to—

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

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

(B) DETERMINATION.—For purposes of subparagraph (A)(ii), the Secretary shall determine the amount of the assessments involved that will be provided under paragraphs (1) through (4) of section 101(d) to States described in such subparagraph based on the ratio described in section 111(b)(2)(A) with respect to such States. Such amount shall be deducted

from the aggregate assessment due from the manufacturer involved.

(2) MANUFACTURER.—A manufacturer described in this section is a manufacturer that has resolved tobacco-related civil actions with more than 25 States prior to January 1, 1998 through judicial consent decrees.

(3) LIMITATION.—The provisions of paragraph (1) shall apply only to assessments on cigarettes to the extent that such cigarettes constitute less than 3 percent of all cigarettes manufactured and distributed for consumer use in any year.

SEC. 103. LICENSING OF MANUFACTURERS.

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

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

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

(2) to be eligible to receive the protections provided under subtitle A of title VII.

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

(d) REVOCATION AND SUSPENSION.—The Secretary shall promulgate regulations to provide for the enforcement of the program established under section (a). Such regulations shall provide for the revocation or suspension of a license for nonpayment of required assessments.

SEC. 104. ENFORCEMENT.

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

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

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

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

(1) beginning on the due date for such payment; and

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

Subtitle B—Payments

CHAPTER 1—TO STATES

SEC. 111. PAYMENTS TO STATES.

(a) AVAILABILITY OF FUNDS.—

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

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

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

(b) REIMBURSEMENT.—

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

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

(2) AMOUNT.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the amount for which a State is eligible under paragraph (1) shall be based on the ratio of the total Federal payments to the State under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) for the fiscal year involved to the total Federal payments to all States under such title for such fiscal year.

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

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

(3) ADJUSTMENT.—With respect to a fiscal year in which the amount determined under paragraphs (1) and (2) of subsection (a) exceeds the limitation under subsection (a)(3), the Secretary shall make pro rata reductions in the amounts provided to States under this subsection.

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

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

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

(B) to reimburse the State for other expenses incurred by the State in providing directly, or reimbursing others for the provision

of, treatment for tobacco-related illnesses or conditions; and

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

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

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

(2) prepare and submit to the Secretary for approval a plan describing the manner in which the State will comply with the requirements of subsection (d) and a certification that all actions described in paragraph (1) have been resolved; and

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

(d) FUNDS FOR LOCAL GOVERNMENTAL ENTITIES.—To be eligible to receive funds under subsection (b), a State shall have adopted procedures to provide an equitable portion of such funds to local governmental entities within the State that can demonstrate that such entities incurred tobacco-related health costs through—

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

(2) the provision of indigent care;

(3) the provision of health care coverage to governmental employees; or

(4) the implementation of tobacco product enforcement or tobacco product regulatory requirements in accordance with this Act.

CHAPTER 2—FEDERAL HEALTH PROGRAMS

SEC. 121. NATIONAL INSTITUTES OF HEALTH TRUST FUND FOR HEALTH RESEARCH.

(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the "National Institutes of Health Trust Fund for Health Research" (hereafter referred to in this section as the "Trust Fund"), consisting of such amounts as may be appropriated or transferred to the Trust Fund as provided in this section.

(b) FUNDING.—There shall be transferred to the Trust Fund an amount equal to the amount made available for a fiscal year under section 101(d)(6) to carry out this section in such fiscal year.

(c) OBLIGATIONS FROM TRUST FUND.—

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

(A) 2 percent of such amounts to the Office of the Director of the National Institutes of Health to be allocated at the Director's discretion—

(i) for carrying out the responsibilities of the Office of the Director, including the Office of Research on Women's Health and the Office of Research on Minority Health, the Office of Alternative Medicine, the Office of Rare Disease Research, the Office of Behavioral and Social Sciences Research (for use for efforts to reduce tobacco use), the Office of Dietary Supplements, and the Office for Disease Prevention; and

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

(B) 2 percent of such amounts for transfer to the National Center for Research Resources to carry out section 1502 of the National Institutes of Health Revitalization Act of 1993 con-

cerning Biomedical and Behavioral Research Facilities;

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

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

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

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

(G) the remainder of such amounts to member institutes and centers, including the Office of AIDS Research, of the National Institutes of Health in the same proportion to such remainder, as the amount of annual appropriations under appropriations Acts for each member institute and center for the fiscal year bears to the total amount of appropriations under appropriations Acts for all member institutes and centers of the National Institutes of Health for the fiscal year.

