108TH CONGRESS
2D SESSION

S. 2558

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

IN THE SENATE OF THE UNITED STATES

JUNE 22, 2004

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

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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 towards 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''.

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

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Health care costs in the United States are rising rapidly. On a per capita basis, the United States spends 40 percent more than any other country on health care as a proportion of our gross domestic product.

(2) The United States spends over $1,800,000,000,000 annually on health care, 75 percent of which is spent on the treatment of chronic disease.

(3) However, only 2 percent of annual health care spending in the United States goes toward the prevention of chronic diseases.

(4) The high cost of chronic disease management and treatment is a major contributing factor to these exploding health care costs.

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

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

(7) In 2000, 38.2 percent of all deaths were due to tobacco use, poor nutrition and physical inactivity, and alcohol consumption.

(8) The economic impact of chronic disease can be seen in the annual costs associated with cardiovascular disease $352,000,000,000 obesity $117,000,000,000, tobacco use $75,000,000,000 and mental illness $150,000,000,000.

(9) In 2001 obesity related health conditions carried a $13,000,000,000 price tag to employers (as determined by the Department of Health and Human Services).

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

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

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

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

(14) An estimated 400,000 deaths a year are associated with being overweight or obese.

(15) Almost 40 percent of Americans are sedentary. More than a third of young people in grades

9 through 12 do not regularly engage in vigorous-intensity physical activity.

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

(17) More than $12,000,000,000 a year is spent on advertising and marketing, mostly unhealthy food to children through television, the insert Internet, movies, magazines, in-school marketing, kids clubs, toys, coupons, product placement in movies and books.

(18) Approximately one-quarter of walking trips take place on roads without sidewalks or shoulders and bike lanes are available for only about 5 percent of bike trips.

(19) 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.

(20) In 2002, 61,000,000 Americans, 26 percent of our population smoked cigarettes.

(21) 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.

(22) Physical and mental health are interconnected. Physical conditions often result in mental health complications, likewise, depression can manifest itself through physical symptoms.

(23) The Surgeon General reported that mental disorders collectively account for 15 percent of the overall burden of disease from all causes, and slightly more than the burden associated with all forms of cancer.

(24) Major depression is the leading cause of disability in the United States.

(25) One of every 2 people who need mental health treatment in the United States does not receive it and 30,000 Americans die by suicide each year.

(26) Early screening and prevention programs in the schools can detect high risk children that are vulnerable to developing mental illness and assist in accessing appropriate services.

(27) People with disabilities report substantial disparities in health compared with people without disabilities. These disparities are caused by a number of factors, including less access to health care

than individuals without disabilities. People with disabilities report more days of pain, depression, and anxiety and they have higher rates of obesity.

(28) Evidence shows that health promotion programs with exercise, nutrition, and wellness components targeting people with disabilities can significantly reduce the incidence of these conditions and lead to healthy outcomes for people with disabilities, as well as save money by reducing the frequency of medical visits.

TITLE I—HEALTHIER KIDS AND SCHOOLS

SEC. 101. FRUIT AND VEGETABLE PROGRAM.

Section 18 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1769) is amended by striking subsection (g) and inserting the following:

''(g) FRUIT AND VEGETABLE PROGRAM.—

''(1) IN GENERAL.—For the school year beginning July 2005 and each subsequent school year, the Secretary shall carry out a program to make free fresh fruits and vegetables available to each school that submits a certification of support for participation in the program that is signed by the school food manager, the school principal, and the district su-

perintendent (or equivalent positions, as determined by the school).

''(2) PROGRAM.—A school participating in the program shall make fresh fruits and vegetables available to students throughout the school day in 1 or more areas designated by the school.

''(3) NOTICE OF AVAILABILITY.—To be eligible to participate in the fresh fruit and vegetable program under this subsection, a school shall widely publicize within the school the availability of free fresh fruits and vegetables under the program.

''(4) PER STUDENT GRANT.—

''(A) IN GENERAL.—For each school year during which a school participates in the program under this subsection, the Secretary shall provide to the school an amount equal to $75 per student, as adjusted under subparagraph (B), to be used to carry out the program in the school.

''(B) ADJUSTMENT.—The amount of the grant for each student under subparagraph (A) shall be adjusted on July 1, 2006, and each subsequent July 1, 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.

"(5) EVALUATION.—

"(A) IN GENERAL.—The Secretary, acting through the Administrator of the Food and Nutrition Service, shall conduct an evaluation of schools participating in the program under this subsection.

"(B) CONTENT.—The evaluation shall measure, at a minimum, the impact of participation in the program and any changes in the school nutrition environment relating to—

"(i) overweight and obesity among children;

"(ii) dietary intake;

"(iii) nutrition education and behavior;

"(iv) rates of physical activity among children; and

"(v) parental and student attitudes about—

''(I) participation in the program; and

''(II) general nutrition, physical activity, and wellness.

''(6) 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 SCHOOL.—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.

"(7) AUTHORIZATION OF APPROPRIATIONS.—

"(A) IN GENERAL.—There are authorized to be appropriated such sums as are necessary to carry out this subsection, to remain available until expended.

"(B) INSUFFICIENT FUNDS.—If the funds appropriated under subparagraph (A) are insufficient to carry out the program under this subsection in all schools that meet the requirements of paragraph (1), the Secretary shall give

priority to schools that have the highest percentage of students enrolled that are eligible for free or reduced price meals under this Act.''.

SEC. 102. SCHOOL WELLNESS POLICY; COMPETITIVE FOODS.

(a) SCHOOL WELLNESS POLICIES.—

(1) IN GENERAL.—Not later than the first day of the school year beginning July 2006, each local educational agency participating in the programs authorized under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.) and the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.) shall establish a local school wellness policy that, at a minimum—

(A) includes goals for nutrition education, physical activity, and such other school-based activities designed to promote student wellness as the local educational agency determines to be appropriate;

(B) includes nutrition guidelines that—

(i) are developed in consultation with representatives described in subparagraph (E);

(ii) are applicable to all foods available during the school day; and

(iii) have as objectives—

(I) promotion of sound nutrition;

(II) improvement of student health; and

(III) reduction in childhood obesity;

(C) ensures that meals and supplements provided in accordance with the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.) and the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.) conform with nutritional guidelines contained in regulations promulgated by the Secretary of Agriculture (referred to in this section as the ''Secretary'') in accordance with the programs authorized under those Acts;

(D) establishes a plan for ensuring implementation of the local wellness policy, including designation of 1 or more individuals within the local educational agency charged with operational responsibility for ensuring that the requirements of the school wellness plan are carried out; and

(E) involves representatives of the school food authority, parents, students, the school

board, school administrators, physical activity professionals, medical and nutrition professionals, and the public in the development of the school wellness policy.

(2) TECHNICAL ASSISTANCE AND BEST PRACTICES TO SCHOOLS AND STATES.—

(A) IN GENERAL.—The Secretary shall make available to local educational agencies, school food authorities, and State school food authorities guidance and technical assistance for use in—

(i) carrying out paragraph (1); and

(ii) otherwise—

(I) establishing healthy school food environments;

(II) reducing childhood obesity; and

(III) preventing diet-related chronic diseases.

(B) CONTENT.—The guidance and technical assistance shall include, at a minimum—

(i) case studies of schools and school districts that have taken steps to provide healthy options in foods sold and served at school, particularly schools and school dis-

tricts that have done so without experiencing adverse effects on revenue from sales of competitive foods;

(ii) recommended nutritional guidelines regarding appropriate standards for the availability, sale, and service of foods of any kind throughout the school day, as provided by the Institute of Medicine under subsection (b)(3) of section 10 of the Child Nutrition Act of 1966 (42 U.S.C. 1779) (as amended by subsection (b)); and

(iii) such other technical assistance as is required to carry out the goals of promoting sound nutrition and establishing healthy school food environments.

(C) GUIDANCE ONLY.—The recommendations of the Institute of Medicine under subsection (b)(3) of section 10 of the Child Nutrition Act of 1966 (42 U.S.C. 1779) (as amended by subsection (b))—

(i) are solely for the purpose of providing guidance to schools to develop school wellness policies in accordance with paragraph (1); and

(ii) shall not be construed as a mandate to local educational agencies, school food authorities, or schools.

(b) COMPETITIVE FOODS IN SCHOOLS.—Section 10 of the Child Nutrition Act of 1966 (42 U.S.C. 1779) is amended—

(1) in subsection (a), by striking ", including" and all that follows through "Lunch Act"; and

(2) by striking subsection (b) and inserting the following:

"(b) COMPETITIVE FOODS IN SCHOOLS.—

"(1) IN GENERAL.—The regulations under subsection (a) may include provisions that regulate the service of food in participating schools and service institutions in competition with the programs authorized under this Act and the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.) (referred to in this subsection as 'competitive foods').

"(2) REGULATIONS.—The regulations promulgated under paragraph (1)—

"(A) shall apply to all school grounds during the duration of the school day;

"(B) shall not supersede or otherwise affect State and local regulations on competitive

foods that, as determined by the Secretary, conform to the nutritional goals of the regulations promulgated by the Secretary;

''(C) shall require that the proceeds from the sale of competitive foods in schools be used for the benefit of the schools or of organizations of students approved by the schools, if those sales are allowed by the regulations;

''(D) shall take into account the differing needs of—

''(i) elementary schools;

''(ii) middle schools and junior high schools; and

''(iii) high schools; and

''(E) shall implement the recommendations of the Institute of Medicine made under paragraph (3).

''(3) INSTITUTE OF MEDICINE RECOMMENDATIONS.—

''(A) IN GENERAL.—The Secretary shall offer to enter into an agreement with the Institute of Medicine of the National Academy of Sciences under which the Institute of Medicine, based on sound nutritional science, shall make recommendations to the Secretary regarding—

"(i) the regulation of competitive foods; and

"(ii) appropriate nutritional guidelines for competitive foods offered in schools.

