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109TH CONGRESS
2D SESSION

H. R. 5951

To improve the health of Americans and reduce health care costs by reorienting the Nation's health care system toward prevention, wellness, and self care.

IN THE HOUSE OF REPRESENTATIVES

JULY 27, 2006

Mr. UDALL of New Mexico (for himself, Ms. WOOLSEY, and Mr. MORAN of Virginia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and the Workforce, and Government Reform, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To improve the health of Americans and reduce health care costs by reorienting the Nation's health care system toward prevention, wellness, and self care.

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 Lifestyles and Prevention America Act" or the "HeLP America Act".

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

Sec. 1. Short title; table of contents.
Sec. 2. Findings.

TITLE I—HEALTHIER KIDS AND SCHOOLS

Sec. 101. Fresh Fruit and Vegetable Program.
Sec. 102. Food of minimal nutritional value.
Sec. 103. School nutrition environment enhancement grants.

TITLE II—HEALTHIER COMMUNITIES AND WORKPLACES

Subtitle A—Incentives for a Healthy Workforce

Sec. 201. Short title.
Sec. 202. Tax credit to employers for costs of implementing wellness programs.
Sec. 203. Income exclusion for employer-provided off-premises health club services.
Sec. 204. CDC and employer-based wellness programs.

Subtitle B—Healthy Communities

Sec. 211. Healthy community grants.
Sec. 212. Preventive medicine and public health training grant program.

Subtitle C—Family Smoking Prevention and Control

Sec. 221. Short title.
Sec. 222. Findings.
Sec. 223. Purpose.
Sec. 224. Scope and effect.
Sec. 225. Severability.

PART I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

Sec. 231. Amendment of Federal Food, Drug, and Cosmetic Act.
Sec. 232. Interim final rule.
Sec. 233. Conforming and other amendments to general provisions.

PART II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CCONSTITUENT DISCLOSURE

Sec. 235. Cigarette label and advertising warnings.
Sec. 236. Authority to revise cigarette WARNING label statements.
Sec. 237. State regulation of cigarette advertising and promotion.
Sec. 238. Smokeless tobacco labels and advertising warnings.
Sec. 239. Authority to revise smokeless tobacco product WARNING label statements.
Sec. 240. Tar, nicotine, and other smoke constituent disclosure to the public.

PART III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

Sec. 241. Labeling, recordkeeping, records inspection.
Sec. 242. Study and report.

TITLE III—RESPONSIBLE MARKETING AND CONSUMER AWARENESS

Subtitle A—General Provisions

Sec. 301. Nutrition labeling of restaurant foods.
Sec. 302. Rulemaking authority for advertising to children.
Sec. 303. Food advertising in schools.
Sec. 304. Disallowance of deductions for advertising and marketing expenses relating to Tobacco product use.
Sec. 305. Federal-State Tobacco counter-advertising programs.

Subtitle B—Penalties for Failure to Reduce Teen Smoking

Sec. 311. Child cigarette use surveys.
Sec. 312. Cigarette use reduction goal and noncompliance.
Sec. 313. Enforcement.

TITLE IV—REIMBURSEMENT AND COVERAGE OF PREVENTIVE SERVICES

Sec. 401. Coverage of substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling.
Sec. 402. Encouragement of cessation of tobacco use.
Sec. 403. Recognition of school-based health centers as model for delivery of primary care for children under Medicaid and the State Children's Health Insurance Program.
Sec. 404. Preventive health care demonstration program.
Sec. 405. Preventive health services for women.

TITLE V—HELP (HEALTHY LIFESTYLES AND PREVENTION) AMERICA TRUST FUND

Sec. 501. HeLP (Healthy Lifestyles and Prevention) America Trust Fund.

TITLE VI—RESEARCH

Sec. 601. Expansion of research regarding obesity.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Health care costs in the United States are
4 rising rapidly. Per capita health spending in the
5 United States is 56 percent higher than the median
6 country that is a member of the Organization for
7 Economic Cooperation and Development.

8 (2) According to the Centers for Medicare and
9 Medicaid Services, total health care spending in the

United States in 2004 was $1,800,000,000,000 and is expected to rise to $3,600,000,000,000 by 2014. Furthermore, chronic disease accounts for approximately 75 percent of health care costs annually.

(3) The United States spends less than 5 percent of annual health care expenditures on prevention

(4) Reducing and preventing the incidence of chronic disease is one means by which to reduce health care costs in the United States.

(5) More than 1,700,000 Americans die of a chronic disease each year, accounting for nearly 70 percent of all deaths in the United States.

(6) The economic impact of chronic disease can be seen in the annual costs associated with cardiovascular disease and stroke ($352,000,000,000), obesity ($117,000,000,000), cancer ($171,600,000,000), and diabetes ($132,000,000,000).

(7) Obesity related health conditions cost employers nearly $13,000,000,000 in health care and other indirect costs.

(8) Health promotion investments by employers on average yield a return of $3 for every $1 invested in a program.

(9) Being overweight or obese increase the risk of diabetes, heart disease, stroke, several types of cancer and other health problems.

(10) An estimated 65 percent of adults and 15 percent of children and adolescents in the United States are overweight or obese.

(11) The rates of obesity have doubled in children and tripled in teens since the 1980's.

(12) Almost 40 percent of Americans are sedentary. More than ⅓ of young people in grades 9 through 12 do not regularly engage in vigorous-intensity physical activity.

(13) Only 1 in 5 young people eat the recommended 5 daily servings of fruits and vegetables.

(14) Food and beverage advertisers collectively spend $10,000,000,000 to $12,000,000,000 a year to reach children and youth.

(15) Between 1977 and 1995, trips made by walking declined by 40 percent for adults while driving trips increased to almost 90 percent of the total.

(16) Virtually all-new users of tobacco products are under the minimum legal age to purchase such products. Every day in America, more than 4,000 kids try their first cigarette. Another 2,000 children become new daily smokers.

(17) In 2002, nearly a quarter of American adults, 46,000,000 people, smoked cigarettes, including almost 40 percent of college-aged students.

(18) Research consistently shows that smoking cessation services offered as a combination of tobacco medication therapy and counseling can be one of the most cost-effective health interventions and can reduce smoking-related health care costs.

TITLE I—HEALTHIER KIDS AND SCHOOLS

SEC. 101. FRESH FRUIT AND VEGETABLE PROGRAM.

(a) ADDITIONAL FUNDING FOR FRESH FRUIT AND VEGETABLE PROGRAM.—Section 18(g)(6)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1769(g)(6)(B)) is amended—

(1) by redesignating clause (ii) as clause (iv); and

(2) by inserting after clause (i) the following:

"(ii) ADDITIONAL MANDATORY FUNDING.—Out of any funds in the Treasury not otherwise appropriated, the Secretary of the Treasury shall transfer to the Secretary of Agriculture to carry out and expand the program under this subsection, to remain available until expended—

"(I) on October 1, 2006, $1,000,000,000; and

"(II) on October 1, 2007, and on each October 1 thereafter, the amount made available for the previous fiscal year, as adjusted under clause (iii).

"(iii) ADJUSTMENT.—On October 1, 2007, and on each October 1 thereafter of a fiscal year the amount made available under subclause (II) of clause (ii) shall be calculated by adjusting the amount made available for the previous fiscal year to reflect changes in the Consumer Price Index of the Bureau of Labor Statistics for fresh fruits and vegetables, with the adjustment—

"(I) rounded down to the nearest dollar increment; and

"(II) based on the unrounded amounts for the preceding 12-month period.".

(b) HEALTHY COOKING PILOT PROGRAM.—Section 18(g) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1769(g)) is amended—

(1) by redesignating paragraphs (4), (5), and (6) as paragraphs (5), (6), and (7), respectively; and

(2) by inserting after paragraph (3) the following:

"(4) HEALTHY COOKING PILOT PROGRAM.—

"(A) IN GENERAL.—As part of the program conducted under this subsection, the Secretary shall carry out a pilot program under which the Secretary shall make competitive grants to selected elementary and secondary schools to teach children—

"(i) how to eat a nutritious diet;

"(ii) how to select foods to make a healthy meal; and

"(iii) how to prepare healthy meals.

"(B) SELECTION OF SCHOOLS.—In selecting schools to participate in the pilot program, the Secretary shall ensure that—

"(i) only schools participating in the fruit and vegetable program under this subsection are eligible to receive funds under this paragraph;

"(ii) to the maximum extent practicable, at least 75 percent of schools selected are schools in which at least 50 per-

cent of the students enrolled are eligible for free or reduced price meals under this Act; and

"(iii) there is appropriate representation, as determined by the Secretary, of—

"(I) rural, urban, and suburban schools; and

"(II) elementary, middle, and secondary schools.

"(C) PRIORITY CONSIDERATION.—In awarding competitive grants under this paragraph, the Secretary shall give priority consideration to schools that submit an application that includes the participation of the parents or families of the children enrolled in the school.".

SEC. 102. FOOD OF MINIMAL NUTRITIONAL VALUE.

Section 10 of the Child Nutrition Act of 1966 (42 U.S.C. 1779) is amended—

(1) by striking the section heading and all that follows through "(a) The Secretary" and inserting the following:

"SEC. 10. REGULATIONS.

"(a) IN GENERAL.—The Secretary"; and

(2) by striking subsections (b) and (c) and inserting the following:

"(b) FOOD OF MINIMAL NUTRITIONAL VALUE.—

"(1) PROPOSED REGULATIONS.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary shall promulgate proposed regulations to revise the definition of 'food of minimal nutritional value' that is used to carry out this Act and the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.).

"(B) APPLICATION.—The revised definition of 'food of minimal nutritional value' shall apply to all foods sold—

"(i) outside the school meal programs;

"(ii) on the school campus; and

"(iii) at any time during the school day.

"(C) REQUIREMENTS.—In revising the definition, the Secretary shall consider—

"(i) both the positive and negative contributions of nutrients, ingredients, and foods (including calories, portion size, saturated fat, trans fat, sodium, and added sugars) to the diets of children;

"(ii) evidence concerning the relationship between consumption of certain nutrients, ingredients, and foods to both preventing and promoting the development of overweight, obesity, and other chronic illnesses;

"(iii) recommendations made by authoritative scientific organizations concerning appropriate nutritional standards for foods sold outside of the reimbursable meal programs in schools; and

"(iv) special exemptions for school-sponsored fundraisers (other than fundraising through vending machines, school stores, snack bars, a la carte sales, and any other exclusions determined by the Secretary), if the fundraisers are approved by the school and are infrequent within the school.

"(2) IMPLEMENTATION.—

"(A) EFFECTIVE DATE.—

"(i) IN GENERAL.—Except as provided in clause (ii), the proposed regulations shall take effect at the beginning of

the school year following the date on which the regulations are finalized.

"(ii) EXCEPTION.—If the regulations are finalized on a date that is not more than 60 days before the beginning of the school year, the proposed regulations shall take effect at the beginning of the following school year.

"(B) FAILURE TO PROMULGATE.—If, on the date that is 1 year after the date of enactment of this paragraph, the Secretary has not promulgated final regulations, the proposed regulations shall be considered to be final regulations.".

SEC. 103. SCHOOL NUTRITION ENVIRONMENT ENHANCEMENT GRANTS.

Section 18 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1769) is amended by adding at the end the following:

"(l) HEALTHY SCHOOL NUTRITION ENVIRONMENT INCENTIVE GRANTS.—

"(1) IN GENERAL.—Following the publication of the recommendations of the Institute of Medicine study carried out using funds made available for public health improvement and leadership under the

heading 'Centers for Disease Control and Prevention' in the Department of Labor Appropriations Act, 2005 (title I of division F of Public Law 108–447; 118 Stat. 3124) regarding appropriate nutritional standards for the availability, sale, content, and consumption of food at school, with particular attention given to foods offered in competition with federally reimbursed meals and snacks, the Secretary may carry out a grant program to—

"(A) provide schools with technical assistance in implementing the recommendations of the Institute of Medicine regarding appropriate school nutrition standards; and

"(B) assess the impact of implementing the recommendations on the health and well-being of children enrolled in the schools.

"(2) SELECTION OF SCHOOLS.—In selecting schools to receive incentive grants under this subsection, the Secretary shall—

"(A) ensure that not less than 75 percent of schools selected to participate in the program established under this subsection are schools in which not less than 50 percent of the students enrolled in each school are eligible for free or reduced price meals under this Act;

"(B) ensure that, of the schools selected to participate in the program, there is appropriate representation of rural, urban, and suburban schools, as determined by the Secretary;

"(C) ensure that, of the schools selected to participate in the program, there is appropriate representation of elementary, middle, and secondary schools, as determined by the Secretary;

"(D) ensure that schools selected to receive a grant under this subsection meet the requirements of paragraph (3);

"(E) give priority to schools that develop comprehensive plans that include the involvement of a broad range of community stakeholders in achieving healthy school nutrition environments; and

"(F) give priority to schools that develop comprehensive plans that include a strategy for maintaining healthy school nutrition environments in the years following the fiscal years for which the schools receive grants under this subsection.

"(3) REQUIREMENTS.—

"(A) CRITERIA FOR HEALTHY SCHOOL ENVIRONMENTS.—The Secretary shall establish

criteria, based upon the recommendations of the Institute of Medicine described in paragraph (1), under which schools may receive grants under this section.

"(B) PLAN.—To be eligible to receive a grant under this subsection, a school shall—

"(i) submit to the Secretary a healthy school nutrition environment plan that describes the actions the school will take to meet the criteria established under subparagraph (A); and

"(ii) take the actions described in the plan.

"(4) GRANTS.—For each of fiscal years 2007 through 2011, the Secretary shall make a grant to each school selected under paragraph (2).

"(5) EVALUATIONS.—

"(A) IN GENERAL.—The Secretary, acting through the Administrator of the Food and Nutrition Service, shall conduct an evaluation of a representative sample of schools that receive grants under this subsection.

"(B) CONTENT.—The evaluation shall measure, at a minimum, the effects of a healthy school nutrition environment on—

"(i) overweight children and obesity;

"(ii) dietary intake;

"(iii) nutrition education and behavior;

"(iv) parental and student attitudes and participation; and

"(v) related funding issues, including the cost of maintaining a healthy school nutrition environment.

"(C) REPORTS.—The Secretary shall submit to the Committee on Education and the Workforce of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate—

"(i) an interim report on the activities of schools evaluated under this subsection; and

"(ii) a final report on the activities of schools evaluated under this subsection.

"(6) AUTHORIZATION OF APPROPRIATIONS.—

"(A) IN GENERAL.—There are authorized to be appropriated such sums as are necessary to carry out this subsection for fiscal year 2007 and each subsequent fiscal year, to remain available until expended.

"(B) EVALUATIONS.—The Secretary may use not more than 10 percent of the total funds made available for a fiscal year under subparagraph (A) to carry out paragraph (5).".

TITLE II—HEALTHIER COMMUNITIES AND WORKPLACES

Subtitle A—Incentives for a Healthy Workforce

SEC. 201. SHORT TITLE.

This subtitle may be cited as the "Healthy Workforce Act of 2006".

SEC. 202. TAX CREDIT TO EMPLOYERS FOR COSTS OF IMPLEMENTING WELLNESS PROGRAMS.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business related credits) is amended by adding at the end the following:

"SEC. 45N. WELLNESS PROGRAM CREDIT.

"(a) ALLOWANCE OF CREDIT.—

"(1) IN GENERAL.—For purposes of section 38, the wellness program credit determined under this section for any taxable year is—

"(A) in the case of a small business employer, an amount equal to 50 percent of the costs paid or incurred by the small business em-

ployer in connection with a qualified small business wellness program during the taxable year, and

"(B) in the case of any other employer, an amount equal to 50 percent of the costs paid or incurred by the employer in connection with a qualified wellness program during the taxable year.

"(2) LIMITATION.—The amount of credit allowed under paragraph (1) for any taxable year shall not exceed the product of $200 and the number of employees of the employer or small business employer, as the case may be.

"(b) QUALIFIED WELLNESS PROGRAM; QUALIFIED SMALL BUSINESS WELLNESS PROGRAM.—For purposes of this section—

"(1) QUALIFIED WELLNESS PROGRAM.—The term 'qualified wellness program' means a program which consists of all of the wellness program components described in subsection (c) and which is certified by the Secretary of Health and Human Services, in consultation with persons who have expertise in employer health promotion and wellness programs, as a qualified wellness program under this section.

1 "(2) QUALIFIED SMALL BUSINESS WELLNESS
2 PROGRAM.—The term 'qualified small business
3 wellness program' means a program which consists
4 of any 2 of the components described in subsection
5 (c) and which is certified by the Secretary of Health
6 and Human Services, in consultation with persons
7 who have expertise in employer health promotion
8 and wellness programs, as a qualified small business
9 wellness program under this section.
10 "(c) WELLNESS PROGRAM COMPONENTS.—For pur-
11 poses of this section, the wellness program components de-
12 scribed in this subsection are the following:
13 "(1) HEALTH AWARENESS COMPONENT.—A
14 health awareness component which provides for the
15 following:
16 "(A) HEALTH EDUCATION.—The dissemi-
17 nation of health information which addresses
18 the specific needs and health risks of employees.
19 "(B) HEALTH SCREENINGS.—The oppor-
20 tunity for periodic screenings for health prob-
21 lems and referrals for appropriate follow up
22 measures.
23 "(2) BEHAVIORAL CHANGE COMPONENT.—A
24 behavioral change component which provides for al-
25 tering employee lifestyles to encourage healthy living

through counseling, seminars, on-line programs, or self-help materials. Such component shall include programs relating to—

"(A) smoking,

"(B) obesity,

"(C) stress management,

"(D) physical fitness,

"(E) nutrition,

"(F) substance abuse,

"(G) depression,

"(H) mental health promotion (including anxiety), and

"(I) sleep (including sleep disorders and the consequences of sleep deprivation).

"(3) SUPPORTIVE ENVIRONMENT COMPONENT.—A supportive environment component which includes the following:

"(A) ON-SITE POLICIES.—Policies and services at the worksite which promote a healthy lifestyle, including policies relating to—

"(i) smoking at the worksite,

"(ii) the nutrition of food available at the worksite through cafeterias and vending options,

"(iii) minimizing stress in the workplace,

"(iv) where applicable, accessible and attractive stairs,

"(v) the encouragement of physical activity during work hours, and

"(vi) the promotion of fatigue countermeasures.

"(B) PARTICIPATION INCENTIVES.—

"(i) IN GENERAL.—Qualified incentive benefits for each employee who participates in the health screenings described in paragraph (1)(B) or the behavioral change programs described in paragraph (2).

"(ii) QUALIFIED INCENTIVE BENEFIT.—For purposes of clause (i), the term 'qualified incentive benefit' means any benefit which is approved by the Secretary of Health and Human Services. Such benefit may include an adjustment in health insurance premiums or co-pays.

"(C) EMPLOYEE INPUT.—The opportunity for employees to participate in the management of any qualified wellness program or qualified

small business wellness program to which this section applies.

"(d) PARTICIPATION REQUIREMENT.—

"(1) IN GENERAL.—No credit shall be allowed under subsection (a) unless the Secretary of Health and Human Services certifies, as a part of any certification described in subsection (b), that each wellness program component of the qualified wellness program or qualified small business wellness program applies to all qualified employees of the employer.

"(2) QUALIFIED EMPLOYEE.—For purposes of paragraph (1), the term 'qualified employee' means an employee who works an average of not less than 25 hours per week during the taxable year.

"(e) OTHER DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

"(1) EMPLOYEE AND EMPLOYER.—

"(A) PARTNERS AND PARTNERSHIPS.—The term 'employee' includes a partner and the term 'employer' includes a partnership.