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

(3) GRANTS AND CONTRACTS FULLY FUNDED IN FIRST YEAR.—With respect to any grant or contract funded by amounts distributed under paragraph (1), the full amount of the total obligation of such grant or contract shall be funded in the first year of such grant or contract, and shall remain available until expended.

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

(A) TRIGGER AND RELEASE.—No expenditure shall be made under paragraph (1) during any fiscal year in which the annual amount appropriated for the National Institutes of Health is less than the amount so appropriated for fiscal year 1999.

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

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

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

(iii) 75 percent of the amount in the Trust Fund is distributed in the third fiscal year for which funds are available; and

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

CHAPTER 3—INVESTMENTS FOR CHILDREN

SEC. 131. IMPROVING CHILD CARE AND EARLY CHILDHOOD DEVELOPMENT.

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

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

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

(2) Enhancing the quality of child care and early childhood development through the provision of grants to States under the Child Care and Development Block Grant Act of 1990 (42 U.S.C. 9858 et seq.).

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

(4) Assisting young children by providing grants to local collaboratives under the Child Care and Development Block Grant Act of 1990 (42 U.S.C. 9858 et seq.) for the purpose of improving parent education and supportive services, strengthening the quality of child care, improving health services, and improving services for children with disabilities.

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

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

SEC. 132. IMPROVING ELEMENTARY EDUCATION.

(a) GRANTS AUTHORIZED.—The Secretary of Education shall use amounts made available under section 101(d)(3) for a fiscal year to award grants to States and local educational agencies to train, recruit and hire elementary school teachers for the purpose of reducing the average class size for students in grades 1 through 3 to not more than 18 students per teacher.

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

(1) the use of funds by the State, including the awarding of grants to local educational agencies;

(2) teacher preparation and certification; and

(3) accountability for improved student achievement.

(c) STATE PLAN.—

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

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

(2) CONTENTS.—Each State plan shall demonstrate to the satisfaction of the Secretary of Education that—

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

(B) the State will use the funds made available under this section to reduce class size for students in grades 1 through 3 in elementary schools throughout the State, focusing on using the funds to train, recruit, and hire teachers for elementary schools serving communities with the least available resources for such activities and the largest class sizes in those grades; and

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

percentage of funds provided to that local educational agency as compared to other local educational agencies in the State under part A of title I of the Elementary and Secondary Education Act of 1965.

(3) APPROVAL.—The Secretary shall approve a State plan submitted under paragraph (1) if the State plan meets the requirements of this subsection.

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

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

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

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

"(A) administrative costs of eligibility determinations that (but for the enactment of this section) would not be incurred; and

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

(2) by striking paragraphs (3) and (4) and inserting the following:

"(3) LIMITATION.—

"(A) IN GENERAL.—Beginning with fiscal year 1998, the total amount of additional Federal funds that are expended as a result of the application of this subsection shall not exceed $525,000,000.

"(B) AVAILABILITY OF APPROPRIATION.—Any amount appropriated in accordance with this paragraph shall remain available until expended.

"(C) EQUITABLE DISTRIBUTION OF FUNDS.—In applying this paragraph, the Secretary shall ensure the equitable distribution of additional funds among the States.".

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

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

(A) in subparagraph (A)(i)—

(i) by striking "or (II)" and inserting ", (II)"; and

(ii) by inserting ", or (III) is an elementary school or secondary school, as such terms are defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801), is a child care resource and referral agency, a child support enforcement agency, or is authorized to determine the eligibility of a child for obtaining child health assistance under title XXI that is in the form of coverage that meets the requirements of section 2103" before the semicolon; and

(B) in subparagraph (C), by striking "limiting the classes of" and inserting "imposing limitations on".