"(B) REGULATIONS.—Not later than 1 year after the date of receipt of final recommendations from the Institute of Medicine, the Secretary shall promulgate regulations to carry out this subsection in accordance with the recommendations of the Institute of Medicine.

"(C) REPORT.—Not later than 1 year after the date of receipt of final recommendations from the Institute of Medicine, 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 a report that describes the actions of the Secretary under subparagraph (B).".

(c) APPLICABILITY.—This section and the amendments made by this section apply only to schools participating in a program authorized under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.) or the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.).

SEC. 103. HEALTHY SCHOOL NUTRITION ENVIRONMENT INCENTIVE 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:

''(h) HEALTHY SCHOOL NUTRITION ENVIRONMENT INCENTIVE GRANTS.—

''(1) IN GENERAL.—The Secretary shall establish a program under which the Secretary shall make competitive grants to selected elementary and secondary schools—

''(A) to create healthy school nutrition environments; and

''(B) to assess the impact of the environments 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) INPUT.—Prior to the solicitation of proposals for grants under this subsection, the

Secretary shall solicit input from appropriate nutrition, health, and education organizations regarding the appropriate criteria for a healthy school environment.

''(B) CRITERIA FOR HEALTHY SCHOOL ENVIRONMENTS.—The Secretary shall, taking into account input received under subparagraph (A), establish criteria for defining a healthy school environment, including criteria that—

''(i) provide program meals that meet nutritional standards for breakfasts and lunches established by the Secretary;

''(ii) ensure that all food served (including food served in participating schools and service institutions in competition with the programs authorized under this Act and the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.)) on school grounds during regular school hours is consistent with the nutritional standards for breakfasts and lunches established by the Secretary;

''(iii) promote the consumption of fruits and vegetables;

"(iv) promote physical education and provide nutrition education to students and staff;

"(v) ensure that all children are included in physical education and nutrition activities, including children with disabilities and children with limited English proficiency;

"(vi) ban foods of minimal nutritional value, as that term is defined in section 210.11 of title 7, Code of Federal Regulations (or any successor regulation), and the marketing and advertising in schools of foods of minimal nutritional value;

"(vii) integrate general wellness goals into the school curriculum; and

"(viii) meet other criteria established by the Secretary.

"(C) PLANS.—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 (B); and

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

''(4) GRANTS.—For each of fiscal years 2006 through 2010, 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) the adequacy of time to eat;

''(v) physical activities;

''(vi) parental and student attitudes and participation; and

''(vii) 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) FUNDING.—

''(A) IN GENERAL.—On October 1, 2004, and each October 1 thereafter on which this program is authorized, 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 this subsection $100,000,000.

''(B) RECEIPT AND ACCEPTANCE.—The Secretary shall be entitled to receive, shall accept, and shall use to carry out this section the funds transferred under subparagraph (A), without further appropriation.

''(C) AVAILABILITY OF FUNDS.—Funds transferred under subparagraph (A) shall remain available until expended.

''(D) EVALUATIONS.—Of the funds made available under this paragraph, the Secretary shall use not more than $5,000,000 to conduct evaluations under paragraph (5).''.

SEC. 104. GRANTS FOR THE INTEGRATION OF SCHOOLS AND MENTAL HEALTH SYSTEMS.

Section 5541 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7269) is amended—

(1) in subsection (c), by adding at the end the following:

''(7) To support schools that work with families and appropriate community partners to implement school-wide prevention strategies, based on mental health research, that will support early and intensive interventions.

''(8) To provide necessary training and support to school personnel on how to recognize and seek needed support for children exhibiting early warning signs of behavioral and academic problems.''; and

(2) in subsection (d)—

(A) in paragraph (4)—

(i) in subparagraph (C), by striking ''and'' after the semicolon;

(ii) in subparagraph (D), by striking the period and inserting ''; and''; and

(iii) by adding at the end the following:

''(E) mental health services provided under this section by schools will be evidence-based or promising early interventions.''; and

(B) by adding at the end the following:

''(7) An explanation of how the applicant will carry out public education programs in support of mental health promotion and prevention by collaborating with—

''(A) an institution of higher education (including a graduate program in psychology, social work, or education at an institution of higher education); and

''(B) private nonprofit community-based organizations that have experience in public education programs relating to mental health promotion and prevention.''.

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 2004''.

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. 45G. 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 employer 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.

''(2) QUALIFIED SMALL BUSINESS WELLNESS PROGRAM.—The term 'qualified small business wellness program' means a program which consists

of any 2 of the 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 small business wellness program under this section.

''(c) WELLNESS PROGRAM COMPONENTS.—For purposes of this section, the wellness program components described in this subsection are the following:

''(1) HEALTH AWARENESS COMPONENT.—A health awareness component which provides for the following:

''(A) HEALTH EDUCATION.—The dissemination of health information which addresses the specific needs and health risks of employees.

''(B) HEALTH SCREENINGS.—The opportunity for periodic screenings for health problems and referrals for appropriate follow up measures.

''(2) BEHAVIORAL CHANGE COMPONENT.—A behavioral change component which provides for altering 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, and

"(G) depression.

"(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, and

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

"(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).

''(4) NO CREDIT WHERE GRANT AWARDED.—No credit shall be allowable under subsection (a) to any person who receives a grant under section 201 of the Health Workforce Act of 2004.

''(f) TERMINATION.—This section shall not apply to any amount paid or incurred after December 31, 2014.''.

(b) TREATMENT AS GENERAL BUSINESS CREDIT.—

(1) IN GENERAL.—Subsection (b) of section 38 of the Internal Revenue Code of 1986 (relating to general business credit) is amended by striking ''plus'' at the end of paragraph (14), by striking the period at the end of paragraph (15) and inserting '', plus'', and by adding at the end the following:

''(16) the wellness program credit determined under section 45G.''.

(2) TRANSITIONAL RULE FOR CARRYBACKS.—Subsection (d) of section 39 of such Code (relating to transitional rules) is amended by adding at the end the following:

''(11) NO CARRYBACK OF SECTION 45G CREDIT BEFORE EFFECTIVE DATE.—No portion of the un-

used business credit for any taxable year which is attributable to the wellness program credit determined under section 45G may be carried back to a taxable year beginning before January 1, 2005.''.

(c) DENIAL OF DOUBLE BENEFIT.—Section 280C of the Internal Revenue Code of 1986 (relating to certain expenses for which credits are allowable) is amended by adding at the end the following new subsection:

''(d) 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 45G) 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 45G.

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

''(A) the amount of the credit determined for the taxable year under section 45G, 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. 45G. Wellness program credit.''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2004.

(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 45G 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).

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 ''sub-

section (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.

(a) AMENDMENT TO PUBLIC HEALTH SERVICE ACT.—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.''.

(b) GRANTS TO HELP SMALL BUSINESSES.—

(1) WELLNESS PROGRAMS.—

(A) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall award grants, on a competitive basis, to hospitals, community wellness providers, and other qualifying entities, as determined by the Director of the Centers for Disease Control and Prevention, to implement wellness programs at qualifying employers.

(B) CRITERIA FOR PROGRAMS.—The wellness programs implemented pursuant to subparagraph (A) shall be certified by the Secretary of Human Services, in the same manner as required under section 45G of the Internal Revenue Code of 1986, as a qualified wellness program (within the meaning of such section) or as a qualified small business wellness program (within the meaning of such section).

(2) QUALIFYING EMPLOYER.—In this subsection, the term ''qualifying employer'' means a business—

(A) that does not have a comprehensive employer-based wellness program; and

(B)(i) with less than 200 employees;

(ii) that is located in an underserved area; or

(iii) that is exempt from tax under section 501 of the Internal Revenue Code of 1986.

(3) REQUIREMENTS BASED ON APPROPRIATED FUNDS.—The Director of the Centers for Disease Control and Prevention shall be required to award grants under this subsection only if funds are appropriated to carry out this subsection.

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 and implementing programs that seek to promote individual and community health and to prevent the incidence of chronic disease.

''(b) ELIGIBILITY.—

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

''(A) be—

''(i) a city, county, or Indian tribe;

''(ii) a local or tribal educational agency;

''(iii) an accredited university, college, or community college;

''(iv) a federally qualified health center;

''(v) a local health department;

''(vi) a health care provider;

''(vii) a community-based organization; or

''(viii) any other entity determined appropriate by the Secretary, including a consortia or partnership of entities described in any of clauses (i) through (vii);

''(B) prepare and submit an application in 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

''(C) mental illness; or

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

''(d) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to—

''(1) entities that demonstrate that they have previously applied successfully for funds to carry out activities that seek to promote individual and community health and to prevent the incidence of chronic disease and that can cite published and peer-reviewed research demonstrating that the activities that the entity proposes to carry out under this subsection are effective;

''(2) entities that will carry out programs or activities that seek to accomplish a goal or goals set by the State in the Healthy People 2010 plan of the State;

''(3) entities that provide non-Federal contributions, either in cash or in kind, to the costs of funding activities under the grant;

''(4) entities that develop comprehensive plans that include a strategy for extending program activities developed under this section in the years following 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. LIVING WELL WITH A DISABILITY AND WORKING WELL WITH A DISABILITY PROGRAMS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.), as amended by section 211, is further amended by adding at the end the following:

''SEC. 399Q. LIVING WELL WITH A DISABILITY PROGRAMS.

''(a) DEFINITIONS.—In this section:

''(1) CENTER FOR INDEPENDENT LIVING.—The term 'center for independent living' means a center described in part C of title VII of the Rehabilitation Act of 1973 (29 U.S.C. 796f et seq.).

''(2) DISABILITY.—The term 'disability' has the meaning given the term in section 3 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12102).