"(B) CERTAIN RULES TO APPLY.—Rules similar to the rules of section 52 shall apply.

"(2) SMALL BUSINESS EMPLOYER.—

"(A) IN GENERAL.—The term 'small business employer' means, with respect to any taxable year, an employer who employed an average of 200 or fewer employees on business days during such taxable year.

"(B) CONTROLLED GROUPS.—For purposes of subparagraph (A), all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as a single employer.

"(3) CERTAIN COSTS NOT INCLUDED.—Costs paid or incurred by an employer or small business employer for food or health insurance shall not be taken into account under subsection (a).

"(f) PORTION OF CREDIT MADE REFUNDABLE.—

"(1) IN GENERAL.—In the case of an eligible employer of an employee, the aggregate credits allowed to a taxpayer under subpart C shall be increased by the lesser of—

"(A) the credit which would be allowed under this section without regard to this subsection and the limitation under section 38(c), or

"(B) the amount by which the aggregate amount of credits allowed by this subpart (de-

termined without regard to this subsection) would increase if the limitation imposed by section 38(c) for any taxable year were increased by the amount of employer payroll taxes imposed on the taxpayer during the calendar year in which the taxable year begins.

The amount of the credit allowed under this subsection shall not be treated as a credit allowed under this subpart and shall reduce the amount of the credit otherwise allowable under subsection (a) without regard to section 38(c).

"(2) ELIGIBLE EMPLOYER.—For purposes of this subsection, the term 'eligible employer' means an employer or small business employer which is—

"(A) a State or political subdivision thereof, the District of Columbia, a possession of the United States, or an agency or instrumentality of any of the foregoing, or

"(B) any organization described in section 501(c) of the Internal Revenue Code of 1986 which is exempt from taxation under section 501(a) of such Code.

"(3) EMPLOYER PAYROLL TAXES.—For purposes of this subsection—

1 ''(A) IN GENERAL.—The term 'employer
2 payroll taxes' means the taxes imposed by—
3 ''(i) section 3111(b), and
4 ''(ii) sections 3211(a) and 3221(a)
5 (determined at a rate equal to the rate
6 under section 3111(b)).
7 ''(B) SPECIAL RULE.—A rule similar to
8 the rule of section 24(d)(2)(C) shall apply for
9 purposes of subparagraph (A).
10 ''(g) TERMINATION.—This section shall not apply to
11 any amount paid or incurred after December 31, 2016.''.
12 (b) TREATMENT AS GENERAL BUSINESS CREDIT.—
13 Subsection (b) of section 38 of the Internal Revenue Code
14 of 1986 (relating to general business credit) is amended
15 by striking ''and'' at the end of paragraph (29), by strik-
16 ing the period at the end of paragraph (30) and inserting
17 '', and'', and by adding at the end the following:
18 ''(31) the wellness program credit determined
19 under section 45N.''.
20 (c) DENIAL OF DOUBLE BENEFIT.—Section 280C of
21 the Internal Revenue Code of 1986 (relating to certain
22 expenses for which credits are allowable) is amended by
23 adding at the end the following new subsection:
24 ''(e) WELLNESS PROGRAM CREDIT.—

"(1) IN GENERAL.—No deduction shall be allowed for that portion of the costs paid or incurred for a qualified wellness program (within the meaning of section 45N) or a qualified small business wellness program (within the meaning of such section) allowable as a deduction for the taxable year which is equal to the amount of the credit allowable for the taxable year under section 45N.

"(2) SIMILAR RULE WHERE TAXPAYER CAPITALIZES RATHER THAN DEDUCTS EXPENSES.—If—

"(A) the amount of the credit determined for the taxable year under section 45N, exceeds

"(B) the amount allowable as a deduction for such taxable year for a qualified wellness program or a qualified small business wellness program, the amount chargeable to capital account for the taxable year for such expenses shall be reduced by the amount of such excess.

"(3) CONTROLLED GROUPS.—In the case of a corporation which is a member of a controlled group of corporations (within the meaning of section 41(f)(5)) or a trade or business which is treated as being under common control with other trades or business (within the meaning of section 41(f)(1)(B)), this subsection shall be applied under

rules prescribed by the Secretary similar to the rules applicable under subparagraphs (A) and (B) of section 41(f)(1).''.

(d) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

''Sec. 45N. Wellness program credit.''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2006.

(f) OUTREACH.—

(1) IN GENERAL.—The Secretary of the Treasury, in conjunction with the Director of the Centers for Disease Control and members of the business community, shall institute an outreach program to inform businesses about the availability of the wellness program credit under section 45N of the Internal Revenue Code of 1986.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out the outreach program described in paragraph (1).

(g) RESTORATION OF HIGHEST INCOME TAX RATE TO PRE-2001 LEVEL.—Section 1(i)(2) of the Internal Revenue Code of 1986 (relating to reductions in rates

after June 30, 2001) is amended by adding at the end the following new flush sentence:

"In the case of taxable years beginning after 2006, the last item in the fourth column in the preceding table shall be applied by substituting '39.6%' for '35.0%' ".

(h) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2006.

SEC. 203. INCOME EXCLUSION FOR EMPLOYER-PROVIDED OFF-PREMISES HEALTH CLUB SERVICES.

(a) TREATMENT AS FRINGE BENEFIT.—Subparagraph (A) of section 132(j)(4) of the Internal Revenue Code of 1986 (relating to on-premises gyms and other athletic facilities) is amended to read as follows:

"(A) IN GENERAL.—Gross income shall not include—

"(i) the value of any on-premises athletic facility provided by an employer to its employees, and

"(ii) fees or membership expenses paid by an employer to an athletic or fitness facility described in subparagraph (C) on behalf of its employees, but only to the

extent that such fees or expenses do not exceed $900.

The preceding sentence shall apply with respect to any highly compensated employee only if access to the facility is available on substantially the same terms to each member of a group of employees which is defined under a reasonable classification set up by the employer which does not discriminate in favor of highly compensated employees.''.

(b) ATHLETIC FACILITIES DESCRIBED.—Paragraph (4) of section 132(j) of such Code is amended by adding at the end the following new subparagraph:

''(C) CERTAIN ATHLETIC OR FITNESS FACILITIES DESCRIBED.—For purposes of subparagraph (A)(ii), an athletic or fitness facility described in this subparagraph is a facility—

''(i) providing instruction in a program of physical exercise or offering facilities for the preservation, maintenance, encouragement, or development of physical fitness,

''(ii) which is not a private club owned and operated by its members,

"(iii) which does not offer golf, hunting, sailing, or riding facilities,

"(iv) whose health or fitness facility is not incidental to its overall function and purpose, and

"(v) which is fully compliant with the State of jurisdiction and Federal anti-discriminations laws.".

(c) EMPLOYER DEDUCTION FOR DUES TO CERTAIN ATHLETIC FACILITIES.—

(1) IN GENERAL.—Paragraph (3) of section 274(a) of such Code (relating to denial of deduction for club dues) is amended—

(A) by striking "Notwithstanding" and inserting the following:

"(A) IN GENERAL.—Notwithstanding", and

(B) by adding at the end the following new subparagraph:

"(B) EXCEPTION FOR ATHLETIC FACILITIES.—This paragraph shall not apply to fees or dues paid to athletic or fitness facilities (within the meaning of section 132(j)(4)(C)) to the extent that such fees or dues do not exceed $900 for any membership.".

(2) CONFORMING AMENDMENT.—Section 274(e)(4) of such Code is amended by striking ''subsection (a)(3)'' and by inserting ''subsection (a)(3)(A)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after the date of the enactment of this Act.

SEC. 204. CDC AND EMPLOYER-BASED WELLNESS PROGRAMS.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

''PART R—CDC AND EMPLOYER-BASED WELLNESS PROGRAMS

''SEC. 399Z–1. EMPLOYER-BASED WELLNESS BEST PRACTICES.

''(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall conduct a study that analyzes employer-based wellness programs and determines—

''(1) best practices of such programs that impact and sustain behavior change in employees;

''(2) the impact that such programs have on reducing health risk prevalence and improving absenteeism of employees; and

"(3) the return to employers on the investment made by such employers in such programs.

"(b) REPORT.—After completing the study under subsection (a), the Director of the Centers for Disease Control and Prevention shall submit to Congress not later than 1 year after the date of enactment of this part—

"(1) a report that includes recommendations of effective employer-based wellness programs; and

"(2) an Employer Wellness Model that is supported by the Centers for Disease Control and Prevention.

"SEC. 399Z–2. WORKPLACE WELLNESS EDUCATION CAMPAIGN FOR EMPLOYERS.

"The Director of the Centers for Disease Control and Prevention, in coordination with relevant worksite health promotion organizations, shall conduct an educational campaign to make employers, employer groups, and other interested parties aware of the benefits of employer-based wellness programs. Such campaign shall include information about the Employer Wellness Model described in section 399Z–1(b)(2) and information on developing, implementing, and maintaining a program based on such model.

"SEC. 399Z–3. EVALUATION OF EMPLOYER-BASED WELLNESS PROGRAMS.

''The Director of the Centers for Disease Control and Prevention shall enter into contracts with entities to—

''(1) provide employers with technical assistance in evaluating such employers' employer-based wellness programs; and

''(2) train employers on how to evaluate such employers' employer-based wellness programs.

"SEC. 399Z–4. REQUIREMENTS BASED ON APPROPRIATED FUNDS.

''The Director of the Centers for Disease Control and Prevention shall be required to carry out the activities in sections 399Z–1, 399Z–2, and 399Z–3 only if funds are appropriated to carry out such sections.''.

Subtitle B—Healthy Communities

SEC. 211. HEALTHY COMMUNITY GRANTS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399P. HEALTHY COMMUNITY GRANTS.

''(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with the Directors of other appropriate Federal agencies, shall award competitive grants to eligible entities for the purpose of planning

1 and implementing programs that seek to promote indi-
2 vidual and community health and to prevent the incidence
3 of chronic disease.

4 "(b) ELIGIBILITY.—

5 "(1) IN GENERAL.—To be eligible to receive a
6 grant under this section an entity shall—

7 "(A) be—

8 "(i) a city, county, or Indian tribe;

9 "(ii) a local or tribal educational
10 agency;

11 "(iii) an accredited university, college,
12 or community college;

13 "(iv) a federally qualified health cen-
14 ter;

15 "(v) a local health department;

16 "(vi) a health care provider;

17 "(vii) a community-based organiza-
18 tion; or

19 "(viii) any other entity determined ap-
20 propriate by the Secretary, including a
21 consortia or partnership of entities de-
22 scribed in any of clauses (i) through (vii);

23 "(B) prepare and submit an application in
24 accordance with paragraph (2); and

"(C) provide assurances that the entity will contribute the non-Federal share as required under paragraph (3) to the cost of the activities carried out under the grant.

"(2) APPLICATION.—

"(A) IN GENERAL.—An entity desiring a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan that meets the requirements of subparagraph (B).

"(B) PLAN.—A plan meets the requirements of this subparagraph if such plan, at a minimum, includes information regarding—

"(i)(I) programs or community-based activities that the applicant proposes to carry out with funds received under this section and which seek to prevent and reduce the incidence of—

"(aa) overweight and obesity, or chronic diseases associated with overweight and obesity;

"(bb) tobacco use; or

"(cc) mental illness; or

"(II) other such activities, as determined appropriate by the Secretary, that are consistent with the goals of promoting individual and community health and preventing chronic disease; and

"(ii) the manner in which the applicant will evaluate the effectiveness of the program or activities carried out under this section.

"(3) NON-FEDERAL SHARE.—To be eligible to receive a grant under this section, an entity shall provide a non-Federal contribution, in cash or in kind, to the costs of activities under the grant in an amount that is equal to not less than 25 percent of the costs of such activities.

"(c) USE OF FUNDS.—An entity that receives a grant under this section shall use the amount made available under the grant to carry out community-based activities, including—

"(1) activities that seek to promote individual health and community wellness and to prevent and reduce the incidence of health problems and chronic diseases associated with—

"(A) being overweight or obese;

"(B) tobacco use; or

1 "(C) mental illness; or

2 "(2) other activities undertaken with the goals
3 of health promotion and chronic disease prevention,
4 as determined appropriate by the Secretary.

5 "(d) PRIORITY.—In awarding grants under sub-
6 section (a), the Secretary shall give priority to—

7 "(1) entities that demonstrate that they have
8 previously applied successfully for funds to carry out
9 activities that seek to promote individual and com-
10 munity health and to prevent the incidence of chron-
11 ic disease and that can cite published and peer-re-
12 viewed research demonstrating that the activities
13 that the entity proposes to carry out under this sub-
14 section are effective;

15 "(2) entities that will carry out programs or ac-
16 tivities that seek to accomplish a goal or goals set
17 by the State in the Healthy People 2010 plan of the
18 State;

19 "(3) entities that provide non-Federal contribu-
20 tions, either in cash or in kind, to the costs of fund-
21 ing activities under the grant;

22 "(4) entities that develop comprehensive plans
23 that include a strategy for extending program activi-
24 ties developed under this section in the years fol-

lowing the fiscal years for which they receive grants under this section;

"(5) entities located in communities that are medically underserved, as determined by the Secretary;

"(6) entities located in areas where the average poverty rate is 150 or higher than the average poverty rate in the State involved, as determined by the Secretary; and

"(7) entities that submit plans that exhibit multisectoral, cooperative conduct that includes the involvement of a broad range of stakeholders, including—

"(A) community-based organizations;

"(B) local governments;

"(C) local educational agencies;

"(D) the private sector;

"(E) State or local departments of health;

"(F) accredited colleges, universities, and community colleges;

"(G) health care providers;

"(H) State and local departments of transportation and city planning; and

"(I) other entities determined appropriate by the Secretary.

"(e) TECHNICAL ASSISTANCE.—From amounts appropriated to carry out this section, the Secretary may reserve not more than 10 percent for each fiscal year to provide entities receiving grants under this section with technical assistance in the implementation of the plans required under subsection (b)(2)(B).

"(f) EVALUATION.—From amounts appropriated to carry out this section, the Secretary may reserve not to exceed 5 percent for each fiscal year for the purpose of carrying out evaluations of the activities carried out under this section. Not later than 90 days after the completion of any such evaluation, the results of such evaluation shall be submitted to the relevant authorizing committees of Congress and to the Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives.

"(g) LIMITATION ON ADMINISTRATIVE COSTS.—An entity may not use more than 10 percent of amounts received under a grant under this section for administrative expenses.

"(h) SUPPLEMENT NOT SUPPLANT.—Amounts provided under a grant under this section shall be used to supplement, and not supplant, other amounts provided for activities of the type to be carried out under this section.

"(i) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.".

SEC. 212. PREVENTIVE MEDICINE AND PUBLIC HEALTH TRAINING GRANT PROGRAM.

Part C of title VII of the Public Health Service Act is amended by inserting after section 747 (42 U.S.C. 293k) the following:

"SEC. 747A. PREVENTIVE MEDICINE AND PUBLIC HEALTH TRAINING GRANT PROGRAM.

"(a) GRANTS.—The Secretary may award grants to, or enter into contracts with, eligible entities to provide training to graduate medical residents in preventive medicine and public health.

"(b) ELIGIBILITY.—To be eligible to receive a grant or contract under subsection (a), an entity shall—

"(1) be a school of public health, public health department, school of medicine or osteopathic medicine, public or private hospital, or public or private non-profit entity; and

"(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(c) PREFERENCE AND SPECIAL CONSIDERATION.—

1 "(1) PREFERENCE.—In awarding grants or
2 contracts under this section, the Secretary shall give
3 preference to one or more eligible entities that have
4 a record of training providers who practice preven-
5 tive medicine or public health as compared to other
6 eligible entities.

7 "(2) SPECIAL CONSIDERATION.—In awarding
8 grants or contracts under this section, the Secretary
9 shall give special consideration to eligible entities
10 that will carry out projects under the grant or con-
11 tract that train physicians in community-based ap-
12 proaches to combating the incidence rates of obesity,
13 diabetes, heart disease, cancer, and other chronic
14 diseases, and institutions that have a record of
15 training qualified individuals from disadvantaged
16 backgrounds.

17 "(d) USE OF FUNDS.—Amounts received under a
18 grant or contract under this section shall be used to—

19 "(1) plan, develop, and operate residency pro-
20 grams for preventive medicine or public health;

21 "(2) provide financial assistance, including tui-
22 tion and stipends, to resident physicians (MD or
23 DO) who plan to specialize in preventive medicine or
24 public health;

"(3) defray the costs associated with the planning, development, and operation of preventive medicine or public health programs, including the development of curriculum to be used in such program; and

"(4) provide for the improvement of academic administrative units.

"(e) DURATION OF AWARD.—A grant or contract under this section shall be for a term not to exceed 5 years.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $43,000,000 for fiscal year 2007, and such sums as may be necessary for each succeeding fiscal year.".

Subtitle C—Family Smoking Prevention and Control

SEC. 221. SHORT TITLE.

This subtitle may be cited as the "Family Smoking Prevention and Tobacco Control Act".

SEC. 222. FINDINGS.

The Congress finds the following:

(1) The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.

(2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

(3) Nicotine is an addictive drug.

(4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.

(5) Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.

(6) Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.

(7) Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.

(8) Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight.

(9) Under article I, section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.

(10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.

(11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products.

(12) It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.

(13) Tobacco use is the foremost preventable cause of premature death in America. It causes over

400,000 deaths in the United States each year and approximately 8,600,000 Americans have chronic illnesses related to smoking.

(14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco induced disease. Such a reduction in youth smoking would also result in approximately $75,000,000,000 in savings attributable to reduced health care costs.

(15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.

(16) In 2002, the tobacco industry spent more than $12,466,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

(17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.

(18) 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.

(19) 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.

(20) 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.

(21) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.

(22) Tobacco advertising expands the size of the tobacco market by increasing consumption of to-

bacco products including tobacco use by young people.

(23) Children are more influenced by tobacco advertising than adults, they smoke the most advertised brands.

(24) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. Children, who tend to be more price-sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices.

(25) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.

(26) 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.

(27) 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.

(28) Text only requirements, although not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising.

(29) It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry.

(30) The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618) for inclusion as part 897 of title 21, Code of Federal Regulations, are consistent with the First Amendment to the United States Constitution and with the standards set forth in the amendments made by this subtitle for the regulation of tobacco products by the Food and Drug Administration and the restriction on the sale and distribution, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this Act.

(31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use ciga-

rettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion plays a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

(32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most like-

ly to be seen or heard by youth and most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.

(33) Tobacco dependence is a chronic disease, one that typically requires repeated interventions to achieve long-term or permanent abstinence.

(34) Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely.

(35) Tobacco products have been used to facilitate and finance criminal activities both domestically and internationally. Illicit trade of tobacco products has been linked to organized crime and terrorist groups.

(36) It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with tobacco products and that it be empowered to review any advertising and labeling for such products. It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole,

taking into account both users of tobacco products and persons who do not currently use tobacco products.

(37) Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.

(38) As the National Cancer Institute has found, many smokers mistakenly believe that ''low tar'' and ''light'' cigarettes cause fewer health problems than other cigarettes. As the National Cancer Institute has also found, mistaken beliefs about the

health consequences of smoking ''low tar'' and ''light'' cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death.

(39) Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from ''low tar'' and ''light'' cigarettes and such products may actually increase the risk of tobacco use.

(40) The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in insuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product.

(41) As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.

(42) Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if

accompanied by disclaimers would be detrimental to the public health.

(43) The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be approved in advance of marketing, and to require that the evidence relied on to support approval of these products is rigorous.

SEC. 223. PURPOSE.

The purposes of this Act are—

(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products;

(2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;

(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote cessation to reduce disease risk and the social costs associated with tobacco related diseases; and

(10) to strengthen legislation against illicit trade in tobacco products.