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

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

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

(1) IN GENERAL.—Section 2104(d) of the Social Security Act (42 U.S.C. 1397dd(d)) is amended to read as follows:

"(d) CERTAIN MEDICAID EXPENDITURES COUNTED AGAINST INDIVIDUAL STATE ALLOTMENTS.—The amount of the allotment otherwise provided to a State under subsection (b) or (c) for a fiscal year shall be reduced by the amount (if any) of the payments made to that State under section 1903(a) for expenditures claimed by the State during such fiscal year that is attributable to the provision of medical assistance to a child for which payment is made under section 1903(a)(1) on the basis of an enhanced FMAP under the fourth sentence of section 1905(b).".

(2) RETROACTIVITY.—The amendment made by paragraph (1) takes effect as if included in the enactment of section 4901 of the Balanced Budget Act of 1997 (Public Law 105–33; 111 Stat. 552).

(d) MEDICAID AND STATE CHILDREN'S HEALTH INSURANCE PROGRAM ELIGIBILITY FOR LEGAL IMMIGRANT CHILDREN WHO ENTERED THE UNITED STATES AFTER AUGUST 1996.—

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

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

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

"(2) medical assistance under title XIX of such Act (42 U.S.C. 1396 et seq.), if the individual is an optional targeted low-income child described in section 1905(u)(2)(B) of such Act (42 U.S.C. 1396d(u)(2)(B)).".

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

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

(A) in the matter preceding subparagraph (A), by striking "Qualified" and inserting "Except as provided in subparagraphs (A), (E), (F), and (G), qualified"; and

(B) by adding at the end the following:

"(G) MEDICAID EXCEPTION FOR CERTAIN CHILDREN.—With respect to eligibility for benefits for the program described in section 403(e)(2), paragraph (1) shall not apply to any individual described in that section.".

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

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

"(x) PERFORMANCE BONUS FOR REDUCTION IN ELIGIBLE BUT UNENROLLED CHILDREN.—

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

"(2) PERFORMANCE BONUS.—

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

"(i) the excess baseline enrollment for the State for the fiscal year;

"(ii) the average per child expenditures by the State under this title for the fiscal year; and

"(iii) the difference between the enhanced FMAP and the Federal medical assistance percentage (as defined in the first sentence of section 1905(b)) of the State for the fiscal year described in section 2105(b).

"(B) DETERMINATION OF THE EXCESS BASELINE ENROLLMENT.—

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

enrollment for a State for a fiscal year is the difference between (I) the actual number of full year equivalent children enrolled under the State plan and (II) the baseline number of full year equivalent children that would be enrolled under the State plan in the absence of the performance bonus outreach efforts of the State.

"(ii) DETERMINATION OF THE BASELINE NUMBER OF FULL YEAR EQUIVALENT CHILDREN.—For purposes of clause (i)(II), the baseline number of full year equivalent children that would be enrolled under the State plan in the absence of the performance bonus outreach efforts of the State is—

"(I) in the case of fiscal year 1999, the actual number of full year equivalent children enrolled under the State plan in fiscal year 1998, increased by the national percentage increase for fiscal year 1999 in the number of full year equivalent children enrolled in all State plans under this title, as projected by the Congres-

sional Budget Office in January 1998; and

"(II) in the case of any succeeding fiscal year, the baseline number of full year equivalent children that would be enrolled under the State plan in the absence of the performance bonus outreach efforts of the State determined for the preceding fiscal year, increased by the national percentage increase for that succeeding fiscal year in the number of full year equivalent children enrolled in all State plans under this title, as projected by the Congressional Budget Office in January 1998.

"(C) DETERMINATION OF AVERAGE PER CHILD EXPENDITURES.—For purposes of subparagraph (A)(ii), the average per child expenditures by a State under this title for a fiscal year is—

"(i) the total amount paid to the State under subsection (a)(1) that is attributable to medical assistance provided to children under the State plan; divided by

"(ii) the actual number of full year equivalent children enrolled under the State plan in that fiscal year.