''(3) INDEPENDENT LIVING SERVICES.—The term 'independent living services' has the meaning given the term in section 7 of the Rehabilitation Act of 1973 (29 U.S.C. 705).

''(b) GRANTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to eligible entities on a competitive basis, to assist the entities in implementing Living Well With a Disability Programs, designed—

''(1) to increase health-promoting behavior, such as engaging in exercise, eating nutritious food, and using stress management techniques, among individuals with disabilities; and

''(2) to reduce the limitations of secondary conditions for such individuals.

''(c) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity—

''(1) shall be a nonprofit organization that serves individuals with disabilities;

''(2) shall be a community-based organization that has experience in providing consumer-directed independent living services; and

''(3) may be a center for independent living.

''(d) APPLICATION.—To be eligible to receive a grant under this section for a program, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including information on—

''(1) the number of individuals with disabilities who will be trained in the program;

''(2) the entity's capacity to collect data and information on outcomes of the program; and

''(3) the entity's experience implementing similar training programs.

''(e) PREFERENCE AND DISTRIBUTION.—

''(1) PREFERENCE.—In making grants under this section, the Secretary shall give preference to eligible entities who—

''(A) are currently (as of the date of submission of the application) serving individuals with disabilities and implementing training and peer support programs;

''(B) indicate a commitment and ability to continue to train participants over several years; and

''(C) have not previously provided training through a Living Well With a Disability Program.

''(2) DISTRIBUTION.—In making grants under this section, the Secretary shall, to the extent practicable, ensure an equitable geographic distribution of the grants.

''(f) CURRICULUM, TRAINING, AND TECHNICAL ASSISTANCE.—An entity that receives a grant under this section may use funds made available through the grant to acquire a curriculum, training, or technical assistance for the program carried out through the grant from an entity qualified to implement, and train participants in, a Living Well With a Disability program.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $2,000,000 for each of fiscal years 2005 through 2009.

''SEC. 399R. WORKING WELL WITH A DISABILITY PROGRAMS.

''(a) DEFINITIONS.—In this section, the terms 'center for independent living', 'disability', and 'independent

living services' have the meanings given the terms in section 399O.

''(b) AUTHORIZATION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a demonstration program promoting the health and wellness of individuals with disabilities in the workplace.

''(c) GRANTS.—In carrying out the program, the Secretary shall make grants to an eligible entity, to assist the entity in preparing for the implementation of, or implementing, Working Well With a Disability Programs, which may include—

''(1) gathering data on the positive effects of healthy behaviors on retention and productivity of individuals with disabilities who are employees or potential employees;

''(2) building relationships between vocational rehabilitation programs and health promotion programs;

''(3) adapting a Living Well With a Disability program to meet the needs of individuals seeking or entering employment;

''(4) training individuals in methods of implementing the program;

''(5) implementing the program; and

''(6) measuring the impact of the program on health and employment outcomes.

''(d) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity shall—

''(1) have experience in implementing a Living Well With a Disability Program; and

''(2) demonstrate that the entity is qualified and able to adapt the program to establish a Working Well With a Disability Program, and implement the program.

''(e) PARTNERSHIP.—An entity that receives a grant under this section shall carry out the activities funded through the grant through a partnership with 1 or more entities that—

''(1) shall be nonprofit organizations that serve individuals with disabilities;

''(2) shall be community-based organizations that have experience in providing consumer-directed independent living services; and

''(3) may be centers for independent living.

''(f) APPLICATION.—To be eligible to receive a grant under this section for a program, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $1,000,000 for the period of fiscal years 2005 through 2007.''.

SEC. 213. ENHANCED STANDARDS FOR ROADS AND INTERSECTION CONTROLS.

Section 133 of title 23, United States Code, is amended by adding at the end the following:

''(g) ENHANCED STANDARDS FOR ROADS AND INTERSECTION CONTROLS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of this subsection, the Secretary, in coordination with the American Association of State Highway and Transportation Officials and the Institute of Transportation Engineers, shall develop recommended enhanced standards for the design of roads and intersection controls (including associated bicycle paths, bicycle lanes, and walkways) to improve pedestrian and bicycle safety.

''(2) ACCOMMODATION OF BICYCLES AND PEDESTRIANS.—The standards under paragraph (1) shall—

''(A) cover all common types of facilities where pedestrians or bicycles are allowed on a

road or on associated walkways and bicycle paths or lanes; and

"(B) specify that generally, when the increased cost is not excessive, as an element of good highway design for new construction or reconstruction facilities on which bicycles or pedestrians are permitted, the design shall include appropriate provisions to accommodate bicycles or pedestrians.

"(3) INCREASED APPORTIONMENT.—

"(A) IN GENERAL.—Beginning with the first fiscal year that begins after the date that is 2 years after the date of enactment of this subsection, if a State accepts the recommended enhanced standards for the State and local units of government to meet, the State shall receive a 4 percent increase in the amount of funds made available to the State under this section for each fiscal year, if, at least 10 days before the beginning of the fiscal year, the State—

"(i) agrees to follow the enhanced standards; or

''(ii) establishes an alternative enhanced standard that the Secretary approves.

''(B) SIGNIFICANT COMMITMENT.—In determining the significance of the required commitment of funds under subparagraph (A), the Secretary shall take into consideration the effectiveness of the criteria required and an estimation of increased costs.

''(4) CONSTRUCTION REQUIREMENTS.—The Secretary and a State may establish differing requirements for the construction of new facilities, for the rehabilitation of facilities, and for modifications specifically to improve safety and for facilities based on the level of expected pedestrian and bicycle traffic.''.

SEC. 214. MENTAL HEALTH SURVEILLANCE.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by inserting after section 506B (42 U.S.C. 290aa-5b) the following:

''SEC. 506C. MENTAL HEALTH SURVEILLANCE.

''(a) IN GENERAL.—The Secretary, acting through the Administrator, and in consultation with the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish and im-

plement public health surveillance measures to address the mental and behavioral health needs of the population of the United States and other populations served by the Administration, that include—

''(1) monitoring the mental health status of the population;

''(2) monitoring mental and behavioral health risks;

''(3) enhancing existing public health surveillance systems to include data on mental and behavioral health status and risks; and

''(4) monitoring the immediate and long-term impact of emergencies on population mental health and behavior.

''(b) REPORT.—Not later than 1 year after the date of enactment of this section, the Secretary shall submit a report to Congress that describes the progress on the implementation of the surveillance measures described in subsection (a).

''(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $5,000,000 for fiscal year 2005 and $15,000,000 for each of the following fiscal years.''.

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, com-

prehensive 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 6,500,000 of today's children from becoming regular, daily smokers, saving over 2,000,000 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 2001, the tobacco industry spent more than $11,000,000,000 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 to-

bacco 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 tobacco 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 subtitle.

(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 cigarettes 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 com-

munication 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 likely 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 thou-

sands 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 advertise-

ments 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 subtitle 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 subtitle (or an amendment made by this subtitle) 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 subtitle (or an amendment made by this subtitle)

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

CHAPTER 1—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 requirements 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, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

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

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

''(11) NICOTINE.—The term 'nicotine' means the chemical substance named 3-(1-Methyl-2-

pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

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

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

under, 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;

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

''(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 condition 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 established, 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 included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;

''(7) if, in the case of any tobacco product distributed or offered for sale in any State—

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

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

''(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed mat-

ter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

"(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

"(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 tobacco 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

915 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 (including smoke constituents), ingredients, components, and additives.

''(b) DATA SUBMISSION.—At the request of the Secretary, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

''(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

''(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof)

that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

''(3) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

''(c) TIME FOR SUBMISSION.—

''(1) IN GENERAL.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the manufacturer of such product shall provide the information required under subsection (a).

''(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the

manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing.

''(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated 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 corporate officer and director, and the State of incorporation.

''(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person.

''(c) REGISTRATION OF NEW OWNERS AND OPERATORS.—Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment.

''(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any addi-

tional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

''(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

''(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

''(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—Every establishment in any State registered with the Secretary under this section shall be subject to inspection under section 704, and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

''(h) FOREIGN ESTABLISHMENTS SHALL REGISTER.—Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) of this section and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

''(i) REGISTRATION INFORMATION.—

''(1) PRODUCT LIST.—Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which has not been

included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied 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 manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

''(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

''(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY-EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—

''(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for intro-

duction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of June 1, 2003, shall, at least 90 days prior to making such 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 the Secretary by a notice published in the Federal Register stating good cause therefore.

''(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 903, 904, 907, 908, 909, 910, 911, or 704, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this chapter, or when relevant in any proceeding under this chapter.

''(d) RESTRICTIONS.—

''(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribu-

tion of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and 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 Sec-

retary 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 pe-

tition, 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 demonstrations 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 product 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, amend-

ment, 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 product 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 standard is no longer appropriate for the protection of the public health.

''(E) CONSIDERATION BY SECRETARY.—The Secretary shall consider all information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand, and shall issue the standard if the Secretary determines that the standard would be appropriate for the protection of the public health.

''(F) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

''(2) PROMULGATION.—

''(A) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a tobacco product standard and after 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 Secretary to issue a regulation establishing a tobacco product standard—

''(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll your own tobacco products; or

''(B) requiring the reduction of nicotine yields of a tobacco product to zero,

Congress expressly reserves to itself such power.

''(4) AMENDMENT; REVOCATION.—

''(A) AUTHORITY.—The Secretary, upon the Secretary's own initiative or upon petition of an interested person may by a regulation, promulgated in accordance with the requirements of paragraphs (1) and (2)(B), amend or revoke a tobacco product standard.

''(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest.

''(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 Secretary 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 eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

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

''(c) RECALL AUTHORITY.—

''(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the

manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity 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 to-

bacco 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 tobacco 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) NEW TOBACCO PRODUCT DEFINED.—For purposes of this section the term 'new tobacco product' means—

"(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of June 1, 2003; or

"(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after June 1, 2003.