SEC. 224. SCOPE AND EFFECT.

(a) INTENDED EFFECT.—Nothing in this Act (or an amendment made by this Act) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

SEC. 225. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the

remainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

PART I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

SEC. 231. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITION OF TOBACCO PRODUCTS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(nn)(1) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

''(2) The term 'tobacco product' does not mean—

''(A) a product in the form of conventional food (including water and chewing gum), a product represented for use as or for use in a conventional food, or a product that is intended for ingestion in capsule, tablet, softgel, or liquid form; or

"(B) an article that is approved or is regulated as a drug by the Food and Drug Administration.

"(3) The products described in paragraph (2)(A) shall be subject to chapter IV or chapter V of this Act and the articles described in paragraph (2)(B) shall be subject to chapter V of this Act.

"(4) A tobacco product may not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetics, medical device, or a dietary supplement).".

(b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX as chapter X;

(2) by redesignating sections 901 through 907 as sections 1001 through 1007; and

(3) by inserting after section 803 the following:

"CHAPTER IX—TOBACCO PRODUCTS

"SEC. 900. DEFINITIONS.

"In this chapter:

"(1) ADDITIVE.—The term 'additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product

(including any substances intended for use as a flavoring, coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

"(2) BRAND.—The term 'brand' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, or packaging, logo, registered trademark or brand name, identifiable pattern of colors, or any combination of such attributes.

"(3) CIGARETTE.—The term 'cigarette' has the meaning given that term by section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)), but also includes tobacco, in any form, that is functional in the product, 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 or as roll-your-own tobacco.

"(4) CIGARETTE TOBACCO.—The term 'cigarette tobacco' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the require-

ments for cigarettes shall also apply to cigarette tobacco.

"(5) COMMERCE.—The term 'commerce' has the meaning given that term by section 3(2) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(2)).

"(6) COUNTERFEIT TOBACCO PRODUCT.—The term 'counterfeit tobacco product' means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).

"(7) DISTRIBUTOR.—The term 'distributor' as regards a tobacco product means any person who furthers the distribution of a tobacco product, 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. Common carriers are not considered distributors for purposes of this chapter.

"(8) ILLICIT TRADE.—The term 'illicit trade' means any practice or conduct prohibited by law which relates to production, shipment, receipt, pos-

1 session, distribution, sale, or purchase of tobacco
2 products including any practice or conduct intended
3 to facilitate such activity.

4 ''(9) INDIAN TRIBE.—The term 'Indian tribe'
5 has the meaning given such term in section 4(e) of
6 the Indian Self Determination and Education Assist-
7 ance Act (25 U.S.C. 450b(e)).

8 ''(10) LITTLE CIGAR.—The term 'little cigar'
9 has the meaning given that term by section 3(7) of
10 the Federal Cigarette Labeling and Advertising Act
11 (15 U.S.C. 1332(7)).

12 ''(11) NICOTINE.—The term 'nicotine' means
13 the chemical substance named 3-(1–Methyl-2-
14 pyrrolidinyl) pyridine or C[10]H[14]N[2], including
15 any salt or complex of nicotine.

16 ''(12) PACKAGE.—The term 'package' means a
17 pack, box, carton, or container of any kind or, if no
18 other container, any wrapping (including cello-
19 phane), in which a tobacco product is offered for
20 sale, sold, or otherwise distributed to consumers.

21 ''(13) RETAILER.—The term 'retailer' means
22 any person who sells tobacco products to individuals
23 for personal consumption, or who operates a facility
24 where self-service displays of tobacco products are
25 permitted.

"(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) SMOKE CONSTITUENT.—The term 'smoke constituent' means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

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

"(17) STATE.—The term 'State' means any State of the United States and, for purposes of this chapter, includes the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern

Mariana Islands, and any other trust territory or possession of the United States.

"(18) TOBACCO PRODUCT MANUFACTURER.—Term 'tobacco product manufacturer' means any person, including any repacker or relabeler, who—

"(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

"(B) imports a finished cigarette or smokeless tobacco product for sale or distribution in the United States.

"(19) UNITED STATES.—The term 'United States' means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

"SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

"(a) IN GENERAL.—Tobacco products shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V, unless—

"(1) such products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention

of disease (within the meaning of section 201(g)(1)(B) or section 201(h)(2)); or

"(2) a claim is made for such products under section 201(g)(1)(C) or 201(h)(3);

other than modified risk tobacco products approved in accordance with section 911.

"(b) APPLICABILITY.—This chapter shall apply to all tobacco products subject to the regulations referred to in section 232 of the Family Smoking Prevention and Tobacco Control Act, and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.

"(c) SCOPE.—

"(1) IN GENERAL.—Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect the Secretary's authority over, or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter.

"(2) LIMITATION OF AUTHORITY.—

"(A) IN GENERAL.—The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco

leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

"(B) EXCEPTION.—Notwithstanding any other provision of this subparagraph, if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer.

"(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

"SEC. 902. ADULTERATED TOBACCO PRODUCTS.

"A tobacco product shall be deemed to be adulterated if—

"(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise

contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

"(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

"(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

"(4) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;

"(5)(A) it is required by section 910(a) to have premarket approval and does not have an approved application in effect; or

"(B) it is in violation of the order approving such an application;

"(6) the methods used in, or the facilities or controls used for, its manufacture, packing or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable con-

dition prescribed by an order under section 906(e)(2); or

"(7) it is in violation of section 911.

"SEC. 903. MISBRANDED TOBACCO PRODUCTS.

"(a) IN GENERAL.—A tobacco product shall be deemed to be misbranded—

"(1) if its labeling is false or misleading in any particular;

"(2) if in package form unless it bears a label containing—

"(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;

"(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

"(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

"(D) the statement required under section 921(a), except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be estab-

lished, by regulations prescribed by the Secretary;

"(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

"(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

"(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

"(6) if it was manufactured, prepared, propagated, compounded, or processed in any State in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not in-

1 cluded in a list required by section 905(i), if a notice
2 or other information respecting it was not provided
3 as required by such section or section 905(j), or if
4 it does not bear such symbols from the uniform sys-
5 tem for identification of tobacco products prescribed
6 under section 905(e) as the Secretary by regulation
7 requires;

8 ''(7) if, in the case of any tobacco product dis-
9 tributed or offered for sale in any State—

10 ''(A) its advertising is false or misleading
11 in any particular; or

12 ''(B) it is sold or distributed in violation of
13 regulations prescribed under section 906(d);

14 ''(8) unless, in the case of any tobacco product
15 distributed or offered for sale in any State, the man-
16 ufacturer, packer, or distributor thereof includes in
17 all advertisements and other descriptive printed mat-
18 ter issued or caused to be issued by the manufac-
19 turer, packer, or distributor with respect to that to-
20 bacco product—

21 ''(A) a true statement of the tobacco prod-
22 uct's established name as described in para-
23 graph (4), printed prominently; and

24 ''(B) a brief statement of—

"(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

"(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

"(9) if it is a tobacco product subject to a tobacco product standard established under section 907, unless it bears such labeling as may be prescribed in such tobacco product standard; or

"(10) if there was a failure or refusal—

"(A) to comply with any requirement prescribed under section 904 or 908; or

"(B) to furnish any material or information required under section 909.

"(b) PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary may, by regulation, require prior approval

of statements made on the label of a tobacco product. No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 911. No advertisement of a tobacco product published after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall, with respect to the language of label statements as prescribed under section 4 of the Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 or the regulations issued under such sections, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55).

"SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

"(a) REQUIREMENT.—Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information:

"(1) A listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each to-

bacco product by brand and by quantity in each brand and subbrand.

"(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 4(a)(4) of the Federal Cigarette Labeling and Advertising Act.

"(3) A listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand. Effective beginning 2 years after the date of enactment of this chapter, the manufacturer, importer, or agent shall comply with regulations promulgated under section 916 in reporting information under this paragraph, where applicable.

"(4) All documents developed after the date of enactment of the Family Smoking Prevention and Tobacco Control Act that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (in-

1 cluding smoke constituents), ingredients, compo-
2 nents, and additives.
3 "(b) DATA SUBMISSION.—At the request of the Sec-
4 retary, each tobacco product manufacturer or importer of
5 tobacco products, or agents thereof, shall submit the fol-
6 lowing:
7 "(1) Any or all documents (including under-
8 lying scientific information) relating to research ac-
9 tivities, and research findings, conducted, supported,
10 or possessed by the manufacturer (or agents thereof)
11 on the health, toxicological, behavioral, or physio-
12 logic effects of tobacco products and their constitu-
13 ents (including smoke constituents), ingredients,
14 components, and additives.
15 "(2) Any or all documents (including under-
16 lying scientific information) relating to research ac-
17 tivities, and research findings, conducted, supported,
18 or possessed by the manufacturer (or agents thereof)
19 that relate to the issue of whether a reduction in
20 risk to health from tobacco products can occur upon
21 the employment of technology available or known to
22 the manufacturer.
23 "(3) Any or all documents (including under-
24 lying scientific or financial information) relating to
25 marketing research involving the use of tobacco

1 products or marketing practices and the effective-
2 ness of such practices used by tobacco manufactur-
3 ers and distributors.
4 An importer of a tobacco product not manufactured in the
5 United States shall supply the information required of a
6 tobacco product manufacturer under this subsection.
7 "(c) TIME FOR SUBMISSION.—
8 "(1) IN GENERAL.—At least 90 days prior to
9 the delivery for introduction into interstate com-
10 merce of a tobacco product not on the market on the
11 date of enactment of the Family Smoking Preven-
12 tion and Tobacco Control Act, the manufacturer of
13 such product shall provide the information required
14 under subsection (a).
15 "(2) DISCLOSURE OF ADDITIVE.—If at any
16 time a tobacco product manufacturer adds to its to-
17 bacco products a new tobacco additive or increases
18 the quantity of an existing tobacco additive, the
19 manufacturer shall, except as provided in paragraph
20 (3), at least 90 days prior to such action so advise
21 the Secretary in writing.
22 "(3) DISCLOSURE OF OTHER ACTIONS.—If at
23 any time a tobacco product manufacturer eliminates
24 or decreases an existing additive, or adds or in-
25 creases an additive that has by regulation been des-

ignated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.

"(d) DATA LIST.—

"(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under subsection (e).

"(2) CONSUMER RESEARCH.—The Secretary shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

"(e) DATA COLLECTION.—Not later than 12 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. The Secretary shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

"SEC. 905. ANNUAL REGISTRATION.

"(a) DEFINITIONS.—In this section:

"(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

"(2) NAME.—The term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each

1 corporate officer and director, and the State of in-
2 corporation.

3 "(b) REGISTRATION BY OWNERS AND OPERATORS.—
4 On or before December 31 of each year every person who
5 owns or operates any establishment in any State engaged
6 in the manufacture, preparation, compounding, or proc-
7 essing of a tobacco product or tobacco products shall reg-
8 ister with the Secretary the name, places of business, and
9 all such establishments of that person.

10 "(c) REGISTRATION OF NEW OWNERS AND OPERA-
11 TORS.—Every person upon first engaging in the manufac-
12 ture, preparation, compounding, or processing of a tobacco
13 product or tobacco products in any establishment owned
14 or operated in any State by that person shall immediately
15 register with the Secretary that person's name, place of
16 business, and such establishment.

17 "(d) REGISTRATION OF ADDED ESTABLISHMENTS.—
18 Every person required to register under subsection (b) or
19 (c) shall immediately register with the Secretary any addi-
20 tional establishment which that person owns or operates
21 in any State and in which that person begins the manufac-
22 ture, preparation, compounding, or processing of a tobacco
23 product or tobacco products.

24 "(e) UNIFORM PRODUCT IDENTIFICATION SYS-
25 TEM.—The Secretary may by regulation prescribe a uni-

1 form system for the identification of tobacco products and
2 may require that persons who are required to list such
3 tobacco products under subsection (i) shall list such to-
4 bacco products in accordance with such system.

5 "(f) PUBLIC ACCESS TO REGISTRATION INFORMA-
6 TION.—The Secretary shall make available for inspection,
7 to any person so requesting, any registration filed under
8 this section.

9 "(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-
10 LISHMENTS.—Every establishment in any State registered
11 with the Secretary under this section shall be subject to
12 inspection under section 704, and every such establish-
13 ment engaged in the manufacture, compounding, or proc-
14 essing of a tobacco product or tobacco products shall be
15 so inspected by 1 or more officers or employees duly des-
16 ignated by the Secretary at least once in the 2-year period
17 beginning with the date of registration of such establish-
18 ment under this section and at least once in every succes-
19 sive 2-year period thereafter.

20 "(h) FOREIGN ESTABLISHMENTS SHALL REG-
21 ISTER.—Any establishment within any foreign country en-
22 gaged in the manufacture, preparation, compounding, or
23 processing of a tobacco product or tobacco products, shall
24 register under this section under regulations promulgated
25 by the Secretary. Such regulations shall require such es-

1 tablishment to provide the information required by sub-
2 section (i) of this section and shall include provisions for
3 registration of any such establishment upon condition that
4 adequate and effective means are available, by arrange-
5 ment with the government of such foreign country or oth-
6 erwise, to enable the Secretary to determine from time to
7 time whether tobacco products manufactured, prepared,
8 compounded, or processed in such establishment, if im-
9 ported or offered for import into the United States, shall
10 be refused admission on any of the grounds set forth in
11 section 801(a).

12 ''(i) REGISTRATION INFORMATION.—

13 ''(1) PRODUCT LIST.—Every person who reg-
14 isters with the Secretary under subsection (b), (c),
15 (d), or (h) shall, at the time of registration under
16 any such subsection, file with the Secretary a list of
17 all tobacco products which are being manufactured,
18 prepared, compounded, or processed by that person
19 for commercial distribution and which has not been
20 included in any list of tobacco products filed by that
21 person with the Secretary under this paragraph or
22 paragraph (2) before such time of registration. Such
23 list shall be prepared in such form and manner as
24 the Secretary may prescribe and shall be accom-
25 panied by—

"(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

"(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

"(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

"(2) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the

Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

"(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

"(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

"(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manu-

1 facture, preparation, compounding, or proc-
2 essing for commercial distribution of the to-
3 bacco product with respect to which such notice
4 of discontinuance was reported, notice of such
5 resumption, the date of such resumption, the
6 identity of such tobacco product by established
7 name, and other information required by para-
8 graph (1), unless the registrant has previously
9 reported such resumption to the Secretary
10 under this subparagraph.

11 ''(D) Any material change in any informa-
12 tion previously submitted under this paragraph
13 or paragraph (1).

14 ''(j) REPORT PRECEDING INTRODUCTION OF CER-
15 TAIN SUBSTANTIALLY-EQUIVALENT PRODUCTS INTO
16 INTERSTATE COMMERCE.—

17 ''(1) IN GENERAL.—Each person who is re-
18 quired to register under this section and who pro-
19 poses to begin the introduction or delivery for intro-
20 duction into interstate commerce for commercial dis-
21 tribution of a tobacco product intended for human
22 use that was not commercially marketed (other than
23 for test marketing) in the United States as of June
24 1, 2003, shall, at least 90 days prior to making such
25 introduction or delivery, report to the Secretary (in

such form and manner as the Secretary shall prescribe)—

"(A) the basis for such person's determination that the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of June 1, 2003, that is in compliance with the requirements of this Act; and

"(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

"(2) APPLICATION TO CERTAIN POST JUNE 1, 2003 PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after June 1, 2003, and prior to the date that is 15 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall be submitted to the Secretary not later than 15 months after such date of enactment.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—The Secretary may by regulation, exempt from the requirements of

this subsection tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

"(i) such modification would be a minor modification of a tobacco product authorized for sale under this Act;

"(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

"(iii) an exemption is otherwise appropriate.

"(B) REGULATIONS.—Not later than 9 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations to implement this paragraph.

"SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

"(a) IN GENERAL.—Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until

the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, section 911, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, section 911, or subsection (d) of this section shall not apply to such tobacco product.

"(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking under section 907, 908, 909, 910, or 911 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

"(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

"(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by

1 the Secretary by a notice published in the Federal
2 Register stating good cause therefore.
3 "(c) LIMITED CONFIDENTIALITY OF INFORMA-
4 TION.—Any information reported to or otherwise obtained
5 by the Secretary or the Secretary's representative under
6 section 903, 904, 907, 908, 909, 910, 911, or 704, or
7 under subsection (e) or (f) of this section, which is exempt
8 from disclosure under subsection (a) of section 552 of title
9 5, United States Code, by reason of subsection (b)(4) of
10 that section shall be considered confidential and shall not
11 be disclosed, except that the information may be disclosed
12 to other officers or employees concerned with carrying out
13 this chapter, or when relevant in any proceeding under
14 this chapter.
15 "(d) RESTRICTIONS.—
16 "(1) IN GENERAL.—The Secretary may by reg-
17 ulation require restrictions on the sale and distribu-
18 tion of a tobacco product, including restrictions on
19 the access to, and the advertising and promotion of,
20 the tobacco product, if the Secretary determines that
21 such regulation would be appropriate for the protec-
22 tion of the public health. The Secretary may by reg-
23 ulation impose restrictions on the advertising and
24 promotion of a tobacco product consistent with and
25 to full extent permitted by the first amendment to

the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

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

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

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

"(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

"(3) LIMITATIONS.—

"(A) IN GENERAL.—No restrictions under paragraph (1) may—

"(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

"(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

"(B) MATCHBOOKS.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products shall be considered as adult written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult written publications.

"(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

"(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

"(A) IN GENERAL.—The Secretary may, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a tobacco product), packing and storage of a tobacco product, conform to current good manufacturing practice, as prescribed in such regulations, to assure that the public health is protected and that the tobacco product is in compliance with this chapter. Good manufacturing practices may include the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

"(B) REQUIREMENTS.—The Secretary shall—

"(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

"(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

"(iii) provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and

"(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices.

"(2) EXEMPTIONS; VARIANCES.—

"(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted

to the Secretary in such form and manner as the Secretary shall prescribe and shall—

"(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter;

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

"(iii) contain such other information as the Secretary shall prescribe.

"(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Secretary may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall

report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

"(i) the date the petition was submitted to the Secretary under subparagraph (A); or

"(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee, whichever occurs later, the Secretary shall by order either deny the petition or approve it.

"(C) APPROVAL.—The Secretary may approve—

"(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this chapter; and

"(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing,

and storage of the tobacco product in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this chapter.

"(D) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.

"(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

"(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the period ending 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

"(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and dem-

onstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes without regard to section 3324(a) and (b) of title 31, United States Code, and section 5 of title 41, United States Code.

"SEC. 907. TOBACCO PRODUCT STANDARDS.

"(a) IN GENERAL.—

"(1) SPECIAL RULE FOR CIGARETTES.—A cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this paragraph.

"(2) REVISION OF TOBACCO PRODUCT STANDARDS.—The Secretary may revise the tobacco prod-

uct standards in paragraph (1) in accordance with subsection (b).

"(3) TOBACCO PRODUCT STANDARDS.—The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health. This finding shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

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

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

"(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—A tobacco product standard established under this section for a tobacco product—

"(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

"(i) for the reduction of nicotine yields of the product;

"(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

"(iii) relating to any other requirement under (B);

"(B) shall, where appropriate for the protection of the public health, include—

"(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;

"(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

"(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

"(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions

of the standard for which the test or tests were required; and

"(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d); and

"(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product.