"(3) DATA REQUIREMENTS.—Each State shall submit to the Secretary such data, at such time and in such manner, as the Secretary determines is necessary to make the payments required under this subsection. The Secretary shall ensure that data is provided under this subsection in a manner that is consistent with other data reporting requirements for information required to be submitted by a State under this title and title XXI, and that avoids duplication of reporting requirements.

"(4) STATES WITH SIGNIFICANTLY HIGHER INCREASED ACTUAL ENROLLMENT THAN THE EXPECTED NATIONAL INCREASE.—For any fiscal year, if a State's actual full year equivalent children enrollment percentage increase over the preceding fiscal year is at least twice the estimated national percentage increase in such enrollment for that fiscal year, as projected by the Congressional Budget Office in January 1998, the State shall submit such additional information as the Secretary determines is necessary to verify that the increase is the result of the State reducing the number of unenrolled chil-

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

"(5) TIMING OF PERFORMANCE BONUS PAYMENTS; RECONCILIATION.—The Secretary shall pay the performance bonuses required under this subsection for a fiscal year not later than September 30 of the succeeding fiscal year based on reporting data that reflects each State's actual number of full year equivalent children enrolled under the State plan and average per child expenditures. A State shall provide the Secretary with access to any records or information relevant to the payment of a performance bonus under this subsection for the purposes of review or audit.

"(6) WAIVERS.—The provisions of this subsection apply to a State providing medical assistance under this title under waiver authority in the same manner as they apply to a State with an approved plan under this title.

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

by subsections (a) through (d) of section 133 of such Act).".

SEC. 134. MEDICARE CANCER PATIENT DEMONSTRATION PROJECT; EVALUATION AND REPORT TO CONGRESS.

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

(1) which are provided to an individual diagnosed with cancer and enrolled in the medicare program under such title as part of the individual's participation in an approved clinical trial program; and

(2) which are not otherwise eligible for payment under such title for individuals who are entitled to benefits under such title.

(b) APPLICATION.—The beneficiary cost sharing provisions under the medicare program, such as deductibles, coinsurance, and copayment amounts, shall apply to any individual participating in a demonstration project conducted under this section.

(c) APPROVED CLINICAL TRIAL PROGRAM.—

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

(A) the National Institutes of Health;

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

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

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

(d) ROUTINE PATIENT CARE COSTS.—

(1) IN GENERAL.—For purposes of this section, "routine patient care costs" shall include the costs associated with the provision of items and services that—

(A) would otherwise be covered under the medicare program if such items and services were not provided in connection with an approved clinical trial program; and

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

(2) EXCLUSION.—For purposes of this section, "routine patient care costs" shall not include the costs associated with the provision of—

(A) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

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

(e) STUDY.—The Secretary shall study the impact on the medicare program under title XVIII of the Social Security Act of covering routine patient care costs for individuals with a diagnosis of cancer and other diagnoses, who are entitled to benefits under such title and who are enrolled in an approved clinical trial program.

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

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

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

TITLE II—FDA JURISDICTION OVER TOBACCO PRODUCTS

SEC. 201. REFERENCE.

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

SEC. 202. STATEMENT OF GENERAL AUTHORITY.

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

SEC. 203. TREATMENT OF TOBACCO PRODUCTS AS DRUGS AND DEVICES.

(a) DEFINITIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(bb) The failure or refusal to comply with any of the requirements of subsections (a), (b) or (e) of section 578.".

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

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

(2) by adding at the end the following:

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

SEC. 204. SAFETY AND EFFICACY STANDARD AND RECALL AUTHORITY.

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

(1) in paragraph (1)(B), by inserting after the first sentence the following: "For a device which is a tobacco product, the assurance in the previous sentence need not be found if the Secretary finds that special controls achieve the best public health result."; and

(2) in paragraph (2)—

(A) by redesignating subparagraphs (A), (B) and (C) as clauses (i), (ii) and (iii), respectively;

(B) by striking "(2) For" and inserting "(2)(A) For"; and

(C) by adding at the end the following:

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

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

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

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

SEC. 205. GENERAL HEALTH AND SAFETY REGULATION OF TOBACCO PRODUCTS.