"(2) PREMARKET APPROVAL REQUIRED.—

"(A) NEW PRODUCTS.—Approval under this section of an application for premarket approval for any new tobacco product is required unless—

"(i) the manufacturer has submitted a report under section 905(j); and

"(ii) the Secretary has issued an order that the tobacco product—

"(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of June 1, 2003; and

"(II)(aa) is in compliance with the requirements of this Act; or

"(bb) is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

"(B) APPLICATION TO CERTAIN POST JUNE 1, 2003 PRODUCTS.—Subparagraph (A) shall not apply to a tobacco product—

"(i) 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; and

"(ii) for which a report was submitted under section 905(j) within such 15-month 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 informa-

tion to show that such aspect of such tobacco product fully meets such tobacco product standard 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 un-

derlying 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 distribu-

tion 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 requirements 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) withdrawing 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 applicant's last known address in the records of the Secretary.

''(f) RECORDS.—

''(1) ADDITIONAL INFORMATION.—In the case of any tobacco product for which an approval of an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such approval.

''(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all rea-

sonable times to have access to and copy and verify such records.

''(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may 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 mar-

keted tobacco products' means a tobacco product—

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

"(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

"(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

"(III) the tobacco product or its smoke does not contain or is free of a substance;

"(ii) the label, labeling, or advertising of which uses the descriptors 'light', 'mild', or 'low' or similar descriptors; or

"(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling or adver-

tising, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, respecting the product that would be reasonably 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.

''(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.

''(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to an advisory committee under paragraph (1), the advisory committee shall report its recommendations on the application to the Secretary.

''(g) APPROVAL.—

''(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Secretary shall approve an application for a modified risk tobacco product filed under this section only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

''(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

''(B) benefit the health of the population as a whole taking into account both users of to-

bacco products and persons who do not currently use tobacco products.

''(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

''(A) IN GENERAL.—The Secretary may approve an application for a tobacco product that has not been approved as a modified risk 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 measurable and substantial reduction in morbidity or mortality among individual tobacco users is anticipated in subsequent studies.

''(B) ADDITIONAL FINDINGS REQUIRED.—In order to approve an application under subparagraph (A) the Secretary must also find that the applicant has demonstrated that—

''(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

''(ii) the product as actually used by consumers will not expose them to higher

levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the anticipated overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

''(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

''(I) is or has been demonstrated to be less harmful; or

''(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

''(iv) approval of the application is expected to 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.

''(C) CONDITIONS OF APPROVAL.—

''(i) IN GENERAL.—Applications approved under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

''(ii) AGREEMENTS BY APPLICANT.—Applications approved under this paragraph shall be conditioned on the applicant's agreement to conduct post-market surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the application approval on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the approval was based in accordance with a protocol approved by the Secretary.

''(iii) ANNUAL SUBMISSION.—The results of such post-market surveillance and studies described in clause (ii) shall be submitted annually.

''(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

''(A) the scientific evidence submitted by the applicant; and

''(B) scientific evidence and other information that is available to the Secretary.

''(4) BENEFIT TO HEALTH OF INDIVIDUALS AND OF POPULATION AS A WHOLE.—In making the determinations under paragraphs (1) and (2), the Secretary shall take into account—

''(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

''(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

''(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

''(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the

use of products for smoking cessation approved under chapter V to treat nicotine dependence; and

''(E) comments, data, and information submitted by interested persons.

''(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 requirements relating to advertising and promotion of the tobacco product.

''(i) POSTMARKET SURVEILLANCE AND STUDIES.—

''(1) IN GENERAL.—The Secretary shall require that an applicant under subsection (g)(1) conduct post market surveillance and studies for a tobacco product for which an application has been approved to determine the impact of the application approval on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the approval was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of post-market surveillance and studies shall be submitted to the Secretary on an annual basis.

''(2) SURVEILLANCE PROTOCOL.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days

after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance 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.

"SEC. 912. JUDICIAL REVIEW.

"(a) RIGHT TO REVIEW.—

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

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

"(B) a denial of an application for approval under section 910(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

"(2) REQUIREMENTS.—

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

''(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which such petition was filed—

''(i) the record of the proceedings on which the regulation or order was based; and

''(ii) a statement of the reasons for the issuance of such a regulation or order.

''(C) DEFINITION OF RECORD.—In this section, the term 'record' means—

''(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

''(ii) all information submitted to the Secretary with respect to such regulation or order;

''(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

''(iv) any hearing held with respect to such regulation or order; and

''(v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regula-

tion or order, as being relevant to such regulation or order.

''(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation 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).

''(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a) shall require testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and subbrand that the Secretary determines should be tested to protect the public health. The regulations may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco related disease.

''(c) AUTHORITY.—The Food and Drug Administration shall have the authority under this chapter to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

"SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHORITY.

''(a) IN GENERAL.—

''(1) PRESERVATION.—Nothing in this chapter, or rules promulgated under this chapter, shall be 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 reduced risk 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 11-member advisory committee, to be known as the 'Tobacco Products Scientific Advisory Committee'.

"(b) MEMBERSHIP.—

"(1) IN GENERAL.—

"(A) MEMBERS.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in the medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

"(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

''(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

''(iii) 1 individual as a representative of the general public;

''(iv) 1 individual as a representative of the interests in the tobacco manufacturing industry; and

''(v) 1 individual as a representative of the interests of the tobacco growers.

''(B) NONVOTING MEMBERS.—The members of the committee appointed under clauses (iv) and (v) of subparagraph (A) shall serve as consultants to those described in clauses (i) through (iii) of subparagraph (A) and shall be nonvoting representatives.

''(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Food and Drug Administration or any agency responsible for the enforcement of this Act. The Secretary may appoint Federal officials as ex officio members.

''(3) CHAIRPERSON.—The Secretary shall designate 1 of the members of the Advisory Committee to serve as chairperson.

''(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Secretary—

''(1) as provided in this chapter;

''(2) on the effects of the alteration of the nicotine yields from tobacco products;

''(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

''(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

''(d) COMPENSATION; SUPPORT; FACA.—

''(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect for level 4 of the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each mem-

ber may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

''(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

''(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) does not apply to the Advisory Committee.

''(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

''SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

''The Secretary shall consider—

''(1) at the request of the applicant, designating nicotine replacement products as fast track research and approval products within the meaning of section 506;

''(2) direct the Commissioner to consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence;

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

''(4) consider—

''(A) relieving companies of premarket burdens under section 505 if the requirement is redundant considering other nicotine replacement therapies already on the market; and

''(B) time and extent applications for nicotine replacement therapies that have been approved by a regulatory body in a foreign country and have marketing experience in such country.

''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 2004, 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 sub-

ject 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 2004 shall be $85,000,000;

"(B) for fiscal year 2005 shall be $175,000,000;

"(C) for fiscal year 2006 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 manufacturers and importers of such class of tobacco products as determined under subsection (e).

''(2) NO FEE IN EXCESS OF MARKET SHARE.—No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the market share of such manufacturer or importer.

''(e) DETERMINATION OF VOLUME OF DOMESTIC SALES.—

''(1) IN GENERAL.—The calculation of gross domestic volume of a class of tobacco product by a manufacturer or importer, and by all manufacturers

and importers as a group, shall be made by the Secretary using information provided by manufacturers and importers pursuant to subsection (f), as well as any other relevant information provided to or obtained by the Secretary.

''(2) MEASUREMENT.—For purposes of the calculations under this subsection and the information provided under subsection (f) by the Secretary, gross domestic volume shall be measured by—

''(A) in the case of cigarettes, the number of cigarettes sold;

''(B) in the case of little cigars, the number 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 subsection or that provides false information under this subsection shall be subject to the penalties described in section 1003 of title 18, United States Code. In addition, such person may be subject to a civil penalty in an amount not to exceed 2 percent of the value of the kind of tobacco products manufactured or imported by such person during the applicable quarter, as determined by the Secretary.

''(h) EFFECTIVE DATE.—The user fees prescribed by this section shall be assessed in fiscal year 2004, based on domestic sales of tobacco products during fiscal year 2003 and shall be assessed in each fiscal year thereafter.''.

SEC. 232. INTERIM FINAL RULE.

(a) CIGARETTES AND SMOKELESS TOBACCO.—

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

(2) CONTENTS OF RULE.—Except as provided in this subsection, the interim final rule published under paragraph (1), shall be identical in its provisions to part 897 of the 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). Such rule shall—

(A) provide for the designation of jurisdictional authority that is in accordance with this subsection;

(B) strike Subpart C—Labeling and section 897.32(c); and

(C) become effective not later than 1 year after the date of enactment of this Act.

(3) AMENDMENTS TO RULE.—Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule

in accordance with the Administrative Procedures Act.

(4) RULE OF CONSTRUCTION.—Except as provided in paragraph (3), nothing in this section shall be construed to limit the authority of the Secretary to amend, in accordance with the Administrative Procedures Act, the regulation promulgated pursuant to this section.

(b) LIMITATION ON ADVISORY OPINIONS.—As of the date of enactment of this Act, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document entitled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents'' (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document entitled ''Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices

Under the Federal Food, Drug, and Cosmetic Act'' (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document entitled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document entitled ''Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional 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.

''(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

''(dd) The charitable distribution of tobacco products.

''(ee) The failure of a manufacturer or distributor to notify the Attorney General of their knowledge of tobacco products used in illicit trade.''.