"(5) PERIODIC RE-EVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

"(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall endeavor to—

"(A) use personnel, facilities, and other technical support available in other Federal agencies;

"(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities; and

"(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

"(b) ESTABLISHMENT OF STANDARDS.—

"(1) NOTICE.—

"(A) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

"(B) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

"(i) set forth a finding with supporting justification that the tobacco prod-

uct standard is appropriate for the protection of the public health;

"(ii) set forth proposed findings with respect to the risk of illness or injury that the tobacco product standard is intended to reduce or eliminate; and

"(iii) invite interested persons to submit an existing tobacco product standard for the tobacco product, including a draft or proposed tobacco product standard, for consideration by the Secretary.

"(C) STANDARD.—Upon a determination by the Secretary that an additive, constituent (including smoke constituent), or other component of the product that is the subject of the proposed tobacco product standard is harmful, it shall be the burden of any party challenging the proposed standard to prove that the proposed standard will not reduce or eliminate the risk of illness or injury.

"(D) FINDING.—A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product

1 standard is no longer appropriate for the pro-
2 tection of the public health.
3 "(E) CONSIDERATION BY SECRETARY.—
4 The Secretary shall consider all information
5 submitted in connection with a proposed stand-
6 ard, including information concerning the coun-
7 tervailing effects of the tobacco product stand-
8 ard on the health of adolescent tobacco users,
9 adult tobacco users, or non-tobacco users, such
10 as the creation of a significant demand for con-
11 traband or other tobacco products that do not
12 meet the requirements of this chapter and the
13 significance of such demand, and shall issue the
14 standard if the Secretary determines that the
15 standard would be appropriate for the protec-
16 tion of the public health.
17 "(F) COMMENT.—The Secretary shall pro-
18 vide for a comment period of not less than 60
19 days.
20 "(2) PROMULGATION.—
21 "(A) IN GENERAL.—After the expiration of
22 the period for comment on a notice of proposed
23 rulemaking published under paragraph (1) re-
24 specting a tobacco product standard and after
25 consideration of such comments and any report

from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

"(i) promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in paragraph (1); or

"(ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

"(B) EFFECTIVE DATE.—A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.

"(3) POWER RESERVED TO CONGRESS.—Because of the importance of a decision of the Sec-

1 retary to issue a regulation establishing a tobacco
2 product standard—
3 "(A) banning all cigarettes, all smokeless
4 tobacco products, all little cigars, all cigars
5 other than little cigars, all pipe tobacco, or all
6 roll your own tobacco products; or
7 "(B) requiring the reduction of nicotine
8 yields of a tobacco product to zero,
9 Congress expressly reserves to itself such power.
10 "(4) AMENDMENT; REVOCATION.—
11 "(A) AUTHORITY.—The Secretary, upon
12 the Secretary's own initiative or upon petition
13 of an interested person may by a regulation,
14 promulgated in accordance with the require-
15 ments of paragraphs (1) and (2)(B), amend or
16 revoke a tobacco product standard.
17 "(B) EFFECTIVE DATE.—The Secretary
18 may declare a proposed amendment of a to-
19 bacco product standard to be effective on and
20 after its publication in the Federal Register and
21 until the effective date of any final action taken
22 on such amendment if the Secretary determines
23 that making it so effective is in the public inter-
24 est.

"(5) REFERENCE TO ADVISORY COMMITTEE.—The Secretary may—

"(A) on the Secretary's own initiative, refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard; or

"(B) upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation, refer such proposed regulation to the Tobacco Products Scientific Advisory Committee, for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation and after independent study of the data and information furnished to it by the Sec-

retary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

"SEC. 908. NOTIFICATION AND OTHER REMEDIES.

"(a) NOTIFICATION.—If the Secretary determines that—

"(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and

"(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk, the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to

1 eliminate such risk. The Secretary may order notifi-
2 cation by any appropriate means, including public
3 service announcements. Before issuing an order
4 under this subsection, the Secretary shall consult
5 with the persons who are to give notice under the
6 order.

7 "(b) NO EXEMPTION FROM OTHER LIABILITY.—
8 Compliance with an order issued under this section shall
9 not relieve any person from liability under Federal or
10 State law. In awarding damages for economic loss in an
11 action brought for the enforcement of any such liability,
12 the value to the plaintiff in such action of any remedy
13 provided under such order shall be taken into account.

14 "(c) RECALL AUTHORITY.—

15 "(1) IN GENERAL.—If the Secretary finds that
16 there is a reasonable probability that a tobacco prod-
17 uct contains a manufacturing or other defect not or-
18 dinarily contained in tobacco products on the market
19 that would cause serious, adverse health con-
20 sequences or death, the Secretary shall issue an
21 order requiring the appropriate person (including
22 the manufacturers, importers, distributors, or retail-
23 ers of the tobacco product) to immediately cease dis-
24 tribution of such tobacco product. The order shall
25 provide the person subject to the order with an op-

portunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

"(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

"(B) NOTICE.—An amended order under subparagraph (A)—

"(i) shall not include recall of a tobacco product from individuals; and

"(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Secretary may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

"(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a) of this section.

"SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

"(a) IN GENERAL.—Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence—

"(1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

"(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;

"(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

"(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request

and identify to the fullest extent practicable such report or information;

"(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

"(6) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (6) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

"(b) REPORTS OF REMOVALS AND CORRECTIONS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall by regulation require a tobacco product manufacturer or importer of a to-

bacco product to report promptly to the Secretary any corrective action taken or removal from the market of a tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—

"(A) to reduce a risk to health posed by the tobacco product; or

"(B) to remedy a violation of this chapter caused by the tobacco product which may present a risk to health.

A tobacco product manufacturer or importer of a tobacco product who undertakes a corrective action or removal from the market of a tobacco product which is not required to be reported under this subsection shall keep a record of such correction or removal.

"(2) EXCEPTION.—No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

"SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.

"(a) IN GENERAL.—

1 "(1) NEW TOBACCO PRODUCT DEFINED.—For
2 purposes of this section the term 'new tobacco prod-
3 uct' means—
4 "(A) any tobacco product (including those
5 products in test markets) that was not commer-
6 cially marketed in the United States as of June
7 1, 2003; or
8 "(B) any modification (including a change
9 in design, any component, any part, or any con-
10 stituent, including a smoke constituent, or in
11 the content, delivery or form of nicotine, or any
12 other additive or ingredient) of a tobacco prod-
13 uct where the modified product was commer-
14 cially marketed in the United States after June
15 1, 2003.
16 "(2) PREMARKET APPROVAL REQUIRED.—
17 "(A) NEW PRODUCTS.—Approval under
18 this section of an application for premarket ap-
19 proval for any new tobacco product is required
20 unless—
21 "(i) the manufacturer has submitted a
22 report under section 905(j); and
23 "(ii) the Secretary has issued an order
24 that the tobacco product—

1 "(I) is substantially equivalent to
2 a tobacco product commercially mar-
3 keted (other than for test marketing)
4 in the United States as of June 1,
5 2003; and
6 "(II)(aa) is in compliance with
7 the requirements of this Act; or
8 "(bb) is exempt from the require-
9 ments of section 905(j) pursuant to a
10 regulation issued under section
11 905(j)(3).
12 "(B) APPLICATION TO CERTAIN POST
13 JUNE 1, 2003 PRODUCTS.—Subparagraph (A)
14 shall not apply to a tobacco product—
15 "(i) that was first introduced or deliv-
16 ered for introduction into interstate com-
17 merce for commercial distribution in the
18 United States after June 1, 2003, and
19 prior to the date that is 15 months after
20 the date of enactment of the Family Smok-
21 ing Prevention and Tobacco Control Act;
22 and
23 "(ii) for which a report was submitted
24 under section 905(j) within such 15-month
25 period, until the Secretary issues an order

that the tobacco product is not substantially equivalent.

"(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

"(A) IN GENERAL.—In this section and section 905(j), the terms 'substantially equivalent' or 'substantial equivalence' mean, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

"(i) has the same characteristics as the predicate tobacco product; or

"(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

"(B) CHARACTERISTICS.—In subparagraph (A), the term 'characteristics' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

"(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

"(4) HEALTH INFORMATION.—

"(A) SUMMARY.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

"(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

"(b) APPLICATION.—

"(1) CONTENTS.—An application for premarket approval shall contain—

"(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

"(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

"(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

"(D) an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product stand-

ard or adequate information to justify any deviation from such standard;

"(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

"(F) specimens of the labeling proposed to be used for such tobacco product; and

"(G) such other information relevant to the subject matter of the application as the Secretary may require.

"(2) REFERENCE TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

"(A) may, on the Secretary's own initiative; or

"(B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

"(c) ACTION ON APPLICATION.—

"(1) DEADLINE.—

"(A) IN GENERAL.—As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

"(i) issue an order approving the application if the Secretary finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

"(ii) deny approval of the application if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

"(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order approving an application for a tobacco product may require as a condition to such approval that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution

of a tobacco product may be restricted under a regulation under section 906(d).

"(2) DENIAL OF APPROVAL.—The Secretary shall deny approval of an application for a tobacco product if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

"(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

"(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

"(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

"(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, compliance with which is a condition to approval of

the application, and there is a lack of adequate information to justify the deviation from such standard.

"(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

"(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether approval of a tobacco product is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

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

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

"(5) BASIS FOR ACTION.—

"(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

"(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

"(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

"(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from an advisory committee, and after due notice and opportunity for informal hearing to the holder of an approved application for a tobacco product, issue an order withdrawing approval of the application if the Secretary finds—

"(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

"(B) that the application contained or was accompanied by an untrue statement of a material fact;

"(C) that the applicant—

"(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;

"(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or

"(iii) has not complied with the requirements of section 905;

"(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the require-

ments of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

"(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

"(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907, compliance with which was a condition to approval of the application, and that there is a lack of adequate information to justify the deviation from such standard.

"(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) with-

drawing approval of the application may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with subsection (e).

"(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an approved application would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

"(e) SERVICE OF ORDER.—An order issued by the Secretary under this section shall be served—

"(1) in person by any officer or employee of the department designated by the Secretary; or

"(2) by mailing the order by registered mail or certified mail addressed to the applicant at the ap-

1 plicant's last known address in the records of the
2 Secretary.
3 "(f) RECORDS.—
4 "(1) ADDITIONAL INFORMATION.—In the case
5 of any tobacco product for which an approval of an
6 application filed under subsection (b) is in effect, the
7 applicant shall establish and maintain such records,
8 and make such reports to the Secretary, as the Sec-
9 retary may by regulation, or by order with respect
10 to such application, prescribe on the basis of a find-
11 ing that such records and reports are necessary in
12 order to enable the Secretary to determine, or facili-
13 tate a determination of, whether there is or may be
14 grounds for withdrawing or temporarily suspending
15 such approval.
16 "(2) ACCESS TO RECORDS.—Each person re-
17 quired under this section to maintain records, and
18 each person in charge or custody thereof, shall, upon
19 request of an officer or employee designated by the
20 Secretary, permit such officer or employee at all rea-
21 sonable times to have access to and copy and verify
22 such records.
23 "(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMP-
24 TION FOR INVESTIGATIONAL USE.—The Secretary may
25 exempt tobacco products intended for investigational use

from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.

"SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.

"(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless approval of an application filed pursuant to subsection (d) is effective with respect to such product.

"(b) DEFINITIONS.—In this section:

"(1) MODIFIED RISK TOBACCO PRODUCT.—The term 'modified risk tobacco product' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

"(2) SOLD OR DISTRIBUTED.—

"(A) IN GENERAL.—With respect to a tobacco product, the term 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' means a tobacco product—

"(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

1 "(I) the tobacco product presents
2 a lower risk of tobacco-related disease
3 or is less harmful than one or more
4 other commercially marketed tobacco
5 products;
6 "(II) the tobacco product or its
7 smoke contains a reduced level of a
8 substance or presents a reduced expo-
9 sure to a substance; or
10 "(III) the tobacco product or its
11 smoke does not contain or is free of a
12 substance;
13 "(ii) the label, labeling, or advertising
14 of which uses the descriptors 'light', 'mild',
15 or 'low' or similar descriptors; or
16 "(iii) the tobacco product manufac-
17 turer of which has taken any action di-
18 rected to consumers through the media or
19 otherwise, other than by means of the to-
20 bacco product's label, labeling or adver-
21 tising, after the date of enactment of the
22 Family Smoking Prevention and Tobacco
23 Control Act, respecting the product that
24 would be reasonably expected to result in
25 consumers believing that the tobacco prod-

uct or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

"(B) LIMITATION.—No tobacco product shall be considered to be 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products', except as described in subparagraph (A).

"(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section and is subject to the requirements of chapter V.

"(d) FILING.—Any person may file with the Secretary an application for a modified risk tobacco product. Such application shall include—

"(1) a description of the proposed product and any proposed advertising and labeling;

"(2) the conditions for using the product;

"(3) the formulation of the product;

"(4) sample product labels and labeling;

"(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

"(6) data and information on how consumers actually use the tobacco product; and

"(7) such other information as the Secretary may require.

"(e) PUBLIC AVAILABILITY.—The Secretary shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

"(f) ADVISORY COMMITTEE.—

"(1) IN GENERAL.—The Secretary shall refer to an advisory committee any application submitted under this subsection.

1 "(2) RECOMMENDATIONS.—Not later than 60
2 days after the date an application is referred to an
3 advisory committee under paragraph (1), the advi-
4 sory committee shall report its recommendations on
5 the application to the Secretary.
6 "(g) APPROVAL.—
7 "(1) MODIFIED RISK PRODUCTS.—Except as
8 provided in paragraph (2), the Secretary shall ap-
9 prove an application for a modified risk tobacco
10 product filed under this section only if the Secretary
11 determines that the applicant has demonstrated that
12 such product, as it is actually used by consumers,
13 will—
14 "(A) significantly reduce harm and the
15 risk of tobacco-related disease to individual to-
16 bacco users; and
17 "(B) benefit the health of the population
18 as a whole taking into account both users of to-
19 bacco products and persons who do not cur-
20 rently use tobacco products.
21 "(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—
22 "(A) IN GENERAL.—The Secretary may
23 approve an application for a tobacco product
24 that has not been approved as a modified risk
25 tobacco product pursuant to paragraph (1) if

the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

"(i) the approval of the application would be appropriate to promote the public health;

"(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b)(2) is limited to an explicit or implicit representation that such tobacco product or its smoke contains or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

"(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

"(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a

1 measurable and substantial reduction in
2 morbidity or mortality among individual
3 tobacco users is anticipated in subsequent
4 studies.

5 "(B) ADDITIONAL FINDINGS REQUIRED.—
6 In order to approve an application under sub-
7 paragraph (A) the Secretary must also find
8 that the applicant has demonstrated that—

9 "(i) the magnitude of the overall re-
10 ductions in exposure to the substance or
11 substances which are the subject of the ap-
12 plication is substantial, such substance or
13 substances are harmful, and the product as
14 actually used exposes consumers to the
15 specified reduced level of the substance or
16 substances;

17 "(ii) the product as actually used by
18 consumers will not expose them to higher
19 levels of other harmful substances com-
20 pared to the similar types of tobacco prod-
21 ucts then on the market unless such in-
22 creases are minimal and the anticipated
23 overall impact of use of the product re-
24 mains a substantial and measurable reduc-

1 tion in overall morbidity and mortality
2 among individual tobacco users;
3 "(iii) testing of actual consumer per-
4 ception shows that, as the applicant pro-
5 poses to label and market the product, con-
6 sumers will not be misled into believing
7 that the product—
8 "(I) is or has been demonstrated
9 to be less harmful; or
10 "(II) presents or has been dem-
11 onstrated to present less of a risk of
12 disease than 1 or more other commer-
13 cially marketed tobacco products; and
14 "(iv) approval of the application is ex-
15 pected to benefit the health of the popu-
16 lation as a whole taking into account both
17 users of tobacco products and persons who
18 do not currently use tobacco products.
19 "(C) CONDITIONS OF APPROVAL.—
20 "(i) IN GENERAL.—Applications ap-
21 proved under this paragraph shall be lim-
22 ited to a term of not more than 5 years,
23 but may be renewed upon a finding by the
24 Secretary that the requirements of this

1 paragraph continue to be satisfied based
2 on the filing of a new application.
3 "(ii) AGREEMENTS BY APPLICANT.—
4 Applications approved under this para-
5 graph shall be conditioned on the appli-
6 cant's agreement to conduct post-market
7 surveillance and studies and to submit to
8 the Secretary the results of such surveil-
9 lance and studies to determine the impact
10 of the application approval on consumer
11 perception, behavior, and health and to en-
12 able the Secretary to review the accuracy
13 of the determinations upon which the ap-
14 proval was based in accordance with a pro-
15 tocol approved by the Secretary.
16 "(iii) ANNUAL SUBMISSION.—The re-
17 sults of such post-market surveillance and
18 studies described in clause (ii) shall be
19 submitted annually.
20 "(3) BASIS.—The determinations under para-
21 graphs (1) and (2) shall be based on—
22 "(A) the scientific evidence submitted by
23 the applicant; and
24 "(B) scientific evidence and other informa-
25 tion that is available to the Secretary.

1 "(4) BENEFIT TO HEALTH OF INDIVIDUALS
2 AND OF POPULATION AS A WHOLE.—In making the
3 determinations under paragraphs (1) and (2), the
4 Secretary shall take into account—
5 "(A) the relative health risks to individuals
6 of the tobacco product that is the subject of the
7 application;
8 "(B) the increased or decreased likelihood
9 that existing users of tobacco products who
10 would otherwise stop using such products will
11 switch to the tobacco product that is the subject
12 of the application;
13 "(C) the increased or decreased likelihood
14 that persons who do not use tobacco products
15 will start using the tobacco product that is the
16 subject of the application;
17 "(D) the risks and benefits to persons
18 from the use of the tobacco product that is the
19 subject of the application as compared to the
20 use of products for smoking cessation approved
21 under chapter V to treat nicotine dependence;
22 and
23 "(E) comments, data, and information
24 submitted by interested persons.
25 "(h) ADDITIONAL CONDITIONS FOR APPROVAL.—

"(1) MODIFIED RISK PRODUCTS.—The Secretary shall require for the approval of an application under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

"(2) COMPARATIVE CLAIMS.—

"(A) IN GENERAL.—The Secretary may require for the approval of an application under this subsection that a claim comparing a tobacco product to 1 or more other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).

"(B) QUANTITATIVE COMPARISONS.—The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco

product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

"(3) LABEL DISCLOSURE.—

"(A) IN GENERAL.—The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.

"(B) CONDITIONS OF USE.—If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.

"(4) TIME.—The Secretary shall limit an approval under subsection (g)(1) for a specified period of time.

"(5) ADVERTISING.—The Secretary may require that an applicant, whose application has been approved under this subsection, comply with require-

1 ments relating to advertising and promotion of the
2 tobacco product.
3 "(i) POSTMARKET SURVEILLANCE AND STUDIES.—
4 "(1) IN GENERAL.—The Secretary shall require
5 that an applicant under subsection (g)(1) conduct
6 post market surveillance and studies for a tobacco
7 product for which an application has been approved
8 to determine the impact of the application approval
9 on consumer perception, behavior, and health, to en-
10 able the Secretary to review the accuracy of the de-
11 terminations upon which the approval was based,
12 and to provide information that the Secretary deter-
13 mines is otherwise necessary regarding the use or
14 health risks involving the tobacco product. The re-
15 sults of post-market surveillance and studies shall be
16 submitted to the Secretary on an annual basis.
17 "(2) SURVEILLANCE PROTOCOL.—Each appli-
18 cant required to conduct a surveillance of a tobacco
19 product under paragraph (1) shall, within 30 days
20 after receiving notice that the applicant is required
21 to conduct such surveillance, submit, for the ap-
22 proval of the Secretary, a protocol for the required
23 surveillance. The Secretary, within 60 days of the
24 receipt of such protocol, shall determine if the prin-
25 cipal investigator proposed to be used in the surveil-

lance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Secretary as necessary to protect the public health.