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

SUBCHAPTER F—TOBACCO PRODUCTS

"SEC. 571. PROMULGATION OF REGULATIONS.

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

"SEC. 572. SCIENTIFIC ADVISORY COMMITTEE.

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

"(b) MEMBERSHIP.—

"(1) IN GENERAL.—The Secretary shall appoint as members of the Scientific Advisory Committee any individuals with expertise in the medical, scientific, or other technological data involving the manufacture and use of tobacco products, and of appropriately diversified professional backgrounds.

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

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

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

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

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

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

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

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

"(1) provide assistance to the Secretary;

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

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

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

"SEC. 573. PERFORMANCE STANDARDS.

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

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

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

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

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

"SEC. 574. DISCLOSURE AND REPORTING OF TOBACCO AND NONTOBACCO INGREDIENTS AND CONSTITUENTS.

"(a) DISCLOSURE OF ALL INGREDIENTS.—

"(1) IMMEDIATE AND ANNUAL DISCLOSURE.—Not later than 30 days after the date of enactment of this subchapter, and annually thereafter, each manufacturer of a tobacco product shall submit to the Secretary an ingredient list for each brand of tobacco product it manufactures that contains the information described in paragraph (2).

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

"(A) a list of all ingredients, constituents, substances, and compounds that are found in or added to the tobacco or tobacco product (including the paper, filter, or packaging of the product if applicable) in the manufacture of the

tobacco product, for each brand or variety of tobacco product so manufactured, including, if determined necessary by the Secretary, any material added to the tobacco used in the product prior to harvesting;

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

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

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

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

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

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

tar, nicotine, and carbon monoxide per cigarette;

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

"(i) the pH level of the tobacco;

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

"(iii) the nicotine content—

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

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

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

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

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

"(b) SAFETY ASSESSMENTS.—

"(1) APPLICATION TO NEW INGREDIENTS.—

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

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

"(C) DEFINITION OF NEW INGREDIENT.—For purposes of subparagraph (A), the term 'new ingredient, constituent, substance, or compound' means an ingredient, constituent

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

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

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

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

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

"(c) PROHIBITION.—

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

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

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

"(2) REVIEW OF ASSESSMENTS.—

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

"(B) INACTION BY SECRETARY.—If the Secretary fails to act with respect to an assessment of an existing ingredient, constituent, substance, or additive during the period referred to in subparagraph (A), the manufacturer of the tobacco product involved may continue to use the ingredient, constituents, substance, or compound involved until such time as the Secretary makes a determination with respect to the assessment.

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

"(1) IN GENERAL.—Except as provided in paragraph (3), a package of a tobacco product shall dis-

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

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

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

"(B) the percentage that is foreign tobacco.

"(3) HEALTH DISCLOSURE.—Notwithstanding section 301(j), the Secretary may require the public disclosure of any ingredient, constituent, substance, or compound contained in a tobacco product that relates to a trade secret or other matter referred to in section 1905 of title 18, United States Code, if the Secretary determines that such disclosure will promote the public health.

"SEC. 575. TOBACCO PRODUCT WARNINGS, LABELING AND PACKAGING.

"(a) CIGARETTE WARNINGS.—

"(1) IN GENERAL.—

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

"WARNING: Cigarettes Are Addictive.

"WARNING: Tobacco Smoke Can Harm Your Children.

"WARNING: Cigarettes Cause Fatal Lung Disease.

"WARNING: Cigarettes Cause Cancer.

"WARNING: Cigarettes Cause Strokes And Heart Disease.

"WARNING: Smoking During Pregnancy Can Harm Your Baby.

"WARNING: Smoking Can Kill You.

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

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

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

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

"WARNING: Cigarettes Are Addictive.

"WARNING: Tobacco Smoke Can Harm Your Children.