(c) SECTION 303.—Section 303 (21 U.S.C. 333(f)) is amended in subsection (f)—

(1) by striking the subsection heading and inserting the following:

''(f) CIVIL PENALTIES; NO-TOBACCO-SALE ORDERS.—'';

(2) in paragraph (1)(A), by inserting ''or tobacco products'' after ''devices'';

(3) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), and inserting after paragraph (2) the following:

''(3) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet 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).'';

(4) 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.'';

(5) 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

(6) 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 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 Control Act, and annually thereafter, the Secretary 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 regarding—

''(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;

''(B) the public health implications of such exports, including any evidence of a negative public health impact; and

''(C) recommendations or assessments of policy alternatives available to Congress and the Executive Branch to reduce any negative public health impact caused by such exports.

''(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.''.

(k) SECTION 1003.—Section 1003(d)(2)(C) (as redesignated by section 101(a)) is amended—

(1) by striking ''and'' after ''cosmetics,''; and

(2) inserting a comma and ''and tobacco products'' after ''devices''.

(l) EFFECTIVE DATE FOR NO-TOBACCO-SALE ORDER AMENDMENTS.—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 by the Secretary of Health and Human Services—

(1) defining the term ''repeated violation'', as used in section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) as amended by subsection (c), by identifying the number of viola-

tions of particular requirements over a specified period of time at a particular retail outlet that constitute a repeated violation;

(2) providing for timely and effective notice to the retailer of each alleged violation at a particular retail outlet and an expedited procedure for the administrative appeal of an alleged violation;

(3) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

(4) establishing a period of time during which, if there are no violations by a particular retail outlet, that outlet will not be considered to have been the site of repeated violations when the next violation occurs; and

(5) providing that good faith reliance on the presentation of a false government issued photographic identification that contains the bearer's 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—

(A) adopting and enforcing a written policy against sales to minors;

(B) informing its employees of all applicable laws;

(C) establishing disciplinary sanctions for employee noncompliance; and

(D) requiring its employees to verify age by way of photographic identification or electronic scanning device.

CHAPTER 2—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

SEC. 241. 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'.

'WARNING: Tobacco smoke causes fatal lung disease in non-smokers'.

'WARNING: Quitting smoking now greatly reduces serious risks to your health'.

''(2) PLACEMENT; TYPOGRAPHY; ETC.—

''(A) IN GENERAL.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Except as provided in subparagraph (B), each label statement shall comprise at least the top 30 percent of the front and rear panels of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the

text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white 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)(4).

''(B) FLIP-TOP BOXES.—For any cigarette brand package manufactured or distributed before January 1, 2000, which employs a flip-top 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 flip-top 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.

''(5) MARKETING REQUIREMENTS.—

''(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 cigarettes 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.

''(6) APPLICABILITY TO RETAILERS.—This subsection 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 displays, in a location open to the public, an advertise-

ment that is not labeled in accordance with the requirements of this subsection.''.

SEC. 242. 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 241, is further amended by adding at the end the following:

''(c) 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. 243. 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. 244. 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 para-

graph. 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. 245. 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 amended by section 243, is further amended by adding at the end the following:

''(d) AUTHORITY TO REVISE WARNING LABEL 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 smokeless tobacco products.''.

SEC. 246. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.

Section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333 (a)), as amended by sec-

tion 241, is further amended by adding at the end the following:

''(4)(A) The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary's sole discretion) 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.''.

CHAPTER 3—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 251. 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 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.

''(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been—

''(A) imported, exported, distributed or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

''(B) imported, exported, distributed or diverted for possible illicit marketing,

the manufacturer or distributor shall promptly notify the Attorney General of such knowledge.

''(e) KNOWLEDGE DEFINED.—For purposes of this subsection, the term 'knowledge' as applied to a manufacturer or distributor means—

''(1) the actual knowledge that the manufacturer or distributor had; or

''(2) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

SEC. 252. 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; and

(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—

''(I) is served in a restaurant or similar retail food establishment; or

''(II) is processed and prepared primarily in a retail 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 of the establishment shall disclose the information described in subclause (ii).

''(ii) INFORMATION REQUIRED TO BE DISCLOSED.—Except as provided in clause (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 approved by the Secretary, the number of calories, grams of saturated fat plus trans fat, and milligrams of sodium contained in a serving of the food, as 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 approved by the Secretary, the number of calories contained in a serving of the food, as offered for sale, in a clear and conspicuous manner.

''(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, other items placed on the table or counter for general use, and items from salad bars or other self-service facilities); or

''(II) daily specials, temporary menu items, or other irregular menu items, as specified by the Secretary by regulation.

''(iv) SELF-SERVICE FACILITIES.—

''(I) IN GENERAL.—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 the name of each food offered.

''(II) VENDING MACHINES.—In the case of an article of food sold from a vending machine or other arrangement that does not permit a

prospective purchaser to examine the article so as to be able to read a statement affixed to the article as required under subclause (I) before purchasing the article, a restaurant or other establishment (or, in the case of a vending machine that is owned and operated by a vending machine operator, the vending machine operator) shall provide a conspicuous sign, in close proximity to the article, identifying the food and including a statement disclosing the number of calories contained in the article.

''(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 pro-

vide 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, identifying the food and including 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 nutri-

tion 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 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) 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 allow 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 or it determines advertising to children to be unfair or deceptive.

(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) is amended by adding at the end the following:

''(d) 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 212, is further amended by adding at the end the following:

"SEC. 399S. 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;

''(C) has expertise in conducting a multimedia communications campaign; and

''(D) has expertise in developing strategies that affect behavior changes in children and other targeted populations.

''(c) APPLICATION.—An eligible entity shall submit an application to the Secretary for a grant under this section at such time, in such manner, and accompanied by such information as the Secretary may require.

''(d) USE OF FUNDS.—An eligible entity shall use amounts received under a grant under this section to—

''(1) design and implement multimedia public education and social marketing campaigns that—

''(A) discourage the use of tobacco products;

''(B) encourage the use of products designed to enable tobacco use cessation; and

''(C) educate the public about the hazards of environmental tobacco smoke exposure; or

''(2) conduct research related to the effectiveness of the campaigns described in paragraph (1).

''(e) ALLOCATION OF GRANTS.—Of the amounts awarded under this section, the Secretary shall award—

''(1) 50 percent of such amounts to eligible 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, 2005, 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, 2005, 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-

mine the percentage reduction (if any) in youth cigarette use for each manufacturer of cigarettes.

(d) PARTICIPATION IN SURVEY.—Notwithstanding any other provision of law, the Secretary may conduct a survey under this section involving minors if the results of such survey with respect to such minors are kept confidential and not disclosed.

(e) NONAPPLICABILITY.—Chapter 35 of title 44, United States Code, shall not apply to information required for the purposes of carrying out this section.

(f) DEFINITION.—In this subtitle the term ''cigarette'' has the meaning given such term in section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)).

SEC. 312. CIGARETTE USE REDUCTION GOAL AND NONCOMPLIANCE.

(a) GOAL.—It shall be the cigarette use reduction goal that each manufacturer reduce youth cigarette use by at least 15 percent during the period between the Monitoring the Future survey referred to in section 311(b)(1) and the completion of the first annual cigarette survey (and such subsequent surveys as compared to the previous year's survey) referred to in section 311(a).

(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, 2005, 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 full.

(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 642(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2322), is amended—

(A) in subparagraph (Y), by striking ''and'' after the semicolon at the end;

(B) in subparagraph (Z), by adding ''and'' after the semicolon at the end; and

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

''(AA) substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in subsection (bbb)(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)(AA))'' 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)), as amended by section 611(d)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2304), are each amended by striking ''subsection (ww)(1)'' and inserting ''subsections (ww)(1) and (bbb)''.

(b) SERVICES DESCRIBED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 706(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2339), is amended by adding at the end the following new subsection:

''Substance Use (Other Than Tobacco), Diet, Exercise, Injury Prevention, and Dental Health Counseling

''(bbb) 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)), as amended by section 302(b)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2229), is amended—

(A) in subparagraph (N), by inserting ''or substance use (other than tobacco), diet, exercise, injury prevention, and dental health coun-

seling (as defined in section 1861(bbb))'' 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(bbb) the amount paid shall be the lesser of the actual charge for the services or the amount determined 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 611(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2304), is amended by inserting ''(2)(AA),'' after ''(2)(W),''.

(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)), as amended by section 614(a) of the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2306), 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(bbb)) 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)) is amended—

(A) by striking ''and'' before ''(6)''; and

(B) by inserting before the period at the end the following: '', and (7) 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(bbb))''.

(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(bbb)(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 take effect as if included in the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2066) and shall apply to services furnished on and after January 1, 2005.

SEC. 402. PREVENTIVE MENTAL HEALTH SCREENINGS.

(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 401(a)(1), 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) screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in subsection (ccc)(1));''.

(2) 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 (bbb)'' and inserting ''(bbb), and (ccc)''.

(b) 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:

''Screenings for Clinical Depression, Anxiety, and Impaired Cognitive Functioning

''(ccc)(1) The term 'screening for clinical depression, anxiety, and impaired cognitive functioning' means a consultation for the purpose of detecting clinical depression, anxiety, and impaired cognitive functioning during which a qualified health professional (as defined in paragraph (2))—

''(A) uses a screening on the list established or identified under paragraph (3);

''(B) assesses the individual's risk of clinical depression, anxiety, and impaired cognitive functioning; and

''(C) if the qualified health professional determines that the individual is at high risk for clinical depression, anxiety, or impaired cognitive functioning, refers the individual for a full diagnostic evaluation and such additional treatment as may be required.

Nothing in subparagraph (C) shall be construed as prohibiting a qualified health professional performing the screening for clinical depression, anxiety, and impaired cognitive functioning with respect to an individual from directly providing the diagnostic evaluation and additional treatment described in such clause to such individual if such profes-

sional is legally authorized to provide such an evaluation and additional treatment under State law (or the State regulatory mechanism provided by State law) of the State in which the screening is performed.