"(j) WITHDRAWAL OF APPROVAL.—The Secretary, after an opportunity for an informal hearing, shall withdraw the approval of an application under this section if the Secretary determines that—

"(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary can no longer make the determinations required under subsection (g);

"(2) the application failed to include material information or included any untrue statement of material fact;

"(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

"(A) a tobacco product standard is established pursuant to section 907;

"(B) an action is taken that affects the risks presented by other commercially marketed

tobacco products that were compared to the product that is the subject of the application; or

"(C) any postmarket surveillance or studies reveal that the approval of the application is no longer consistent with the protection of the public health;

"(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or (i); or

"(5) the applicant failed to meet a condition imposed under subsection (h).

"(k) CHAPTER IV OR V.—A product approved in accordance with this section shall not be subject to chapter IV or V.

"(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

"(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

"(A) establish minimum standards for scientific studies needed prior to approval to show

that a substantial reduction in morbidity or mortality among individual tobacco users is likely;

"(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

"(C) establish minimum standards for post market studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

"(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception; and

"(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product.

"(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and

medical experts, on the design and conduct of such studies and surveillance.

"(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

"(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 910 and for which the applicant seeks approval as a modified risk tobacco product under this section.

"(m) DISTRIBUTORS.—No distributor may take any action, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

1 **"SEC. 912. JUDICIAL REVIEW.**

2 "(a) RIGHT TO REVIEW.—

3 "(1) IN GENERAL.—Not later than 30 days
4 after—

5 "(A) the promulgation of a regulation
6 under section 907 establishing, amending, or
7 revoking a tobacco product standard; or

8 "(B) a denial of an application for ap-
9 proval under section 910(c), any person ad-
10 versely affected by such regulation or denial
11 may file a petition for judicial review of such
12 regulation or denial with the United States
13 Court of Appeals for the District of Columbia
14 or for the circuit in which such person resides
15 or has their principal place of business.

16 "(2) REQUIREMENTS.—

17 "(A) COPY OF PETITION.—A copy of the
18 petition filed under paragraph (1) shall be
19 transmitted by the clerk of the court involved to
20 the Secretary.

21 "(B) RECORD OF PROCEEDINGS.—On re-
22 ceipt of a petition under subparagraph (A), the
23 Secretary shall file in the court in which such
24 petition was filed—

1 "(i) the record of the proceedings on
2 which the regulation or order was based;
3 and
4 "(ii) a statement of the reasons for
5 the issuance of such a regulation or order.
6 "(C) DEFINITION OF RECORD.—In this
7 section, the term 'record' means—
8 "(i) all notices and other matter pub-
9 lished in the Federal Register with respect
10 to the regulation or order reviewed;
11 "(ii) all information submitted to the
12 Secretary with respect to such regulation
13 or order;
14 "(iii) proceedings of any panel or ad-
15 visory committee with respect to such reg-
16 ulation or order;
17 "(iv) any hearing held with respect to
18 such regulation or order; and
19 "(v) any other information identified
20 by the Secretary, in the administrative pro-
21 ceeding held with respect to such regula-
22 tion or order, as being relevant to such
23 regulation or order.
24 "(b) STANDARD OF REVIEW.—Upon the filing of the
25 petition under subsection (a) for judicial review of a regu-

lation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

"(c) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

"(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

"(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 906, 907, 908, 909, 910, or 916 shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

"SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.

"The Secretary shall issue regulations to require that retail establishments for which the predominant business

is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

"SEC. 914. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

"(a) JURISDICTION.—

"(1) IN GENERAL.—Except where expressly provided in this chapter, nothing in this chapter shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

"(2) ENFORCEMENT.—Any advertising that violates this chapter or a provision of the regulations referred to in section 232 of the Family Smoking Prevention and Tobacco Control Act, is an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45(a)) and shall be considered a violation of a rule promulgated under section 18 of that Act (15 U.S.C. 57a).

"(b) COORDINATION.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402)—

"(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of such Act as such enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

"(2) the Secretary shall consult with the Chairman of such Commission in revising the label statements and requirements under such sections.

"SEC. 915. CONGRESSIONAL REVIEW PROVISIONS.

"In accordance with section 801 of title 5, United States Code, Congress shall review, and may disapprove, any rule under this chapter that is subject to section 801. This section and section 801 do not apply to the regulations referred to in section 232 of the Family Smoking Prevention and Tobacco Control Act.

"SEC. 916. REGULATION REQUIREMENT.

"(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary, acting through the Commissioner of the Food and Drug Administration, shall promulgate regulations under this Act that meet the requirements of subsection (b).

1 "(b) CONTENTS OF RULES.—The regulations pro-
2 mulgated under subsection (a) shall require testing and
3 reporting of tobacco product constituents, ingredients, and
4 additives, including smoke constituents, by brand and sub-
5 brand that the Secretary determines should be tested to
6 protect the public health. The regulations may require
7 that tobacco product manufacturers, packagers, or import-
8 ers make disclosures relating to the results of the testing
9 of tar and nicotine through labels or advertising or other
10 appropriate means, and make disclosures regarding the re-
11 sults of the testing of other constituents, including smoke
12 constituents, ingredients, or additives, that the Secretary
13 determines should be disclosed to the public to protect the
14 public health and will not mislead consumers about the
15 risk of tobacco related disease.

16 "(c) AUTHORITY.—The Food and Drug Administra-
17 tion shall have the authority under this chapter to conduct
18 or to require the testing, reporting, or disclosure of to-
19 bacco product constituents, including smoke constituents.

20 **"SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHOR-**
21 **ITY.**

22 "(a) IN GENERAL.—

23 "(1) PRESERVATION.—Nothing in this chapter,
24 or rules promulgated under this chapter, shall be
25 construed to limit the authority of a Federal agency

(including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this chapter shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

"(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

"(A) IN GENERAL.—Except as provided in paragraph (1) and subparagraph (B), no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket approval,

adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

"(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 554(b)(4) of title 5, United States Code, shall be treated as trade secret and confidential information by the State.

"(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"SEC. 918. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish an

1 11-member advisory committee, to be known as the 'To-
2 bacco Products Scientific Advisory Committee'.
3 "(b) MEMBERSHIP.—
4 "(1) IN GENERAL.—
5 "(A) MEMBERS.—The Secretary shall ap-
6 point as members of the Tobacco Products Sci-
7 entific Advisory Committee individuals who are
8 technically qualified by training and experience
9 in the medicine, medical ethics, science, or tech-
10 nology involving the manufacture, evaluation, or
11 use of tobacco products, who are of appro-
12 priately diversified professional backgrounds.
13 The committee shall be composed of—
14 "(i) 7 individuals who are physicians,
15 dentists, scientists, or health care profes-
16 sionals practicing in the area of oncology,
17 pulmonology, cardiology, toxicology, phar-
18 macology, addiction, or any other relevant
19 specialty;
20 "(ii) 1 individual who is an officer or
21 employee of a State or local government or
22 of the Federal Government;
23 "(iii) 1 individual as a representative
24 of the general public;

1 "(iv) 1 individual as a representative
2 of the interests in the tobacco manufac-
3 turing industry; and
4 "(v) 1 individual as a representative
5 of the interests of the tobacco growers.
6 "(B) NONVOTING MEMBERS.—The mem-
7 bers of the committee appointed under clauses
8 (iv) and (v) of subparagraph (A) shall serve as
9 consultants to those described in clauses (i)
10 through (iii) of subparagraph (A) and shall be
11 nonvoting representatives.
12 "(2) LIMITATION.—The Secretary may not ap-
13 point to the Advisory Committee any individual who
14 is in the regular full-time employ of the Food and
15 Drug Administration or any agency responsible for
16 the enforcement of this Act. The Secretary may ap-
17 point Federal officials as ex officio members.
18 "(3) CHAIRPERSON.—The Secretary shall des-
19 ignate 1 of the members of the Advisory Committee
20 to serve as chairperson.
21 "(c) DUTIES.—The Tobacco Products Scientific Ad-
22 visory Committee shall provide advice, information, and
23 recommendations to the Secretary—
24 "(1) as provided in this chapter;

1 ''(2) on the effects of the alteration of the nico-
2 tine yields from tobacco products;
3 ''(3) on whether there is a threshold level below
4 which nicotine yields do not produce dependence on
5 the tobacco product involved; and
6 ''(4) on its review of other safety, dependence,
7 or health issues relating to tobacco products as re-
8 quested by the Secretary.
9 ''(d) COMPENSATION; SUPPORT; FACA.—
10 ''(1) COMPENSATION AND TRAVEL.—Members
11 of the Advisory Committee who are not officers or
12 employees of the United States, while attending con-
13 ferences or meetings of the committee or otherwise
14 engaged in its business, shall be entitled to receive
15 compensation at rates to be fixed by the Secretary,
16 which may not exceed the daily equivalent of the
17 rate in effect for level 4 of the Senior Executive
18 Schedule under section 5382 of title 5, United
19 States Code, for each day (including travel time)
20 they are so engaged; and while so serving away from
21 their homes or regular places of business each mem-
22 ber may be allowed travel expenses, including per
23 diem in lieu of subsistence, as authorized by section
24 5703 of title 5, United States Code, for persons in
25 the Government service employed intermittently.

1 "(2) ADMINISTRATIVE SUPPORT.—The Sec-
2 retary shall furnish the Advisory Committee clerical
3 and other assistance.
4 "(3) NONAPPLICATION OF FACA.—Section 14 of
5 the Federal Advisory Committee Act (5 U.S.C.
6 App.) does not apply to the Advisory Committee.
7 "(e) PROCEEDINGS OF ADVISORY PANELS AND COM-
8 MITTEES.—The Advisory Committee shall make and
9 maintain a transcript of any proceeding of the panel or
10 committee. Each such panel and committee shall delete
11 from any transcript made under this subsection informa-
12 tion which is exempt from disclosure under section 552(b)
13 of title 5, United States Code.

14 **"SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**
15 **PENDENCE.**

16 "The Secretary shall—
17 "(1) at the request of the applicant, consider
18 designating nicotine replacement products as fast
19 track research and approval products within the
20 meaning of section 506;
21 "(2) consider approving the extended use of nic-
22 otine replacement products (such as nicotine patch-
23 es, nicotine gum, and nicotine lozenges) for the
24 treatment of tobacco dependence; and

"(3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.

"SEC. 920. USER FEE.

"(a) ESTABLISHMENT OF QUARTERLY USER FEE.—The Secretary shall assess a quarterly user fee with respect to every quarter of each fiscal year commencing fiscal year 2007, calculated in accordance with this section, upon each manufacturer and importer of tobacco products subject to this chapter.

"(b) FUNDING OF FDA REGULATION OF TOBACCO PRODUCTS.—The Secretary shall make user fees collected pursuant to this section available to pay, in each fiscal year, for the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this chapter.

"(c) ASSESSMENT OF USER FEE.—

"(1) AMOUNT OF ASSESSMENT.—Except as provided in paragraph (4), the total user fees assessed each year pursuant to this section shall be sufficient, and shall not exceed what is necessary, to pay for the costs of the activities described in subsection (b) for each fiscal year.

"(2) ALLOCATION OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—

"(A) IN GENERAL.—Subject to paragraph (3), the total user fees assessed each fiscal year with respect to each class of importers and manufacturers shall be equal to an amount that is the applicable percentage of the total costs of activities of the Food and Drug Administration described in subsection (b).

"(B) APPLICABLE PERCENTAGE.—For purposes of subparagraph (A) the applicable percentage for a fiscal year shall be the following:

"(i) 92.07 percent shall be assessed on manufacturers and importers of cigarettes;

"(ii) 0.05 percent shall be assessed on manufacturers and importers of little cigars;

"(iii) 7.15 percent shall be assessed on manufacturers and importers of cigars other than little cigars;

"(iv) 0.43 percent shall be assessed on manufacturers and importers of snuff;

"(v) 0.10 percent shall be assessed on manufacturers and importers of chewing tobacco;

"(vi) 0.06 percent shall be assessed on manufacturers and importers of pipe tobacco; and

"(vii) 0.14 percent shall be assessed on manufacturers and importers of roll-your-own tobacco.

"(3) DISTRIBUTION OF FEE SHARES OF MANUFACTURERS AND IMPORTERS EXEMPT FROM USER FEE.—Where a class of tobacco products is not subject to a user fee under this section, the portion of the user fee assigned to such class under subsection (d)(2) shall be allocated by the Secretary on a pro rata basis among the classes of tobacco products that are subject to a user fee under this section. Such pro rata allocation for each class of tobacco products that are subject to a user fee under this section shall be the quotient of—

"(A) the sum of the percentages assigned to all classes of tobacco products subject to this section; divided by

"(B) the percentage assigned to such class under paragraph (2).

"(4) ANNUAL LIMIT ON ASSESSMENT.—The total assessment under this section—

"(A) for fiscal year 2007 shall be $85,000,000;

"(B) for fiscal year 2008 shall be $175,000,000;

"(C) for fiscal year 2009 shall be $300,000,000; and

"(D) for each subsequent fiscal year, shall not exceed the limit on the assessment imposed during the previous fiscal year, as adjusted by the Secretary (after notice, published in the Federal Register) to reflect the greater of—

"(i) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending on June 30 of the preceding fiscal year for which fees are being established; or

"(ii) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section

5304 of such title for Federal employees stationed in the District of Columbia.

"(5) TIMING OF USER FEE ASSESSMENT.—The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under subsection (f) during each quarter of each fiscal year. Such notifications shall occur not earlier than 3 months prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made not later than 60 days after each such notification.

"(d) DETERMINATION OF USER FEE BY COMPANY MARKET SHARE.—

"(1) IN GENERAL.—The user fee to be paid by each manufacturer or importer of a given class of tobacco products shall be determined in each quarter by multiplying—

"(A) such manufacturer's or importer's market share of such class of tobacco products; by

"(B) the portion of the user fee amount for the current quarter to be assessed on manu-

1 facturers and importers of such class of tobacco
2 products as determined under subsection (e).
3 "(2) NO FEE IN EXCESS OF MARKET SHARE.—
4 No manufacturer or importer of tobacco products
5 shall be required to pay a user fee in excess of the
6 market share of such manufacturer or importer.
7 "(e) DETERMINATION OF VOLUME OF DOMESTIC
8 SALES.—
9 "(1) IN GENERAL.—The calculation of gross
10 domestic volume of a class of tobacco product by a
11 manufacturer or importer, and by all manufacturers
12 and importers as a group, shall be made by the Sec-
13 retary using information provided by manufacturers
14 and importers pursuant to subsection (f), as well as
15 any other relevant information provided to or ob-
16 tained by the Secretary.
17 "(2) MEASUREMENT.—For purposes of the cal-
18 culations under this subsection and the information
19 provided under subsection (f) by the Secretary, gross
20 domestic volume shall be measured by—
21 "(A) in the case of cigarettes, the number
22 of cigarettes sold;
23 "(B) in the case of little cigars, the num-
24 ber of little cigars sold;

"(C) in the case of large cigars, the number of cigars weighing more than 3 pounds per thousand sold; and

"(D) in the case of other classes of tobacco products, in terms of number of pounds, or fraction thereof, of these products sold.

"(f) MEASUREMENT OF GROSS DOMESTIC VOLUME.—

"(1) IN GENERAL.—Each manufacturer and importer of tobacco products shall submit to the Secretary a certified copy of each of the returns or forms described by this paragraph that are required to be filed with a Government agency on the same date that those returns or forms are filed, or required to be filed, with such agency. The returns and forms described by this paragraph are those returns and forms related to the release of tobacco products into domestic commerce, as defined by section 5702(k) of the Internal Revenue Code of 1986, and the repayment of the taxes imposed under chapter 52 of such Code (ATF Form 500.24 and United States Customs Form 7501 under currently applicable regulations).

"(2) PENALTIES.—Any person that knowingly fails to provide information required under this sub-

1 section or that provides false information under this
2 subsection shall be subject to the penalties described
3 in section 1003 of title 18, United States Code. In
4 addition, such person may be subject to a civil pen-
5 alty in an amount not to exceed 2 percent of the
6 value of the kind of tobacco products manufactured
7 or imported by such person during the applicable
8 quarter, as determined by the Secretary.

9 ''(g) EFFECTIVE DATE.—The user fees prescribed by
10 this section shall be assessed in fiscal year 2007, based
11 on domestic sales of tobacco products during fiscal year
12 2006 and shall be assessed in each fiscal year thereafter.''.

13 **SEC. 232. INTERIM FINAL RULE.**

14 (a) CIGARETTES AND SMOKELESS TOBACCO.—

15 (1) IN GENERAL.—Not later than 30 days after
16 the date of enactment of this Act, the Secretary of
17 Health and Human Services shall publish in the
18 Federal Register an interim final rule regarding
19 cigarettes and smokeless tobacco, which is hereby
20 deemed to be in compliance with the Administrative
21 Procedures Act and other applicable law.

22 (2) CONTENTS OF RULE.—Except as provided
23 in this subsection, the interim final rule published
24 under paragraph (1), shall be identical in its provi-
25 sions to part 897 of the regulations promulgated by

1 the Secretary of Health and Human Services in the
2 August 28, 1996, issue of the Federal Register (61
3 Fed. Reg., 44615–44618). Such rule shall—
4 (A) provide for the designation of jurisdic-
5 tional authority that is in accordance with this
6 subsection;
7 (B) strike Subpart C—Labeling and sec-
8 tion 897.32(c); and
9 (C) become effective not later than 1 year
10 after the date of enactment of this Act.
11 (3) AMENDMENTS TO RULE.—Prior to making
12 amendments to the rule published under paragraph
13 (1), the Secretary shall promulgate a proposed rule
14 in accordance with the Administrative Procedures
15 Act.
16 (4) RULE OF CONSTRUCTION.—Except as pro-
17 vided in paragraph (3), nothing in this section shall
18 be construed to limit the authority of the Secretary
19 to amend, in accordance with the Administrative
20 Procedures Act, the regulation promulgated pursu-
21 ant to this section.
22 (b) LIMITATION ON ADVISORY OPINIONS.—As of the
23 date of enactment of this Act, the following documents
24 issued by the Food and Drug Administration shall not
25 constitute advisory opinions under section 10.85(d)(1) of

1 title 21, Code of Federal Regulations, except as they apply
2 to tobacco products, and shall not be cited by the Sec-
3 retary of Health and Human Services or the Food and
4 Drug Administration as binding precedent:

5 (1) The preamble to the proposed rule in the
6 document entitled ''Regulations Restricting the Sale
7 and Distribution of Cigarettes and Smokeless To-
8 bacco Products to Protect Children and Adoles-
9 cents'' (60 Fed. Reg. 41314–41372 (August 11,
10 1995)).

11 (2) The document entitled ''Nicotine in Ciga-
12 rettes and Smokeless Tobacco Products is a Drug
13 and These Products Are Nicotine Delivery Devices
14 Under the Federal Food, Drug, and Cosmetic Act''
15 (60 Fed. Reg. 41453–41787 (August 11, 1995)).

16 (3) The preamble to the final rule in the docu-
17 ment entitled ''Regulations Restricting the Sale and
18 Distribution of Cigarettes and Smokeless Tobacco to
19 Protect Children and Adolescents'' (61 Fed. Reg.
20 44396–44615 (August 28, 1996)).

21 (4) The document entitled ''Nicotine in Ciga-
22 rettes and Smokeless Tobacco is a Drug and These
23 Products are Nicotine Delivery Devices Under the
24 Federal Food, Drug, and Cosmetic Act; Jurisdic-

tional Determination'' (61 Fed. Reg. 44619–45318 (August 28, 1996)).