"WARNING: Cigarettes Cause Fatal Lung Disease.

"WARNING: Cigarettes Cause Cancer.

"WARNING: Cigarettes Cause Strokes And Heart Disease.

"WARNING: Smoking During Pregnancy Can Harm Your Baby.

"WARNING: Smoking Can Kill You.

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

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

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

that such warnings would be more effective in deterring the use of cigarettes.

"(2) REQUIREMENTS FOR LABELING.—

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

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

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

"(3) REQUIREMENTS FOR ADVERTISING.—

"(A) LOCATION.—Each label statement required by subparagraph (B) of paragraph (1) shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area and shall occupy not less than 20 percent of the area of the advertisement involved.

"(B) TYPE, COLOR AND FORMAT.—

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

label statement shall be printed in the following types:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(4) ROTATION OF LABEL STATEMENTS.—

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

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

"(C) APPROVAL OF PLANS.—The Secretary shall review each plan submitted by a manufacturer, importer, distributor or retailer of cigarettes under this paragraph and approve such plan if the plan will provide for the equal distribution and display on packaging and the rotation required in advertising under this paragraph and if such plan assures that all of the labels required under subparagraphs (A) and (B) will be displayed by the manufacturer, importer, distributor or retailer at the same time.

"(b) SMOKELESS TOBACCO PRODUCTS.—

"(1) IN GENERAL.—

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

accordance with the requirements of this subsection, one of the following labels:

"WARNING: This Product Can Cause Mouth Cancer.

"WARNING: This Product Can Kill You.

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

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

"WARNING: This Product Contains Cancer-Causing Chemicals.

"WARNING: Smokeless Tobacco Is Addictive.

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

"WARNING: This Product Can Cause Mouth Cancer.

"WARNING: This Product Can Kill You.

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

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

"WARNING: This Product Contains Cancer-Causing Chemicals.

"WARNING: Smokeless Tobacco Is Addictive.

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

"(2) REQUIREMENTS FOR LABELING.—

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

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

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

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

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

"(d) CONSTRUCTION.—

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

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

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

"(e) LIMITED PREEMPTION.—

"(1) STATE AND LOCAL ACTION.—No warning label with respect to cigarettes or smokeless tobacco products, or any other tobacco product for which warning labels have been required under this section, other than the warning labels required under this Act, shall be required by any State or local statute or regulation to be included on any package of cigarettes or a smokeless tobacco product.

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

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

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

"SEC. 576. PRESERVATION OF STATE AND LOCAL AUTHORITY.

"Except as otherwise provided for in section 575(e), nothing in this subchapter shall be construed as prohibiting a State or locality from imposing requirements, prohibitions, penalties or other measures to further the purposes of this subchapter that are in addition to the requirements, prohibitions, or penalties required under this subchapter. State and local governments may impose additional tobacco product control measures to further restrict or limit the use of such products.

"SEC. 577. RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS.

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

"(b) STATE LICENSING.—

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

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

"(2) START-UP PERIOD.—

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

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

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

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

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

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

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

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

tion of tobacco products without a license and for appropriate penalties for other violations of laws relating to youth access to tobacco products;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(d) ENFORCEMENT.—

"(1) IN GENERAL.—The Secretary may enter into agreements with, and provide grants to, States to enforce this section. Any State that elects to enforce the provisions of this section within the State shall conduct sting operations and other compliance

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

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

"(3) VIOLATIONS.—If the Secretary determines that the provisions of subsection (a) are being violated within a State, the Secretary shall have the authority to enforce such provisions in the State.

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

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

provides greater restrictions than those required in this section.

"(g) FEDERAL LICENSING OF ENTITIES.—

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

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

"(B) in any United States embassy;

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

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

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

"(2) REQUIREMENTS.—The program established under paragraph (1) shall apply requirements (including those for penalties, suspensions, and rev-

ocations) similar to those required to be implemented by States under this section.

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

"SEC. 578. PUBLIC DISCLOSURE OF HEALTH RESEARCH.

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

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

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