''(2) For purposes of this subsection, the term 'qualified health professional' means an individual who—

''(A) is—

''(i) a physician (as defined in subsection (r)(1));

''(ii) a nurse practitioner (as defined in subsection (aa)(5)); or

''(iii) a mental health care professional (including clinical psychologists (as defined by the Secretary for purposes of section 1861(ii)) and clinical social workers (as defined in subsection 1861(hh))) that is licensed or certified to perform mental health services by the State in which the screenings are performed; and

''(B) has an agreement in effect with the Secretary to accept—

''(i) the amount determined under section 1833(a)(1)(W) as full payment for screenings for clinical depression, anxiety, and impaired cognitive functioning; and

''(ii) an assignment described in section 1842(b)(3)(B)(ii) with respect to payment for each screening furnished by the professional to an individual enrolled under part B.

''(3) The Secretary shall, in consultation with mental health professionals and other stakeholders with experience in screening for clinical depression, anxiety, and impaired cognitive functioning, shall establish or identify a list of approved screenings to be used under this paragraph. The Secretary, in consultation with such professionals and stakeholders, shall review and update such list not less frequently than once every 5 years.''.

(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)), as amended by section 401(c)(1), is amended—

(A) in subparagraph (N), by striking ''or substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in section 1861(bbb))'' and inserting ''substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in section

1861(bbb)), or screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))''; and

(B) in subparagraph (W), by inserting ''and screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))'' after ''(as defined in section 1861(bbb))''.

(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 401(c)(2), 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)), as amended by section 401(c)(3)(A), is amended by striking ''or substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as defined in section 1861(bbb))'' and inserting ''substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling (as de-

fined in section 1861(bbb)), or screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))''.

(B) CONFORMING AMENDMENT.—Section 1833(a)(2)(H) of the Social Security Act (42 U.S.C. 1395l(a)(2)(H)), as added by section 401(c)(3)(B)(iii), is amended by inserting ''and screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))'' after ''(as defined in section 1861(bbb))''.

(4) ELIMINATION OF DEDUCTIBLE.—Section 1833(b)(7) of the Social Security Act (42 U.S.C. 1395l(b)(7)), as amended by section 401(c)(4), is amended by inserting ''or screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))'' before the period at the end.

(d) 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) A mental health care professional described in section 1861(ccc)(2) that is authorized to

perform screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc)(1)) that is not otherwise described in this subparagraph.''.

(e) FREQUENCY.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)), as amended by section 613(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2306), is amended—

(1) in subparagraph (L), by striking ''and'' after the comma at the end;

(2) in subparagraph (M), by striking the semicolon at the end and inserting '', and''; and

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

''(N) in the case of screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc)(1)), which is performed more frequently than is covered under such section;''.

(f) EFFECTIVE DATE.—The amendments made by this section shall take effect as if included in the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117

Stat. 2066) and shall apply to services furnished on and after January 1, 2005.

SEC. 403. 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 402(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 402(a)(2), 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 402(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 products or who are being treated for tobacco use which are furnished—

''(A) by or under the supervision of a physician; or

''(B) by any other health care professional who—

''(i) 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

''(ii) is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose.

''(2) Such term is limited to—

''(A) services recommended in 'Treating Tobacco Use and Dependence: A Clinical Practice Guideline', published by the Public Health Service in June 2000, or any subsequent modification of such Guideline; and

''(B) such other services that the Secretary recognizes to be effective.

''(3) Each individual who is described in paragraph (1) and enrolled under part B shall be eligible for the services described in this subsection for up to 3 attempts to cease the use of tobacco.''.

(3) PAYMENT AND ELIMINATION OF COST-SHARING.—

(A) PAYMENT AND ELIMINATION OF COINSURANCE.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)), as amended by section 402(c)(1), is amended—

(i) in subparagraph (N) by striking ''or screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))'' and insert-

ing ", screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc)), or counseling and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd))"; and

(ii) in subparagraph (W), by striking "and screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))" and inserting "screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc)), and counseling and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd))".

(B) 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 402(c)(2), is amended by inserting "(2)(CC) (with separate payment amounts for pharmacotherapy, including prescription and nonprescription tobacco cessation agents approved by the Food and Drug Administration)," after "(2)(BB),".

(C) ELIMINATION OF COINSURANCE IN OUTPATIENT HOSPITAL SETTINGS.—

(i) 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)), as amended by section 402(c)(3)(A), is amended by striking ''or screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))'' and inserting ''screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc)), or counseling and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd))''.

(ii) CONFORMING AMENDMENT.—Section 1833(a)(2)(H) of the Social Security Act (42 U.S.C. 1395l(a)(2)(H)), as added by section 402(c)(3)(B), is amended by striking ''and screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))'' and inserting ''screenings for clinical depression, anxiety, and impaired

cognitive functioning (as defined in section 1861(ccc)), and counseling and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd))''.

(D) ELIMINATION OF DEDUCTIBLE.—Section 1833(b)(7) of the Social Security Act (42 U.S.C. 1395l(b)(7)), as added by section 402(c)(4), is amended by striking ''or screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc))'' and inserting ''screenings for clinical depression, anxiety, and impaired cognitive functioning (as defined in section 1861(ccc)), or counseling and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd))''.

(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 402(d), is amended by adding at the end the following new clause:

''(ix) 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 402(e), 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;''.

(b) PROMOTING CESSATION OF TOBACCO USE UNDER THE MEDICAID PROGRAM.—

(1) DROPPING EXCEPTION FROM MEDICAID PRESCRIPTION DRUG COVERAGE FOR TOBACCO CESSATION MEDICATIONS.—Section 1927(d)(2) of the Social Security Act (42 U.S.C. 1396r–8(d)(2)) is amended—

(A) by striking subparagraph (E);

(B) by redesignating subparagraphs (F) through (J) as subparagraphs (E) through (I), respectively; and

(C) in subparagraph (F) (as redesignated by paragraph (2)), by inserting before the period at the end the following: ‘‘, except agents approved by the Food and Drug Administration for purposes of promoting, and when used to promote, tobacco cessation’’.

(2) REQUIRING COVERAGE OF TOBACCO CESSATION COUNSELING AND PHARMACOTHERAPY SERVICES FOR PREGNANT WOMEN.—Section 1905(a)(4) of the Social Security Act (42 U.S.C. 1396d(a)(4)) is amended—

(A) by striking ‘‘and’’ before ‘‘(C)’’; and

(B) by inserting before the semicolon at 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 take effect as if included in the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2066) and shall apply to services furnished on and after January 1, 2005.

SEC. 404. 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 paragraph (1) through (3), and ensuring, to the extent practicable, the provision of appropriate follow-up services; and

''(5) to evaluate the activities conducted under paragraphs (1) through (4) through appropriate surveillance, research, or program monitoring activities.

''(b) STATUS AS PARTICIPANT IN PROGRAM REGARDING BREAST AND CERVICAL CANCER.—The Secretary

may not make a grant to a State under subsection (a) unless the State involved agrees that services under the grant will be provided in conjunction with entities that are screening women for breast or cervical cancer pursuant to a grant under section 1501.

''(c) APPLICABILITY OF PROVISIONS.—The provisions of this title shall apply to a grant under subsection (a) to the same extent and in the same manner as such provisions apply to a grant under section 1501.

''(d) FUNDING.—

''(1) IN GENERAL.—There is authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2004 and for each subsequent fiscal year.

''(2) LIMITATION REGARDING FUNDING WITH RESPECT TO BREAST AND CERVICAL CANCER.—No additional resources shall be appropriated for a fiscal 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 VII 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 2005) 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) Smoking cessation drugs under title XIX of the Social Security Act as identified by the Secretary of Health and Human Services.

(B) Coverage of smoking cessation under the Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code.

(C) The amendments made to the medicare program under title XVIII of the Social Security Act by sections 401 and 402 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 $1,600,000,000 shall be available, as provided in appropriation Acts, for each fiscal year (beginning with fiscal year 2005) only for purposes of making expenditures to carry out the following:

(A) Fruit and vegetable program under section 18(g) of the Richard B. Russell National School Lunch Act.

(B) Healthy school and child care nutrition under section 18(h) of the Richard B. Russell National School Lunch Act.

(C) Mental health services in schools under paragraphs (7) and (8) of section 5541(c) of the Elementary and Secondary Education Act of 1965.

(D) Healthy workforce grants under part R of title III of the Public Health Service Act.

(E) Community grants to prevent and reduce the incidence of chronic disease under section 399P of the Public Health Service Act.

(F) Living well with a disability and working well with a disability programs under sections 399Q and 399R of the Public Health Service Act.

(G) Complete streets incentive program under section 133(g) of title 23, United States Code.

(H) Mental health surveillance measures under section 506C of the Public Health Service Act.

(I) Federal-State tobacco counter-advertising programs under section 399S of the Public Health Service Act.

(J) 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.

(K) Carol M. White Physical Education Program under subpart 10 of part D of title V of the Elementary and Secondary Education Act of 1965.

(L) Research regarding obesity under section 601 of this Act.

(M) Expanded Food and Nutrition Education Program under section 3175 of title 23, United States Code.

(N) 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) Coordinated school health.

(iii) Verb Campaign.

(iv) Prevention research centers.

(v) 5-a-day programs.

(vi) Steps to a healthier United States.

(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.

TITLE VII—PROVISIONS DESIGNED TO CURTAIL TAX SHELTERS

SEC. 700. AMENDMENT OF 1986 CODE.

Except as otherwise expressly provided, whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.

SEC. 701. CLARIFICATION OF ECONOMIC SUBSTANCE DOCTRINE.