SEC. 233. CONFORMING AND OTHER AMENDMENTS TO GENERAL PROVISIONS.

(a) AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise expressly provided, whenever in this section an amendment is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (a), by inserting ''tobacco product,'' after ''device,'';

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (c), by inserting ''tobacco product,'' after ''device,'';

(4) in subsection (e), by striking ''515(f), or 519'' and inserting ''515(f), 519, or 909'';

(5) in subsection (g), by inserting ''tobacco product,'' after ''device,'';

(6) in subsection (h), by inserting ''tobacco product,'' after ''device,'';

(7) in subsection (j), by striking ''708, or 721'' and inserting ''708, 721, 904, 905, 906, 907, 908, 909, or section 921(b)'';

(8) in subsection (k), by inserting ''tobacco product,'' after ''device,'';

(9) by striking subsection (p) and inserting the following:

''(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(2).'';

(10) by striking subsection (q)(1) and inserting the following:

''(q)(1) The failure or refusal—

''(A) to comply with any requirement prescribed under section 518, 520(g), 903(b)(8), or 908, or condition prescribed under section 903(b)(6)(B)(ii)(II);

''(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or section 921; or

''(C) to comply with a requirement under section 522 or 913.'';

(11) in subsection (q)(2), by striking ''device,'' and inserting ''device or tobacco product,'';

(12) in subsection (r), by inserting ''or tobacco product'' after ''device'' each time that it appears; and

(13) by adding at the end the following:

''(aa) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

''(bb) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

''(cc)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

''(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

1 "(3) The doing of any act that causes a tobacco prod-
2 uct to be a counterfeit tobacco product, or the sale or dis-
3 pensing, or the holding for sale or dispensing, of a coun-
4 terfeit tobacco product.
5 "(dd) The charitable distribution of tobacco products.
6 "(ee) The failure of a manufacturer or distributor to
7 notify the Attorney General of their knowledge of tobacco
8 products used in illicit trade.".
9 (c) SECTION 303.—Section 303 (21 U.S.C. 333(f))
10 is amended in subsection (f)—
11 (1) by striking the subsection heading and in-
12 serting the following:
13 "(f) CIVIL PENALTIES; NO-TOBACCO-SALE OR-
14 DERS.—";
15 (2) in paragraph (1)(A), by inserting "or to-
16 bacco products" after "devices";
17 (3) in paragraph (2)(C), by striking "paragraph
18 (3)(A)" and inserting "paragraph (4)(A)";
19 (4) by redesignating paragraphs (3), (4), and
20 (5) as paragraphs (4), (5), and (6), and inserting
21 after paragraph (2) the following:
22 "(3) If the Secretary finds that a person has
23 committed repeated violations of restrictions promul-
24 gated under section 906(d) at a particular retail out-
25 let then the Secretary may impose a no-tobacco-sale

order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1).'';

(5) in paragraph (4) as so redesignated—

(A) in subparagraph (A)—

(i) by striking ''assessed'' the first time it appears and inserting ''assessed, or a no-tobacco-sale order may be imposed,''; and

(ii) by striking ''penalty'' and inserting ''penalty, or upon whom a no-tobacco-order is to be imposed,'';

(B) in subparagraph (B)—

(i) by inserting after ''penalty,'' the following: ''or the period to be covered by a no-tobacco-sale order,''; and

(ii) by adding at the end the following: ''A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.''; and

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

''(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.'';

(6) in paragraph (5) as so redesignated—

(A) by striking ''(3)(A)'' as redesignated, and inserting ''(4)(A)'';

(B) by inserting ''or the imposition of a no-tobacco-sale order'' after ''penalty'' the first 2 places it appears; and

(C) by striking ''issued.'' and inserting ''issued, or on which the no-tobacco-sale order was imposed, as the case may be.''; and

(7) in paragraph (6), as so redesignated, by striking ''paragraph (4)'' each place it appears and inserting ''paragraph (5)''.

(d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking ''and'' before ''(D)''; and

(B) by striking ''device.'' and inserting the following: '', (E) Any adulterated or misbranded tobacco product.'';

(2) in subsection (d)(1), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (g)(1), by inserting ''or tobacco product'' after ''device'' each place it appears; and

(4) in subsection (g)(2)(A), by inserting ''or tobacco product'' after ''device'' each place it appears.

(e) SECTION 702.—Section 702(a) (21 U.S.C. 372(a)) is amended—

(1) by inserting ''(1)'' after ''(a)''; and

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

''(2) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with paragraph (1) to carry out inspections of retailers within that State in connection with the enforcement of this Act.''.

(f) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by inserting ''tobacco product,'' after ''device,'' each place it appears; and

(2) by inserting ''tobacco products,'' after ''devices,'' each place it appears.

(g) SECTION 704.—Section 704 (21 U.S.C. 374) is amended—

(1) in subsection (a)(1)(A), by inserting ''tobacco products,'' after ''devices,'' each place it appears;

(2) in subsection (a)(1)(B), by inserting ''or tobacco product'' after ''restricted devices'' each place it appears; and

(3) in subsection (b), by inserting ''tobacco product,'' after ''device,''.

(h) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting ''tobacco products,'' after ''devices,''.

(i) SECTION 709.—Section 709 (21 U.S.C. 379) is amended by inserting ''or tobacco product'' after ''device''.

(j) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting ''tobacco products,'' after ''devices,'' the first time it appears;

(B) by inserting ''or section 905(j)'' after ''section 510''; and

(C) by striking ''drugs or devices'' each time it appears and inserting ''drugs, devices, or tobacco products'';

(2) in subsection (e)(1), by inserting ''tobacco product,'' after ''device,''; and

(3) by adding at the end the following:

''(p)(1) Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco

1 Control Act, and annually thereafter, the Secretary shall
2 submit to the Committee on Health, Education, Labor,
3 and Pensions of the Senate and the Committee on Energy
4 and Commerce of the House of Representatives, a report
5 regarding—

6 ''(A) the nature, extent, and destination of
7 United States tobacco product exports that do not
8 conform to tobacco product standards established
9 pursuant to this Act;

10 ''(B) the public health implications of such ex-
11 ports, including any evidence of a negative public
12 health impact; and

13 ''(C) recommendations or assessments of policy
14 alternatives available to Congress and the Executive
15 Branch to reduce any negative public health impact
16 caused by such exports.

17 ''(2) The Secretary is authorized to establish appro-
18 priate information disclosure requirements to carry out
19 this subsection.''.

20 (k) SECTION 1003.—Section 1003(d)(2)(C) (as re-
21 designated by section 231(a)) is amended—

22 (1) by striking ''and'' after ''cosmetics,''; and

23 (2) inserting a comma and ''and tobacco prod-
24 ucts'' after ''devices''.

25 (l) GUIDANCE AND EFFECTIVE DATES.—

1 (1) IN GENERAL.—The Secretary of Health and
2 Human Services shall issue guidance—
3 (A) defining the term ''repeated violation'',
4 as used in section 303(f) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 333(f)) as
6 amended by subsection (c), by identifying the
7 number of violations of particular requirements
8 over a specified period of time at a particular
9 retail outlet that constitute a repeated violation;
10 (B) providing for timely and effective no-
11 tice to the retailer of each alleged violation at
12 a particular retail outlet;
13 (C) providing for an expedited procedure
14 for the administrative appeal of an alleged vio-
15 lation;
16 (D) providing that a person may not be
17 charged with a violation at a particular retail
18 outlet unless the Secretary has provided notice
19 to the retailer of all previous violations at that
20 outlet;
21 (E) establishing a period of time during
22 which, if there are no violations by a particular
23 retail outlet, that outlet will not be considered
24 to have been the site of repeated violations
25 when the next violation occurs; and

(F) providing that good faith reliance on the presentation of a false government issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—

(i) adopting and enforcing a written policy against sales to minors;

(ii) informing its employees of all applicable laws;

(iii) establishing disciplinary sanctions for employee noncompliance; and

(iv) requiring its employees to verify age by way of photographic identification or electronic scanning device.

(2) GENERAL EFFECTIVE DATE.—The amendments made by subsection (c), other than the amendment made by paragraph (2) of such subsection, shall take effect upon the issuance of guidance described in paragraph (1).

(3) SPECIAL EFFECTIVE DATE.—The amendments made by paragraph (2) of subsection (c) shall take effect on the date of enactment of this Act.

PART II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CCONSTITUENT DISCLOSURE

SEC. 235. CIGARETTE LABEL AND ADVERTISING WARNINGS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"SEC. 4. LABELING.

''(a) LABEL REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, 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

1 "'WARNING: Tobacco smoke causes fatal lung
2 disease in non-smokers
3 "'WARNING: Quitting smoking now greatly
4 reduces serious risks to your health'.
5 "(2) PLACEMENT; TYPOGRAPHY; ETC.—
6 "(A) IN GENERAL.—Each label statement
7 required by paragraph (1) shall be located in
8 the upper portion of the front and rear panels
9 of the package, directly on the package under-
10 neath the cellophane or other clear wrapping.
11 Except as provided in subparagraph (B), each
12 label statement shall comprise at least the top
13 30 percent of the front and rear panels of the
14 package. The word 'WARNING' shall appear in
15 capital letters and all text shall be in con-
16 spicuous and legible 17-point type, unless the
17 text of the label statement would occupy more
18 than 70 percent of such area, in which case the
19 text may be in a smaller conspicuous and leg-
20 ible type size, provided that at least 60 percent
21 of such area is occupied by required text. The
22 text shall be black on a white background, or
23 white on a black background, in a manner that
24 contrasts, by typography, layout, or color, with
25 all other printed material on the package, in an

alternating fashion under the plan submitted under subsection (b)(4).

"(B) HINGED LID BOXES.—For any cigarette brand package manufactured or distributed before January 1, 2000, which employs a hinged lid style (if such packaging was used for that brand in commerce prior to June 21, 1997), the label statement required by paragraph (1) shall be located on the hinged lid area of the package, even if such area is less than 25 percent of the area of the front panel. Except as provided in this paragraph, the provisions of this subsection shall apply to such packages.

"(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

"(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that is supplied to the retailer by a tobacco product manufacturer, importer, or distributor and is not altered by the retailer in a way

that is material to the requirements of this subsection except that this paragraph shall not relieve a retailer of liability if the retailer sells or distributes tobacco products that are not labeled in accordance with this subsection.

"(b) ADVERTISING REQUIREMENTS.—

"(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a) of this section.

"(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) of this section in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such

area in such manner as the Secretary determines appropriate. The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under paragraph (4) of this subsection. 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 downstroke of the capital 'W' of the word 'WARNING' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that in the case of—

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

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

"(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

"(4) ADJUSTMENT BY SECRETARY.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section or the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures, or to establish the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et. seq.). The text

of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2) of this subsection. The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

''(c) MARKETING REQUIREMENTS.—

''(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(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 the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

"(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

"(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

"(B) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

"(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that is not labeled in accordance with the requirements of this subsection and subsection (b).".

SEC. 236. AUTHORITY TO REVISE CIGARETTE WARNING LABEL STATEMENTS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 235, is further amended by adding at the end the following:

"(d) CHANGE IN REQUIRED STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.".

SEC. 237. STATE REGULATION OF CIGARETTE ADVERTISING AND PROMOTION.

Section 5 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334) is amended by adding at the end the following:

"(c) EXCEPTION.—Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.".

SEC. 238. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

"SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

'' 'WARNING: This product can cause mouth cancer

'' 'WARNING: This product can cause gum disease and tooth loss

'' 'WARNING: This product is not a safe alternative to cigarettes

'' 'WARNING: Smokeless tobacco is addictive'.

''(2) Each label statement required by paragraph (1) shall be—

''(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

"(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

"(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

"(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

"(5) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that is supplied to the retailer by a tobacco products manufacturer, importer, or distributor and that is not altered by the retailer unless the retailer offers for sale, sells, or distributes a smokeless tobacco product that is not labeled in accordance with this subsection.

"(b) REQUIRED LABELS.—

"(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

"(2) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall—

"(A) comprise at least 20 percent of the area of the advertisement, and the warning area

shall be delineated by a dividing line of contrasting color from the advertisement; and

"(B) the word 'WARNING' shall appear in capital letters and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

"(3)(A) The label statements specified in subsection (a)(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 the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

"(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

"(C) The Secretary shall review each plan submitted under subparagraph (B) and approve it if the plan—

"(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

"(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

"(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays in a location open to the public, an advertisement that is not labeled in accordance with the requirements of this subsection.

"(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.".

SEC. 239. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT WARNING LABEL STATEMENTS.

Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as

1 amended by section 237, is further amended by adding
2 at the end the following:

3 "(d) AUTHORITY TO REVISE WARNING LABEL
4 STATEMENTS.—The Secretary may, by a rulemaking con-
5 ducted under section 553 of title 5, United States Code,
6 adjust the format, type size, and text of any of the label
7 requirements, require color graphics to accompany the
8 text, increase the required label area from 30 percent up
9 to 50 percent of the front and rear panels of the package,
10 or establish the format, type size, and text of any other
11 disclosures required under the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary
13 finds that such a change would promote greater public un-
14 derstanding of the risks associated with the use of smoke-
15 less tobacco products.".

16 **SEC. 240. TAR, NICOTINE, AND OTHER SMOKE CON-**
17 **STITUENT DISCLOSURE TO THE PUBLIC.**

18 Section 4(a) of the Federal Cigarette Labeling and
19 Advertising Act (15 U.S.C. 1333 (a)), as amended by sec-
20 tion 235, is further amended by adding at the end the
21 following:

22 "(4)(A) The Secretary shall, by a rulemaking
23 conducted under section 553 of title 5, United
24 States Code, determine (in the Secretary's sole dis-
25 cretion) whether cigarette and other tobacco product

manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

''(B) Any differences between the requirements established by the Secretary under subparagraph (A) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

''(C) In addition to the disclosures required by subparagraph (A) of this paragraph, the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure

would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

''(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements required under this section, except that this paragraph shall not relieve a retailer of liability if the retailer sells or distributes tobacco products that are not labeled in accordance with the requirements of this subsection.''.

PART III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 241. LABELING, RECORDKEEPING, RECORDS INSPECTION.

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as added by section 231, is further amended by adding at the end the following:

"SEC. 921. LABELING, RECORDKEEPING, RECORDS INSPECTION.

"(a) ORIGIN LABELING.—The label, packaging, and shipping containers of tobacco products for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'sale only allowed in the United States.'

"(b) REGULATIONS CONCERNING RECORDKEEPING FOR TRACKING AND TRACING.—

"(1) IN GENERAL.—Not later than 9 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.

"(2) INSPECTION.—In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling or counterfeiting of tobacco products.

"(3) CODES.—The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.

"(4) SIZE OF BUSINESS.—The Secretary shall take into account the size of a business in promulgating regulations under this section.

"(5) RECORDKEEPING BY RETAILERS.—The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.

"(c) RECORDS INSPECTION.—If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling or counterfeiting of tobacco products.

1 "(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

2 "(1) IN GENERAL.—If the manufacturer or dis-
3 tributor of a tobacco product has knowledge which
4 reasonably supports the conclusion that a tobacco
5 product manufactured or distributed by such manu-
6 facturer or distributor that has left the control of
7 such person may be or has been—

8 "(A) imported, exported, distributed or of-
9 fered for sale in interstate commerce by a per-
10 son without paying duties or taxes required by
11 law; or

12 "(B) imported, exported, distributed or di-
13 verted for possible illicit marketing, the manu-
14 facturer or distributor shall promptly notify the
15 Attorney General of such knowledge.

16 "(2) KNOWLEDGE DEFINED.—For purposes of
17 this subsection, the term 'knowledge' as applied to
18 a manufacturer or distributor means—

19 "(A) the actual knowledge that the manu-
20 facturer or distributor had; or

21 "(B) the knowledge which a reasonable
22 person would have had under like circumstances
23 or which would have been obtained upon the ex-
24 ercise of due care.".

SEC. 242. STUDY AND REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of cross-border trade in tobacco products to—

(1) collect data on cross-border trade in tobacco products, including illicit trade and trade of counterfeit tobacco products and make recommendations on the monitoring of such trade;

(2) collect data on cross-border advertising (any advertising intended to be broadcast, transmitted, or distributed from the United States to another country) of tobacco products and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, cross-border advertising.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study described in subsection (a).

TITLE III—RESPONSIBLE MARKETING AND CONSUMER AWARENESS

Subtitle A—General Provisions

SEC. 301. NUTRITION LABELING OF RESTAURANT FOODS.

Section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(A)(i)) is amended—

(1) in clause (A)—

(A) in subclause (i), by inserting ''except as provided in clauses (H) and (I),'' before ''which'' the first place it appears; and

(B) in subclause (ii), by inserting ''except as provided in clauses (H) and (I),'' before ''which'' the first place it appears; and

(2) by adding at the end the following:

''(H) RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—

''(i) IN GENERAL.—Except for food described in subclause (iii), in the case of food that is served, processed, or prepared in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same trade name (regardless of the type of ownership of the locations), the restaurant or establishment shall

disclose the information described in subclause (ii).

"(ii) INFORMATION REQUIRED TO BE DISCLOSED.—Except as provided in subclause (iii), the establishment shall disclose—

"(I)(aa) in a statement adjacent to the name of the food on any menu listing the food for sale, or by any other means deemed equivalent by the Secretary, the number of calories, grams of saturated fat plus trans fat, and milligrams of sodium contained in a standard serving of the food, as usually offered for sale, in a clear and conspicuous manner; and

"(bb) information, specified by the Secretary by regulation, designed to enable the public to understand, in the context of a total daily diet, the significance of the nutrition information that is provided; and

"(II) in a statement adjacent to the name of the food on any menu board or other sign listing the food for sale, or by any other means deemed equivalent by the Secretary—

"(aa) the number of calories contained in a serving of the food, as usually offered for sale, in a clear and conspicuous manner; and

"(bb) notification that the information required by subitems (aa) and (bb) of item (I) shall be provided in writing at the request of a prospective purchaser.

"(iii) NONAPPLICABILITY TO CERTAIN FOOD.—This clause does not apply to—

"(I) items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use); or

"(II) daily specials, temporary menu items, or other irregular menu items, as specified by the Secretary by regulation.

"(iv) SELF-SERVICE FACILITIES.—In the case of food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, a restaurant or other establishment shall place a sign that lists calories per standard serving adjacent to each food offered.

"(v) VOLUNTARY PROVISION OF NUTRITION INFORMATION; STATE REGULATION OF NUTRITION INFORMATION FOR RESTAURANT FOOD.—

"(I) RETAIL FOOD ESTABLISHMENTS.—Nothing in this clause precludes a restaurant or similar retail food establishment from providing additional nutrition information, voluntarily, if the information complies with the nutrition labeling requirements contained in this subparagraph.

"(II) STATE OR LOCAL REQUIREMENTS.—Nothing in this clause precludes a State or political subdivision of a State from requiring that a restaurant or similar food establishment provide nutrition information in addition to that required under this clause.

"(vi) REGULATIONS.—

"(I) PROPOSED REGULATION.—Not later than 1 year after the date of enactment of this clause, the Secretary shall promulgate proposed regulations to carry out this clause.

"(II) CONTENTS.—The regulations shall allow for the variations in serving sizes and in food preparation that can reasonably be expected to result from inadvertent human error, training of food service workers, and other factors.

"(III) FINAL REGULATIONS.—Not later than 2 years after the date of enactment of this clause, the Secretary shall promulgate final regulations to implement this clause.

"(IV) FAILURE TO PROMULGATE FINAL REGULATIONS BY REQUIRED DATE.—If the Secretary does not promulgate final regulations under item (III) by the date that is 2 years after the date of enactment of this clause—

"(aa) the proposed regulations issued in accordance with item (I) shall become effective as the final regulations on the day after that date; and

"(bb) the Secretary shall publish in the Federal Register notice of the final regulations.

"(I) VENDING MACHINES.—

"(i) IN GENERAL.—In the case of an article of food sold from a vending machine that—

"(I) does not permit a prospective purchaser to examine the article so as to be able to read a statement affixed to the article before purchasing the article; and

"(II) is operated by a person that is engaged in the business of owning and operating 20 or more vending machines;

the vending machine operator shall provide a conspicuous sign in close proximity to the article that includes a statement disclosing the number of calories contained in the article.

"(ii) VOLUNTARY PROVISION OF NUTRITION INFORMATION; STATE REGULATION OF NUTRITION INFORMATION FOR VENDING MACHINES.—

"(I) VENDING MACHINE OPERATORS.—Nothing in this clause precludes a vending machine operator from providing additional nutrition information, voluntarily, if the information complies with the nutrition labeling requirements contained in this subparagraph.

"(II) STATE OR LOCAL REQUIREMENTS.—Nothing in this title precludes a State or political subdivision of a State from requiring that a vending machine operator provide nutrition information in addition to that required under this clause.

"(iii) REGULATIONS.—

"(I) PROPOSED REGULATIONS.—Not later than 1 year after the date of enactment of this clause, the Secretary shall promulgate proposed regulations to carry out this clause.

"(II) FINAL REGULATIONS.—Not later than 2 years after the date of enactment of this clause, the Secretary shall promulgate final regulations to implement this clause.

"(III) FAILURE TO PROMULGATE FINAL REGULATIONS BY REQUIRED DATE.—If the Secretary does not promulgate final regulations under item (II) by the date that is 2 years after the date of enactment of this clause—

"(aa) the proposed regulations issued in accordance with item (I)

shall become effective as the final regulations on the day after that date; and

"(bb) the Secretary shall publish in the Federal Register notice of the final regulations.".

SEC. 302. RULEMAKING AUTHORITY FOR ADVERTISING TO CHILDREN.

(a) PURPOSE.—The purpose of this section is to restore the authority of the Federal Trade Commission to issue regulations that restrict the marketing or advertising of foods and beverages to children under the age of 18 years if the Federal Trade Commission determines that there is evidence that consumption of certain foods and beverages is detrimental to the health of children.

(b) AUTHORITY.—Section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) is amended by striking subsection (h).

SEC. 303. FOOD ADVERTISING IN SCHOOLS.

Section 10 of the Child Nutrition Act of 1966 (42 U.S.C. 1779), as amended by section 102 of this Act, is further amended by adding at the end the following:

"(c) FOOD ADVERTISING.—The Secretary may prohibit the advertising of food in participating schools if the Secretary determines that consumption of the advertised

food has a detrimental effect on the diets or health of children.''.

SEC. 304. DISALLOWANCE OF DEDUCTIONS FOR ADVERTISING AND MARKETING EXPENSES RELATING TO TOBACCO PRODUCT USE.

(a) IN GENERAL.—Part IX of subchapter B of chapter 1 of subtitle A of the Internal Revenue Code of 1986 (relating to items not deductible) is amended by adding at the end the following new section:

''SEC. 280I. DISALLOWANCE OF DEDUCTION FOR TOBACCO ADVERTISING AND MARKETING EXPENSES.

''No deduction shall be allowed under this chapter for expenses relating to advertising or marketing cigars, cigarettes, smokeless tobacco, pipe tobacco, or any similar tobacco product. For purposes of this section, any term used in this section which is also used in section 5702 shall have the same meaning given such term by section 5702.''.

(b) CONFORMING AMENDMENT.—The table of sections for such part IX is amended by adding after the item relating to section 280H the following new item:

''Sec. 280I. Disallowance of deduction for tobacco advertising and marketing expenses.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after the date of the enactment of this Act.

SEC. 305. FEDERAL-STATE TOBACCO COUNTER-ADVERTISING PROGRAMS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.), as amended in section 211, is further amended by adding at the end the following:

"SEC. 399Q. FEDERAL-STATE TOBACCO COUNTER-ADVERTISING PROGRAMS.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants to and enter into contracts with eligible entities for the implementation of national and local media (such as counter-advertising) and non-media campaigns designed to reduce the use of tobacco products.

"(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall be—

"(1) a public entity, including a State public health department; or

"(2) a private, nonprofit entity that—

"(A) is not affiliated with a manufacturer or importer of a tobacco product;

"(B) has demonstrated a record of conducting a national antitobacco public education campaign to effectively reduce the use of tobacco products;

1 "(C) has expertise in conducting a multi-
2 media communications campaign; and
3 "(D) has expertise in developing strategies
4 that affect behavior changes in children and
5 other targeted populations.
6 "(c) APPLICATION.—An eligible entity shall submit
7 an application to the Secretary for a grant under this sec-
8 tion at such time, in such manner, and accompanied by
9 such information as the Secretary may require.
10 "(d) USE OF FUNDS.—An eligible entity shall use
11 amounts received under a grant under this section to—
12 "(1) design and implement multimedia public
13 education and social marketing campaigns that—
14 "(A) discourage the use of tobacco prod-
15 ucts;
16 "(B) encourage the use of products de-
17 signed to enable tobacco use cessation; and
18 "(C) educate the public about the hazards
19 of environmental tobacco smoke exposure; or
20 "(2) conduct research related to the effective-
21 ness of the campaigns described in paragraph (1).
22 "(e) ALLOCATION OF GRANTS.—Of the amounts
23 awarded under this section, the Secretary shall award—
24 "(1) 50 percent of such amounts to eligible
25 public entities; and

"(2) 50 percent of such amounts to eligible private, nonprofit entities.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $200,000,000 to carry out this section.".

Subtitle B—Penalties for Failure to Reduce Teen Smoking

SEC. 311. CHILD CIGARETTE USE SURVEYS.

(a) ANNUAL PERFORMANCE SURVEY.—

(1) IN GENERAL.—Not later than August 31, 2007, and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall publish the results of an annual cigarette survey, to be carried out after the date of enactment of this Act and completed prior to August 21, 2007, and prior to August 21 of each year thereafter, to determine—

(A) the percentage of all young individuals who used a type of cigarette within the 30-day period prior to the conduct of the survey involved; and

(B) the percentage of young individuals who identify each brand of each type of cigarette as the usual brand smoked within such 30-day period.

(2) YOUNG INDIVIDUALS.—For the purposes of this subtitle, the term ''young individuals'' means individuals who are under 18 years of age.

(b) SIZE AND METHODOLOGY.—

(1) IN GENERAL.—The survey referred to in subsection (a) shall be comparable in size and methodology to the Monitoring the Future survey that was completed in 1999 to measure the use of cigarettes (by brand) by youths under 18 years of age within the 30-day period prior to the conduct of the study.

(2) CONCLUSIVE ACCURATENESS.—A survey using the methodology described in paragraph (1) shall be deemed conclusively proper, correct, and accurate for purposes of this section.

(3) DEFINITION.—In this subtitle, the term ''Monitoring the Future survey'' means the combined survey of 8th, 10th, and 12th grade students that was conducted at the Institute for Social Research at the University of Michigan.

(c) REDUCTION.—The Secretary, based on a comparison of the results of the first annual cigarette survey referred to in subsection (a) and the Monitoring the Future survey referred to in subsection (b)(1), shall deter-

1 mine the percentage reduction (if any) in youth cigarette
2 use for each manufacturer of cigarettes.

3 (d) PARTICIPATION IN SURVEY.—Notwithstanding
4 any other provision of law, the Secretary may conduct a
5 survey under this section involving minors if the results
6 of such survey with respect to such minors are kept con-
7 fidential and not disclosed.

8 (e) NONAPPLICABILITY.—Chapter 35 of title 44,
9 United States Code, shall not apply to information re-
10 quired for the purposes of carrying out this section.

11 (f) DEFINITION.—In this subtitle the term ''ciga-
12 rette'' has the meaning given such term in section 3(1)
13 of the Federal Cigarette Labeling and Advertising Act (15
14 U.S.C. 1332(1)).

15 **SEC. 312. CIGARETTE USE REDUCTION GOAL AND NON-**
16 **COMPLIANCE.**

17 (a) GOAL.—It shall be the cigarette use reduction
18 goal that each manufacturer reduce youth cigarette use
19 by at least 15 percent during the period between the Moni-
20 toring the Future survey referred to in section 311(b)(1)
21 and the completion of the first annual cigarette survey
22 (and such subsequent surveys as compared to the previous
23 year's survey) referred to in section 311(a).

24 (b) NONCOMPLIANCE.—

(1) INDUSTRY-WIDE PENALTY.—If the Secretary determines that the cigarette use reduction goal under subsection (a) has not been achieved, the Secretary shall, not later than September 10, 2007, and September 10 of each year thereafter, impose an industry-wide penalty on the manufacturers of cigarettes in an amount that is in the aggregate equal to—

(A) if youth cigarette use has been reduced by 5 percent or less, $6,000,000,000;

(B) if youth cigarette use has been reduced by at least 6 percent but less than 10 percent, $4,000,000,000; and

(C) if youth cigarette use has been reduced by at least 11 percent but less than 15 percent, $2,000,000,000.

(2) PAYMENT.—The industry-wide penalty imposed under this subsection shall be paid by each manufacturer based on the percentage of cigarettes of each such manufacturer that are used by youth (as determined under the Monitoring the Future survey and compared to the cigarettes manufactured by all manufacturers) as such percentage relates to the total amount to be paid by all manufacturers.

(3) FINAL DETERMINATION.—The determination of the Secretary as to the amount and allocation of a surcharge under this subtitle shall be final and the manufacturer shall pay such surcharge within 10 days of the date on which the manufacturer is assessed. Such payment shall be retained by the Secretary pending final judicial review of what, if any, change in the surcharge is appropriate.

(4) COMPLIANCE BY CERTAIN MANUFACTURERS.—A manufacturer that individually complies with the goal under subsection (a) shall not be liable for the payment of any portion of the penalty under this subsection.

(5) LIMITATION.—With respect to cigarettes, a manufacturer with a market share of 1 percent or less of youth cigarette use shall not be liable for the payment of a surcharge under this section.

(c) PENALTIES NONDEDUCTIBLE.—The payment of penalties under this subtitle 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.

(d) JUDICIAL REVIEW.—

(1) AFTER PAYMENT.—A manufacturer of cigarettes may seek judicial review of any action under

this subtitle only after the assessment involved has been paid by the manufacturer to the Department of the Treasury and only in the United States District Court for the District of Columbia.

(2) REVIEW BY ATTORNEY GENERAL.—Prior to the filing of an action by a manufacturer seeking judicial review of an action under this subtitle, the manufacturer shall notify the Attorney General of such intent to file and the Attorney General shall have 30 days in which to respond to the action.

(3) REVIEW.—The amount of any surcharge paid under this subtitle shall be subject to judicial review by the United States Court of Appeals for the District of Columbia Circuit, based on the arbitrary and capricious standard of section 706 of title 5, United States Code. Notwithstanding any other provision of law, no court shall have the authority to stay any surcharge payment due to the Secretary under this subtitle pending judicial review until the Secretary has made or failed to make a compliance determination, as described under this subtitle, that has adversely affected the person seeking the review.

SEC. 313. ENFORCEMENT.

(a) INITIAL PENALTY.—There is hereby imposed an initial penalty on the failure of any manufacturer to make

any payment required under this subtitle within 10 days after the date on which such payment is due.

(b) AMOUNT OF PENALTY.—The amount of the penalty imposed by subsection (a) on any failure with respect to a manufacturer shall be an amount equal to 2 percent of the penalty owed under section 312 for each day during the noncompliance period.

(c) NONCOMPLIANCE PERIOD.—For purposes of this section, the term ''noncompliance period'' means, with respect to any failure to make the surcharge payment required under this subtitle, the period—

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

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

(d) LIMITATIONS.—No penalty shall be imposed by subsection (a) on—

(1) any failure to make a surcharge payment under this subtitle during any period for which it is established to the satisfaction of the Secretary that none of the persons responsible for such failure knew or, exercising reasonable diligence, would have known, that such failure existed; or

(2) any manufacturer that produces less than 1 percent of cigarettes used by youth in that year (as determined by the annual survey).

TITLE IV—REIMBURSEMENT AND COVERAGE OF PREVENTIVE SERVICES

SEC. 401. COVERAGE OF SUBSTANCE USE (OTHER THAN TOBACCO), DIET, EXERCISE, INJURY PREVENTION, AND DENTAL HEALTH COUNSELING.

(a) COVERAGE.—

(1) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)), as amended by section 5112(a) of the Deficit Reduction Act of 2005, is amended—

(A) in subparagraph (Z), by striking ''and'' after the semicolon at the end;

(B) in subparagraph (AA), by adding ''and'' after the semicolon at the end; and

(C) by adding at the end the following new subparagraph:

''(BB) substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in subsection (ccc)(1));''.

(2) CONFORMING AMENDMENTS.—(A) Section 1862(a)(12) of the Social Security Act (42 U.S.C.

1395y(a)(12)) is amended by inserting "(except as otherwise allowed under subsection 1861(s)(2)(BB))" after "directly supporting teeth".

(B) Clauses (i) and (ii) of section 1861(s)(2)(K) of the Social Security Act (42 U.S.C. 1395x(s)(2)(K)) are each amended by striking "subsection (ww)(1)" and inserting "subsections (ww)(1) and (ccc)".

(b) SERVICES DESCRIBED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 5112(a) of the Deficit Reduction Act of 2005, is amended by adding at the end the following new subsection:

"Substance Use (other Than Tobacco), Diet, Exercise, Injury Prevention, and Dental Health Counseling

"(ccc) The term 'substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling' means therapy and counseling relating to substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling that is furnished—

"(1) by or under the supervision of a physician; or

"(2) by any other health care professional who—

"(A) is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished; and

"(B) is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose.".

(c) PAYMENT AND ELIMINATION OF COST-SHARING.—

(1) PAYMENT AND ELIMINATION OF COINSURANCE.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(A) in subparagraph (N), by inserting "or substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in section 1861(ccc))" after "(as defined in section 1848(j)(3))";

(B) by striking "and" before "(V)"; and

(C) by inserting before the semicolon at the end the following: "and (W) with respect to substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in section 1861(ccc) the amount paid shall be the lesser of the actual charge for the services or the amount deter-

mined under the payment basis determined under section 1848''.

(2) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—Section 1848(j)(3) of the Social Security Act (42 U.S.C. 1395w–4(j)(3)), as amended by section 5112(c) of the Deficit Reduction Act of 2005, is amended by inserting ''(2)(BB),'' after ''(2)(AA),''.

(3) ELIMINATION OF COINSURANCE IN OUTPATIENT HOSPITAL SETTINGS.—

(A) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by striking ''and diagnostic mammography'' and inserting '', diagnostic mammography, or substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in section 1861(bbb))''.

(B) CONFORMING AMENDMENTS.—Section 1833(a)(2) of the Social Security Act (42 U.S.C. 1395l(a)(2)) is amended—

(i) in subparagraph (F), by striking ''and'' after the semicolon at the end;

(ii) in subparagraph (G)(ii), by striking the comma at the end and inserting "; and"; and

(iii) by inserting after subparagraph (G)(ii) the following new subparagraph:

"(H) with respect to substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in section 1861(ccc)) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(W),".

(4) ELIMINATION OF DEDUCTIBLE.—The first sentence of section 1833(b) of the Social Security Act (42 U.S.C. 1395l(b)), as amended by section 5112(e) of the Deficit Reduction Act of 2005, is amended—

(A) by striking "and" before "(7)"; and

(B) by inserting before the period at the end the following: ", and (8) such deductible shall not apply with respect to substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in section 1861(ccc))".

(d) APPLICATION OF LIMITS ON BILLING.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C.

1395u(b)(18)(C)) is amended by adding at the end the following new clause:

"(vii) Any health care professional designated under section 1861(ccc)(2)(B) to perform substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling that is not otherwise described in this subparagraph.".

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on and after January 1, 2007.

SEC. 402. ENCOURAGEMENT OF CESSATION OF TOBACCO USE.

(a) MEDICARE COVERAGE OF COUNSELING AND PHARMACOTHERAPY FOR CESSATION OF TOBACCO USE.—

(1) COVERAGE.—

(A) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)), as amended by section 401(a)(1), is amended—

(i) in subparagraph (AA), by striking "and" after the semicolon at the end;

(ii) in subparagraph (BB), by adding "and" after the semicolon at the end; and

(iii) by adding at the end the following new subparagraph:

"(CC) counseling and pharmacotherapy for cessation of tobacco use (as defined in subsection (ddd)(1));".

(B) CONFORMING AMENDMENTS.—Clauses (i) and (ii) of section 1861(s)(2)(K) of the Social Security Act (42 U.S.C. 1395x(s)(2)(K)), as amended by section 401(a)(2)(B), are each amended by striking "and (ccc)" and inserting "(ccc), and (ddd)".

(2) SERVICES DESCRIBED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 401(b), is amended by adding at the end the following new subsection:

"Counseling and Pharmacotherapy for Cessation of Tobacco Use

"(ddd)(1) Subject to paragraphs (2) and (3), the term 'counseling and pharmacotherapy for cessation of tobacco use' means diagnostic, therapy, and counseling services and pharmacotherapy (including the coverage of prescription and nonprescription tobacco cessation agents approved by the Food and Drug Administration) for cessation of tobacco use for individuals who use tobacco prod-

1 ucts or who are being treated for tobacco use which are
2 furnished—
3 "(A) by or under the supervision of a physician;
4 or
5 "(B) by any other health care professional
6 who—
7 "(i) is legally authorized to furnish
8 such services under State law (or the State
9 regulatory mechanism provided by State
10 law) of the State in which the services are
11 furnished; and
12 "(ii) is authorized to receive payment
13 for other services under this title or is des-
14 ignated by the Secretary for this purpose.
15 "(2) Such term is limited to—
16 "(A) services recommended in 'Treating To-
17 bacco Use and Dependence: A Clinical Practice
18 Guideline', published by the Public Health Service in
19 June 2000, or any subsequent modification of such
20 Guideline; and
21 "(B) such other services that the Secretary rec-
22 ognizes to be effective.
23 "(3) Each individual who is described in paragraph
24 (1) and enrolled under part B shall be eligible for the serv-

1 ices described in this subsection for up to 3 attempts to
2 cease the use of tobacco.''.

3 (3) PAYMENT AND ELIMINATION OF COST-
4 SHARING.—

5 (A) PAYMENT AND ELIMINATION OF COIN-
6 SURANCE.—Section 1833(a)(1) of the Social
7 Security Act (42 U.S.C. 1395l(a)(1)), as
8 amended by section 401(c)(1), is amended—

9 (i) in subparagraph (N), by striking
10 ''or'' before ''substance abuse'' and by in-
11 serting after ''(ccc))'' the following: ''or
12 counseling and pharmacotherapy for ces-
13 sation of tobacco use (as defined in section
14 1861(ddd))''; and

15 (ii) in subparagraph (W), by inserting
16 ''and counseling and pharmacotherapy for
17 cessation of tobacco use (as defined in sec-
18 tion 1861(ddd))'' after ''1861(ccc))''.