(a) IN GENERAL.—Section 7701 is amended by redesignating subsection (n) as subsection (o) and by inserting after subsection (m) the following new subsection:

''(n) CLARIFICATION OF ECONOMIC SUBSTANCE DOCTRINE; ETC.—

''(1) GENERAL RULES.—

''(A) IN GENERAL.—In any case in which a court determines that the economic substance doctrine is relevant for purposes of this title to a transaction (or series of transactions), such transaction (or series of transactions) shall have economic substance only if the requirements of this paragraph are met.

''(B) DEFINITION OF ECONOMIC SUBSTANCE.—For purposes of subparagraph (A)—

''(i) IN GENERAL.—A transaction has economic substance only if—

''(I) the transaction changes in a meaningful way (apart from Federal tax effects) the taxpayer's economic position, and

''(II) the taxpayer has a substantial nontax purpose for entering into such transaction and the transaction is a reasonable means of accomplishing such purpose.

In applying subclause (II), a purpose of achieving a financial accounting benefit shall not be taken into account in determining whether a transaction has a substantial nontax purpose if the origin of

such financial accounting benefit is a reduction of income tax.

''(ii) SPECIAL RULE WHERE TAXPAYER RELIES ON PROFIT POTENTIAL.—A transaction shall not be treated as having economic substance by reason of having a potential for profit unless—

''(I) the present value of the reasonably expected pre-tax profit from the transaction is substantial in relation to the present value of the expected net tax benefits that would be allowed if the transaction were respected, and

''(II) the reasonably expected pre-tax profit from the transaction exceeds a risk-free rate of return.

''(C) TREATMENT OF FEES AND FOREIGN TAXES.—Fees and other transaction expenses and foreign taxes shall be taken into account as expenses in determining pre-tax profit under subparagraph (B)(ii).

''(2) SPECIAL RULES FOR TRANSACTIONS WITH TAX-INDIFFERENT PARTIES.—

''(A) SPECIAL RULES FOR FINANCING TRANSACTIONS.—The form of a transaction which is in substance the borrowing of money or the acquisition of financial capital directly or indirectly from a tax-indifferent party shall not be respected if the present value of the deductions to be claimed with respect to the transaction is substantially in excess of the present value of the anticipated economic returns of the person lending the money or providing the financial capital. A public offering shall be treated as a borrowing, or an acquisition of financial capital, from a tax-indifferent party if it is reasonably expected that at least 50 percent of the offering will be placed with tax-indifferent parties.

''(B) ARTIFICIAL INCOME SHIFTING AND BASIS ADJUSTMENTS.—The form of a transaction with a tax-indifferent party shall not be respected if—

''(i) it results in an allocation of income or gain to the tax-indifferent party in excess of such party's economic income or gain, or

"(ii) it results in a basis adjustment or shifting of basis on account of overstating the income or gain of the tax-indifferent party.

"(3) DEFINITIONS AND SPECIAL RULES.—For purposes of this subsection—

"(A) ECONOMIC SUBSTANCE DOCTRINE.—The term 'economic substance doctrine' means the common law doctrine under which tax benefits under subtitle A with respect to a transaction are not allowable if the transaction does not have economic substance or lacks a business purpose.

"(B) TAX-INDIFFERENT PARTY.—The term 'tax-indifferent party' means any person or entity not subject to tax imposed by subtitle A. A person shall be treated as a tax-indifferent party with respect to a transaction if the items taken into account with respect to the transaction have no substantial impact on such person's liability under subtitle A.

"(C) EXCEPTION FOR PERSONAL TRANSACTIONS OF INDIVIDUALS.—In the case of an individual, this subsection shall apply only to transactions entered into in connection with a

trade or business or an activity engaged in for the production of income.

''(D) TREATMENT OF LESSORS.—In applying paragraph (1)(B)(ii) to the lessor of tangible property subject to a lease, the expected net tax benefits with respect to the leased property shall not be taken into account.

''(4) OTHER COMMON LAW DOCTRINES NOT AFFECTED.—Except as specifically provided in this subsection, the provisions of this subsection shall not be construed as altering or supplanting any other rule of law, and the requirements of this subsection shall be construed as being in addition to any such other rule of law.

''(5) REGULATIONS.—The Secretary shall prescribe such regulations as may be necessary or appropriate to carry out the purposes of this subsection. Such regulations may include exemptions from the application of this subsection.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to transactions entered into after the date of the enactment of this Act.

SEC. 702. PENALTY FOR FAILING TO DISCLOSE REPORTABLE TRANSACTION.

(a) IN GENERAL.—Part I of subchapter B of chapter 68 (relating to assessable penalties) is amended by inserting after section 6707 the following new section:

"SEC. 6707A. PENALTY FOR FAILURE TO INCLUDE REPORTABLE TRANSACTION INFORMATION WITH RETURN OR STATEMENT.

"(a) IMPOSITION OF PENALTY.—Any person who fails to include on any return or statement any information with respect to a reportable transaction which is required under section 6011 to be included with such return or statement shall pay a penalty in the amount determined under subsection (b).

"(b) AMOUNT OF PENALTY.—

"(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), the amount of the penalty under subsection (a) shall be $50,000.

"(2) LISTED TRANSACTION.—The amount of the penalty under subsection (a) with respect to a listed transaction shall be $100,000.

"(3) INCREASE IN PENALTY FOR LARGE ENTITIES AND HIGH NET WORTH INDIVIDUALS.—

"(A) IN GENERAL.—In the case of a failure under subsection (a) by—

"(i) a large entity, or

"(ii) a high net worth individual,

the penalty under paragraph (1) or (2) shall be twice the amount determined without regard to this paragraph.

"(B) LARGE ENTITY.—For purposes of subparagraph (A), the term 'large entity' means, with respect to any taxable year, a person (other than a natural person) with gross receipts in excess of $10,000,000 for the taxable year in which the reportable transaction occurs or the preceding taxable year. Rules similar to the rules of paragraph (2) and subparagraphs (B), (C), and (D) of paragraph (3) of section 448(c) shall apply for purposes of this subparagraph.

"(C) HIGH NET WORTH INDIVIDUAL.—For purposes of subparagraph (A), the term 'high net worth individual' means, with respect to a reportable transaction, a natural person whose net worth exceeds $2,000,000 immediately before the transaction.

"(c) DEFINITIONS.—For purposes of this section—

"(1) REPORTABLE TRANSACTION.—The term 'reportable transaction' means any transaction with respect to which information is required to be in-

cluded with a return or statement because, as determined under regulations prescribed under section 6011, such transaction is of a type which the Secretary determines as having a potential for tax avoidance or evasion.

''(2) LISTED TRANSACTION.—Except as provided in regulations, the term 'listed transaction' means a reportable transaction which is the same as, or substantially similar to, a transaction specifically identified by the Secretary as a tax avoidance transaction for purposes of section 6011.

''(d) AUTHORITY TO RESCIND PENALTY.—

''(1) IN GENERAL.—The Commissioner of Internal Revenue may rescind all or any portion of any penalty imposed by this section with respect to any violation if—

''(A) the violation is with respect to a reportable transaction other than a listed transaction,

''(B) the person on whom the penalty is imposed has a history of complying with the requirements of this title,

''(C) it is shown that the violation is due to an unintentional mistake of fact;

''(D) imposing the penalty would be against equity and good conscience, and

''(E) rescinding the penalty would promote compliance with the requirements of this title and effective tax administration.

''(2) DISCRETION.—The exercise of authority under paragraph (1) shall be at the sole discretion of the Commissioner and may be delegated only to the head of the Office of Tax Shelter Analysis. The Commissioner, in the Commissioner's sole discretion, may establish a procedure to determine if a penalty should be referred to the Commissioner or the head of such Office for a determination under paragraph (1).

''(3) NO APPEAL.—Notwithstanding any other provision of law, any determination under this subsection may not be reviewed in any administrative or judicial proceeding.

''(4) RECORDS.—If a penalty is rescinded under paragraph (1), the Commissioner shall place in the file in the Office of the Commissioner the opinion of the Commissioner or the head of the Office of Tax Shelter Analysis with respect to the determination, including—

''(A) the facts and circumstances of the transaction,

''(B) the reasons for the rescission, and

''(C) the amount of the penalty rescinded.

''(5) REPORT.—The Commissioner shall each year report to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate—

''(A) a summary of the total number and aggregate amount of penalties imposed, and rescinded, under this section, and

''(B) a description of each penalty rescinded under this subsection and the reasons therefor.

''(e) PENALTY REPORTED TO SEC.—In the case of a person—

''(1) which is required to file periodic reports under section 13 or 15(d) of the Securities Exchange Act of 1934 or is required to be consolidated with another person for purposes of such reports, and

''(2) which—

''(A) is required to pay a penalty under this section with respect to a listed transaction,

''(B) is required to pay a penalty under section 6662A with respect to any reportable transaction at a rate prescribed under section 6662A(c), or

''(C) is required to pay a penalty under section 6662B with respect to any noneconomic substance transaction,

the requirement to pay such penalty shall be disclosed in such reports filed by such person for such periods as the Secretary shall specify. Failure to make a disclosure in accordance with the preceding sentence shall be treated as a failure to which the penalty under subsection (b)(2) applies.

''(f) COORDINATION WITH OTHER PENALTIES.—The penalty imposed by this section is in addition to any penalty imposed under this title.''.

(b) DISCLOSURE BY SECRETARY.—

(1) IN GENERAL.—Section 6103 is amended by redesignating subsection (q) as subsection (r) and by inserting after subsection (p) the following new subsection:

''(q) DISCLOSURE RELATING TO PAYMENTS OF CERTAIN PENALTIES.—Notwithstanding any other provision of this section, the Secretary shall make public the name

of any person required to pay a penalty described in section 6707A(e)(2) and the amount of the penalty.''.

(2) RECORDS.—Section 6103(p)(3)(A) is amended by striking ''or (n)'' and inserting ''(n), or (q)''.