19 (B) PAYMENT UNDER PHYSICIAN FEE
20 SCHEDULE.—Section 1848(j)(3) of the Social
21 Security Act (42 U.S.C. 1395w–4(j)(3)), as
22 amended by section 401(c)(2), is amended by
23 inserting ''(2)(CC) (with separate payment
24 amounts for pharmacotherapy, including pre-
25 scription and nonprescription tobacco cessation

1 agents approved by the Food and Drug Admin-
2 istration),'' after ''(2)(BB),''.
3 (C) ELIMINATION OF COINSURANCE IN
4 OUTPATIENT HOSPITAL SETTINGS.—
5 (i) EXCLUSION FROM OPD FEE
6 SCHEDULE.—Section 1833(t)(1)(B)(iv) of
7 the Social Security Act (42 U.S.C.
8 1395l(t)(1)(B)(iv)), as amended by section
9 401(c)(3)(A), is amended by striking ''or''
10 before ''screenings'' and inserting after
11 ''1861(ccc))'' the following: ''or counseling
12 and pharmacotherapy for cessation of to-
13 bacco use (as defined in section
14 1861(ddd))''.
15 (ii) CONFORMING AMENDMENT.—Sec-
16 tion 1833(a)(2)(H) of the Social Security
17 Act (42 U.S.C. 1395l(a)(2)(H)), as added
18 by section 401(c)(4), is amended by insert-
19 ing ''and counseling and pharmacotherapy
20 for cessation of tobacco use (as defined in
21 section 1861(ddd))'' after ''1861(ccc))''.
22 (D) ELIMINATION OF DEDUCTIBLE.—Sec-
23 tion 1833(b)(8) of the Social Security Act (42
24 U.S.C. 1395l(b)(7)), as added by section
25 401(c)(4), is amended by inserting ''or coun-

seling and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd))'' before the period at the end.

(4) APPLICATION OF LIMITS ON BILLING.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)), as amended by section 401(d), is amended by adding at the end the following new clause:

''(viii) Any individual designated by the Secretary under section 1861(ddd)(1)(B)(ii).''.

(5) FREQUENCY.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)), as amended by section 5112(d) of the Deficit Reduction Act of 2005, is amended—

(A) in subparagraph (M), by striking ''and'' after the comma at the end;

(B) in subparagraph (N), by striking the semicolon at the end and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(O) in the case of counseling and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd)), which is performed with respect to more attempts to cease tobacco use than is covered under such section;''.

1 (b) PROMOTING CESSATION OF TOBACCO USE
2 UNDER THE MEDICAID PROGRAM.—
3 (1) DROPPING EXCEPTION FROM MEDICAID
4 PRESCRIPTION DRUG COVERAGE FOR TOBACCO CES-
5 SATION MEDICATIONS.—Section 1927(d)(2) of the
6 Social Security Act (42 U.S.C. 1396r–8(d)(2)) is
7 amended—
8 (A) by striking subparagraph (E);
9 (B) by redesignating subparagraphs (F)
10 through (J) as subparagraphs (E) through (I),
11 respectively; and
12 (C) in subparagraph (F) (as redesignated
13 by paragraph (2)), by inserting before the pe-
14 riod at the end the following: ", except agents
15 approved by the Food and Drug Administration
16 for purposes of promoting, and when used to
17 promote, tobacco cessation".
18 (2) REQUIRING COVERAGE OF TOBACCO CES-
19 SATION COUNSELING AND PHARMACOTHERAPY
20 SERVICES FOR PREGNANT WOMEN.—Section
21 1905(a)(4) of the Social Security Act (42 U.S.C.
22 1396d(a)(4)) is amended—
23 (A) by striking "and" before "(C)"; and
24 (B) by inserting before the semicolon at
25 the end the following: "; and (D) counseling

and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd)) for pregnant women''.

(3) REMOVAL OF COST-SHARING FOR TOBACCO CESSATION COUNSELING AND PHARMACOTHERAPY SERVICES FOR PREGNANT WOMEN.—Section 1916 of the Social Security Act (42 U.S.C. 1396o) is amended in each of subsections (a)(2)(B) and (b)(2)(B), by inserting '', and counseling for cessation of tobacco use (as defined in section 1861(ddd))'' after ''complicate the pregnancy''.

(c) COVERAGE UNDER FEHBP.—The last sentence of section 8904(a) of title 5, United States Code, is amended by striking ''both for costs associated with care in a general hospital and for other health services of a catastrophic nature'' and inserting ''for costs associated with care in a general hospital, for other health services of a catastrophic nature, and for counseling and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd)(1) of the Social Security Act)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on and after January 1, 2007.

SEC. 403. RECOGNITION OF SCHOOL-BASED HEALTH CENTERS AS MODEL FOR DELIVERY OF PRIMARY CARE FOR CHILDREN UNDER MEDICAID AND THE STATE CHILDREN'S HEALTH INSURANCE PROGRAM.

(a) IN GENERAL.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1911 the following:

"SCHOOL-BASED HEALTH CENTERS

"SEC. 1911A. Not later than 12 months after the date of enactment of this section, the Secretary shall establish procedures to encourage a State program established under this title, title XXI, or both, to recognize school-based health centers as a model of delivery for primary care for children who are eligible for medical assistance under this title or child health assistance under title XXI. Such procedures shall include the following:

"(1) RECOGNITION OF, AND REIMBURSEMENT FOR, SERVICES PROVIDED THROUGH SCHOOL-BASED HEALTH CENTERS.—Procedures that encourage a State to recognize as primary care providers under this title and title XXI, providers who furnish physical or mental health services that are available as medical assistance under this title or child health assistance under title XXI to children who are eligible for such assistance through school-based health cen-

1 ters, and to reimburse such providers or centers (as
2 appropriate) for furnishing such services to such
3 children.

4 "(2) EXCEPTIONS TO THE 'FREE CARE'
5 RULE.—Procedures that allow a State the option to
6 permit school-based health centers to bill the State
7 for physical or mental health services that are avail-
8 able as medical assistance under this title or child
9 health assistance under title XXI and that are fur-
10 nished to children who are eligible for such assist-
11 ance through such centers without billing all chil-
12 dren who are provided such services.

13 "(3) EXCEPTIONS TO THE 'THIRD PARTY LI-
14 ABILITY' COST AVOIDANCE POLICY.—Procedures
15 that encourage a State to include physical or mental
16 health services that are available as medical assist-
17 ance under this title and that are provided through
18 school-based health centers in the list of diagnosis
19 billing codes for preventive pediatric care services
20 that the State will pay for under this title and then
21 seek reimbursement from any liable third party in
22 accordance with the requirements of section
23 1902(a)(25).

24 "(4) ASSURANCE OF PAYMENT FOR SERVICES
25 COVERED BY A CONTRACT WITH A MANAGED CARE

1 ENTITY.—Procedures that encourage a State to in-
2 clude in any contract entered into with a managed
3 care entity (as defined in section 1932(a)(1)(B))
4 under this title or title XXI provisions which ensure
5 that the entity will make prompt payment to a
6 school-based health center for furnishing physical or
7 mental health services to a child who is eligible for
8 medical assistance under this title or child health as-
9 sistance under title XXI that are within the scope of
10 items and services for which benefits are available
11 with respect to the child under the contract between
12 the entity and the State (or to a provider who fur-
13 nishes such services to such a child through a
14 school-based health center), regardless of whether
15 the center (or provider) is a participating provider
16 with respect to such entity, at a rate established by
17 the entity for such services that is not less than the
18 level and amount of payment which the entity would
19 make for the services if the services were furnished
20 by a participating provider.''.
21 (b) REPORT TO CONGRESS.—Not later than 36
22 months after the date of enactment of this section, the
23 Secretary of Health and Human Services shall submit a
24 report to Congress on the effectiveness of the procedures
25 established in accordance with section 1911A of the Social

1 Security Act (as added by subsection (a)) in encouraging
2 the use of school-based health centers for the delivery of
3 primary care physical and mental health services to chil-
4 dren who are eligible for medical assistance under title
5 XIX of the Social Security Act (42 U.S.C. 1396 et seq.)
6 or child health assistance under title XXI of such Act (42
7 U.S.C. 1397aa et seq.), together with such recommenda-
8 tions for administrative or legislative action as the Sec-
9 retary determines to be appropriate.

10 **SEC. 404. PREVENTIVE HEALTH CARE DEMONSTRATION**
11 **PROGRAM.**

12 (a) ESTABLISHMENT.—

13 (1) IN GENERAL.—Not later than 18 months
14 after the date of enactment of this Act, the Sec-
15 retary of Health and Human Services (in this sec-
16 tion referred to as the ''Secretary'') shall conduct a
17 5-year demonstration program under part B of title
18 XVIII of the Social Security Act under which the
19 Secretary establishes demonstration projects to con-
20 tract with appropriate entities to provide preventive
21 health care to eligible beneficiaries through the de-
22 velopment and implementation of a disease preven-
23 tion plan (as described in subsection (b)).

(2) SITES.—The Secretary shall designate at least 2 sites at which to conduct the demonstration program under this section, of which—

(A) 1 shall be in an urban area; and

(B) 1 shall be in a rural area.

(3) NUMBER OF ELIGIBLE BENEFICIARIES.—Each demonstration project site under this section shall consist of at least 1,000 eligible beneficiaries representative of the population of individuals entitled to benefits under part A of title XVIII of the Social Security Act, and enrolled under part B of such title. The Secretary may expand the population as needed to measure statistical significance.

(4) IDENTIFYING ELIGIBLE BENEFICIARIES.—The Secretary shall develop a method for identifying eligible beneficiaries who may benefit from the demonstration program and communicate with them regarding their eligibility.

(5) VOLUNTARY PARTICIPATION.—Participation of health care providers, and individual beneficiaries, in the demonstration program shall be voluntary.

(b) DISEASE PREVENTION PLAN.—

(1) IN GENERAL.—The disease prevention plan described in this subsection is a plan, developed in consultation with an eligible beneficiary participating

in the demonstration program, to mitigate the risk factors associated with a particular disease.

(2) PLAN CONTENTS.—The disease prevention plan should include the following:

(A) POINT OF CONTACT.—The disease prevention plan shall provide for a point of contact responsible for communicating with the participating beneficiary and with other health care providers on behalf of such beneficiary.

(B) PERSONAL HEALTH CARE.—The disease prevention plan shall provide for instruction on personal health care.

(C) PHYSICIAN AND HEALTH CARE PROVIDER TRAINING.—The disease prevention plan shall provide for the training of physicians or other health care providers in the communication of relevant clinical information.

(D) MONITORING TECHNOLOGY.—The disease prevention plan may provide for necessary monitoring technology to facilitate the exchange of information, including information such as vital signs, symptoms, and health self assessments.

(c) PROGRAM STANDARDS AND CRITERIA.—The Secretary shall establish performance standards for the dem-

1 onstration program under this section, including best
2 practices for the prevention of chronic diseases. Such prac-
3 tices shall be standardized to the greatest extent possible.
4 The eligibility of entities or individuals to enter into a con-
5 tract to provide preventive health care under the dem-
6 onstration program shall be conditioned, at a minimum,
7 on performance that meets or exceeds such standards.

8 (d) PAYMENT.—The Secretary shall develop a meth-
9 od and level of payment for entities that participate in
10 the program under this section based on best practices,
11 as determined by the Secretary.

12 (e) WAIVER AUTHORITY.—The Secretary may waive
13 such requirements of titles XI and XVIII of the Social
14 Security Act as may be necessary to carry out the pur-
15 poses of the demonstration program under this section.

16 (f) EVALUATION AND REPORT.—

17 (1) EVALUATION.—The Secretary shall conduct
18 evaluations of—

19 (A) the benefits due to a reduction, if any,
20 in disease incidence for participants in the dem-
21 onstration projects compared to the medicare
22 population as a whole, as determined by the use
23 of appropriate statistical techniques;

24 (B) the long term cost effectiveness of the
25 demonstration projects to the medicare program

in terms of acute care costs avoided due to disease prevention; and

(C) patient satisfaction under the demonstration projects.

(2) REPORT.—Not later than 6 months after the date on which the demonstration program under this section ends, the Secretary shall prepare and submit to Congress a report on the demonstration program together with—

(A) recommendations on whether the demonstration program should be expanded in terms of its success in disease prevention and the cost effectiveness of the demonstration program; and

(B) such recommendations for legislation or administrative action as the Secretary determines appropriate.

(g) FUNDING.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) of such funds, not to exceed $50,000,000, as are necessary for the costs of carrying out the demonstration program under this Act.

(h) DEFINITIONS.—In this section:

1 (1) APPROPRIATE ENTITY.—The term ''appro-
2 priate entity'' means—
3 (A) a chronic care improvement program;
4 (B) a hospital; and
5 (C) any other entity that the Secretary de-
6 termines appropriate based on clinical, finan-
7 cial, or other requirements appropriate to carry
8 out the purposes of the demonstration program
9 under this section.
10 (2) ELIGIBLE BENEFICIARY.—The term ''eligi-
11 ble beneficiary'' means an individual who—
12 (A) is entitled to benefits under part A of
13 title XVIII of the Social Security Act or en-
14 rolled under part B of such title; and
15 (B) has 2 or more risk factors associated
16 with—
17 (i) chronic obstructive pulmonary dis-
18 ease;
19 (ii) diabetes; or
20 (iii) any other chronic condition that
21 the Secretary determines would be appro-
22 priate for the purpose of providing signifi-
23 cant potential cost benefits to the medicare
24 program through the prevention of such
25 condition.

SEC. 405. PREVENTIVE HEALTH SERVICES FOR WOMEN.

Section 1509 of the Public Health Service Act (42 U.S.C. 300n–4a) is amended to read as follows:

"SEC. 1509. ESTABLISHMENT OF PROGRAM FOR ADDITIONAL PREVENTIVE HEALTH SERVICES.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, through a competitive review process, award grants to States that have received grants under section 1501 for a fiscal year, to enable such State to carry out programs—

"(1) to provide preventive health services, in addition to the services authorized in such section 1501, for diseases such as cardiovascular diseases, osteoporosis, and obesity;

"(2) to provide screenings, such as screening for blood pressure, cholesterol, and osteoporosis, and other services that the Secretary, acting through the Director of the Centers for Disease Control and Prevention, determines to be appropriate and feasible;

"(3) for health education, counseling, and interventions for behavioral risk factors, such as physical inactivity and poor nutrition, and diseases referred to in paragraph (1);

"(4) to provide appropriate referrals for medical treatment of women receiving services pursuant to

1 paragraph (1) through (3), and ensuring, to the ex-
2 tent practicable, the provision of appropriate follow-
3 up services; and

4 "(5) to evaluate the activities conducted under
5 paragraphs (1) through (4) through appropriate sur-
6 veillance, research, or program monitoring activities.

7 "(b) STATUS AS PARTICIPANT IN PROGRAM REGARD-
8 ING BREAST AND CERVICAL CANCER.—The Secretary
9 may not make a grant to a State under subsection (a)
10 unless the State involved agrees that services under the
11 grant will be provided in conjunction with entities that are
12 screening women for breast or cervical cancer pursuant
13 to a grant under section 1501.

14 "(c) APPLICABILITY OF PROVISIONS.—The provi-
15 sions of this title shall apply to a grant under subsection
16 (a) to the same extent and in the same manner as such
17 provisions apply to a grant under section 1501.

18 "(d) FUNDING.—

19 "(1) IN GENERAL.—There is authorized to be
20 appropriated such sums as may be necessary to
21 carry out this section for fiscal year 2007 and for
22 each subsequent fiscal year.

23 "(2) LIMITATION REGARDING FUNDING WITH
24 RESPECT TO BREAST AND CERVICAL CANCER.—No
25 additional resources shall be appropriated for a fis-

cal year under paragraph (1) unless the amount appropriated under section 1510(a) for such fiscal year is at least $173,920,000.''.

TITLE V—HELP (HEALTHY LIFESTYLES AND PREVENTION) AMERICA TRUST FUND

SEC. 501. HELP (HEALTHY LIFESTYLES AND PREVENTION) AMERICA TRUST FUND.

(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the ''HeLP (Healthy Lifestyles and Prevention) America Trust Fund'' (referred to in this section as the ''Trust Fund''), consisting of such amounts as may be appropriated or credited to the Trust Fund as provided in this section.

(b) TRANSFERS TO TRUST FUND.—There is hereby appropriated to the Trust Fund an amount equivalent to—

(1) the increase in revenues received in the Treasury as the result of the amendment made by section 304 of this Act,

(2) the increase in revenues received in the Treasury as the result of the amendments made by title II of this Act, and

(3) the receipts paid by tobacco companies under subtitle B of title III of this Act.

(c) DISTRIBUTION OF AMOUNTS IN TRUST FUND.—

(1) MANDATORY EXPENDITURES.—On a fiscal year basis (beginning with fiscal year 2007) and without further appropriation the Secretary of the Treasury shall distribute from amounts in the Trust Fund such amounts as are necessary to provide for the Federal expenditures attributable to the following:

(A) The amendments made to the Fruit and Vegetable Program by section 101 of this Act.

(B) Smoking cessation drugs under title XIX of the Social Security Act as identified by the Secretary of Health and Human Services.

(C) Coverage of smoking cessation under the Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code (as amended by section 402(c)).

(D) The amendments made to the medicare program under title XVIII of the Social Security Act by sections 401 and 402 of this Act.

(E) The preventive health care demonstration program carried out under section 404 of this Act.

Such amounts shall be in addition to any other amounts appropriated for such purposes.

(2) DISCRETIONARY EXPENDITURES.—Amounts in the Trust Fund not to exceed $2,050,000,000 shall be available, as provided in appropriation Acts, for each fiscal year (beginning with fiscal year 2007) only for purposes of making expenditures to carry out the following:

(A) School nutrition environment enhancement grants under section 18(l) of the Richard B. Russell National School Lunch Act (as added by section 103).

(B) Community grants to prevent and reduce the incidence of chronic disease under section 399P of the Public Health Service Act (as added by section 211).

(C) The preventive medicine and public health training grant program carried out under section 747A of the Public Health Service Act (as added by section 212).

(D) Federal-State tobacco counter-advertising programs under section 399Q of the Pub-

lic Health Service Act (as added by section 305).

(E) Preventive health services for women, including well-integrated screening and evaluation for women across the Nation, under section 1509 of the Public Health Service Act (as added by section 405).

(F) Carol M. White Physical Education Program under subpart 10 of part D of title V of the Elementary and Secondary Education Act of 1965.

(G) Research regarding obesity under section 601 of this Act.

(H) Expanded Food and Nutrition Education Program under section 3175 of title 23, United States Code.

(I) The following programs under the authority of the Secretary of Health and Human Services through the Centers for Disease Control and Prevention:

(i) Nutrition and physical activity grants.

(ii) Division of Adolescent and School Health.

(iii) Verb Campaign.

(iv) Prevention research centers.

(v) 5-a-day programs.

(vi) Steps to a healthier United States.

(J) Access to local foods and school gardens, as authorized by section 122 of the Child Nutrition and WIC Reauthorization Act of 2004 (Public Law 108–265).

(d) APPLICATION OF CERTAIN RULES.—For purposes of this section, rules similar to the rules of sections 9601 and 9602 of the Internal Revenue Code of 1986 shall apply.

TITLE VI—RESEARCH

SEC. 601. EXPANSION OF RESEARCH REGARDING OBESITY.

The Secretary of Health and Human Services shall, based on the conclusions of the United States Preventive Services Task Force on Obesity, conduct research on obesity prevention, treatment, and control with regard to the following:

(1) The effectiveness of physical activity and dietary counseling with children and adolescents in the primary care setting to prevent, treat, and control obesity.

(2) The cost-effectiveness of intensive dietary and physical activity counseling to prevent, treat, and control obesity in a variety of populations.

(3) The effectiveness of dietary and physical activity counseling among children and adolescents, low income populations, and minority groups in the primary care setting to prevent, treat, and control obesity.

(4) The effectiveness of the assessment of obesity by a primary care physician and subsequent referral for obesity counseling to a nonaffiliated obesity expert or specialist.

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