(c) CONFORMING AMENDMENT.—The table of sections for part I of subchapter B of chapter 68 is amended by inserting after the item relating to section 6707 the following:

''Sec. 6707A. Penalty for failure to include reportable transaction information with return or statement.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to returns and statements the due date for which is after the date of the enactment of this Act.

SEC. 703. ACCURACY-RELATED PENALTY FOR LISTED TRANSACTIONS AND OTHER REPORTABLE TRANSACTIONS HAVING A SIGNIFICANT TAX AVOIDANCE PURPOSE.

(a) IN GENERAL.—Subchapter A of chapter 68 is amended by inserting after section 6662 the following new section:

"SEC. 6662A. IMPOSITION OF ACCURACY-RELATED PENALTY ON UNDERSTATEMENTS WITH RESPECT TO REPORTABLE TRANSACTIONS.

"(a) IMPOSITION OF PENALTY.—If a taxpayer has a reportable transaction understatement for any taxable year, there shall be added to the tax an amount equal to 20 percent of the amount of such understatement.

"(b) REPORTABLE TRANSACTION UNDERSTATEMENT.—For purposes of this section—

"(1) IN GENERAL.—The term 'reportable transaction understatement' means the sum of—

"(A) the product of—

"(i) the amount of the increase (if any) in taxable income which results from a difference between the proper tax treatment of an item to which this section applies and the taxpayer's treatment of such item (as shown on the taxpayer's return of tax), and

"(ii) the highest rate of tax imposed by section 1 (section 11 in the case of a taxpayer which is a corporation), and

"(B) the amount of the decrease (if any) in the aggregate amount of credits determined under subtitle A which results from a difference between the taxpayer's treatment of an item to

which this section applies (as shown on the taxpayer's return of tax) and the proper tax treatment of such item.

For purposes of subparagraph (A), any reduction of the excess of deductions allowed for the taxable year over gross income for such year, and any reduction in the amount of capital losses which would (without regard to section 1211) be allowed for such year, shall be treated as an increase in taxable income.

''(2) ITEMS TO WHICH SECTION APPLIES.—This section shall apply to any item which is attributable to—

''(A) any listed transaction, and

''(B) any reportable transaction (other than a listed transaction) if a significant purpose of such transaction is the avoidance or evasion of Federal income tax.

''(c) HIGHER PENALTY FOR NONDISCLOSED LISTED AND OTHER AVOIDANCE TRANSACTIONS.—

''(1) IN GENERAL.—Subsection (a) shall be applied by substituting '30 percent' for '20 percent' with respect to the portion of any reportable transaction understatement with respect to which the requirement of section 6664(d)(2)(A) is not met.

''(2) RULES APPLICABLE TO ASSERTION AND COMPROMISE OF PENALTY.—

''(A) IN GENERAL.—Only upon the approval by the Chief Counsel for the Internal Revenue Service or the Chief Counsel's delegate at the national office of the Internal Revenue Service may a penalty to which paragraph (1) applies be included in a 1st letter of proposed deficiency which allows the taxpayer an opportunity for administrative review in the Internal Revenue Service Office of Appeals. If such a letter is provided to the taxpayer, only the Commissioner of Internal Revenue may compromise all or any portion of such penalty.

''(B) APPLICABLE RULES.—The rules of paragraphs (2), (3), (4), and (5) of section 6707A(d) shall apply for purposes of subparagraph (A).

''(d) DEFINITIONS OF REPORTABLE AND LISTED TRANSACTIONS.—For purposes of this section, the terms 'reportable transaction' and 'listed transaction' have the respective meanings given to such terms by section 6707A(c).

''(e) SPECIAL RULES.—

''(1) COORDINATION WITH PENALTIES, ETC., ON OTHER UNDERSTATEMENTS.—In the case of an understatement (as defined in section 6662(d)(2))—

''(A) the amount of such understatement (determined without regard to this paragraph) shall be increased by the aggregate amount of reportable transaction understatements and noneconomic substance transaction understatements for purposes of determining whether such understatement is a substantial understatement under section 6662(d)(1), and

''(B) the addition to tax under section 6662(a) shall apply only to the excess of the amount of the substantial understatement (if any) after the application of subparagraph (A) over the aggregate amount of reportable transaction understatements and noneconomic substance transaction understatements.

''(2) COORDINATION WITH OTHER PENALTIES.—

''(A) APPLICATION OF FRAUD PENALTY.—References to an underpayment in section 6663 shall be treated as including references to a reportable transaction understatement and a noneconomic substance transaction understatement.

''(B) NO DOUBLE PENALTY.—This section shall not apply to any portion of an understatement on which a penalty is imposed under section 6662B or 6663.

''(3) SPECIAL RULE FOR AMENDED RETURNS.—Except as provided in regulations, in no event shall any tax treatment included with an amendment or supplement to a return of tax be taken into account in determining the amount of any reportable transaction understatement or noneconomic substance transaction understatement if the amendment or supplement is filed after the earlier of the date the taxpayer is first contacted by the Secretary regarding the examination of the return or such other date as is specified by the Secretary.

''(4) NONECONOMIC SUBSTANCE TRANSACTION UNDERSTATEMENT.—For purposes of this subsection, the term 'noneconomic substance transaction understatement' has the meaning given such term by section 6662B(c).

''(5) CROSS REFERENCE.—

"For reporting of section 6662A(c) penalty to the Securities and Exchange Commission, see section 6707A(e).".

(b) DETERMINATION OF OTHER UNDERSTATEMENTS.—Subparagraph (A) of section 6662(d)(2) is

amended by adding at the end the following flush sentence:

''The excess under the preceding sentence shall be determined without regard to items to which section 6662A applies and without regard to items with respect to which a penalty is imposed by section 6662B.''.

(c) REASONABLE CAUSE EXCEPTION.—

(1) IN GENERAL.—Section 6664 is amended by adding at the end the following new subsection:

''(d) REASONABLE CAUSE EXCEPTION FOR REPORTABLE TRANSACTION UNDERSTATEMENTS.—

''(1) IN GENERAL.—No penalty shall be imposed under section 6662A with respect to any portion of a reportable transaction understatement if it is shown that there was a reasonable cause for such portion and that the taxpayer acted in good faith with respect to such portion.

''(2) SPECIAL RULES.—Paragraph (1) shall not apply to any reportable transaction understatement unless—

''(A) the relevant facts affecting the tax treatment of the item are adequately disclosed in accordance with the regulations prescribed under section 6011,

''(B) there is or was substantial authority for such treatment, and

''(C) the taxpayer reasonably believed that such treatment was more likely than not the proper treatment.

A taxpayer failing to adequately disclose in accordance with section 6011 shall be treated as meeting the requirements of subparagraph (A) if the penalty for such failure was rescinded under section 6707A(d).

''(3) RULES RELATING TO REASONABLE BELIEF.—For purposes of paragraph (2)(C)—

''(A) IN GENERAL.—A taxpayer shall be treated as having a reasonable belief with respect to the tax treatment of an item only if such belief—

''(i) is based on the facts and law that exist at the time the return of tax which includes such tax treatment is filed, and

''(ii) relates solely to the taxpayer's chances of success on the merits of such treatment and does not take into account the possibility that a return will not be audited, such treatment will not be raised on

audit, or such treatment will be resolved through settlement if it is raised.

''(B) CERTAIN OPINIONS MAY NOT BE RELIED UPON.—

''(i) IN GENERAL.—An opinion of a tax advisor may not be relied upon to establish the reasonable belief of a taxpayer if—

''(I) the tax advisor is described in clause (ii), or

''(II) the opinion is described in clause (iii).

''(ii) DISQUALIFIED TAX ADVISORS.—A tax advisor is described in this clause if the tax advisor—

''(I) is a material advisor (within the meaning of section 6111(b)(1)) who participates in the organization, management, promotion, or sale of the transaction or who is related (within the meaning of section 267(b) or 707(b)(1)) to any person who so participates,

''(II) is compensated directly or indirectly by a material advisor with respect to the transaction,

''(III) has a fee arrangement with respect to the transaction which is contingent on all or part of the intended tax benefits from the transaction being sustained,

''(IV) has an arrangement with respect to the transaction which provides that contractual disputes between the taxpayer and the advisor are to be settled by arbitration or which limits damages by reference to fees paid to the advisor for such transaction, or

''(V) as determined under regulations prescribed by the Secretary, has a disqualifying financial interest with respect to the transaction.

''(iii) DISQUALIFIED OPINIONS.—For purposes of clause (i), an opinion is disqualified if the opinion—

''(I) is based on unreasonable factual or legal assumptions (including assumptions as to future events),

''(II) unreasonably relies on representations, statements, findings, or agreements of the taxpayer or any other person,

''(III) does not identify and consider all relevant facts,

''(IV) is not signed by all individuals who are principal authors of the opinion, or

''(V) fails to meet any other requirement as the Secretary may prescribe.''.

(2) CONFORMING AMENDMENT.—The heading for subsection (c) of section 6664 is amended by inserting ''FOR UNDERPAYMENTS'' after ''EXCEPTION''.

(d) CONFORMING AMENDMENTS.—

(1) Subparagraph (C) of section 461(i)(3) is amended by striking ''section 6662(d)(2)(C)(iii)'' and inserting ''section 1274(b)(3)(C)''.

(2) Paragraph (3) of section 1274(b) is amended—

(A) by striking ''(as defined in section 6662(d)(2)(C)(iii))'' in subparagraph (B)(i), and

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

''(C) TAX SHELTER.—For purposes of subparagraph (B), the term 'tax shelter' means—

''(i) a partnership or other entity,

''(ii) any investment plan or arrangement, or

''(iii) any other plan or arrangement, if a significant purpose of such partnership, entity, plan, or arrangement is the avoidance or evasion of Federal income tax.''.

(3) Section 6662(d)(2) is amended by striking subparagraphs (C) and (D).

(4) Section 6664(c)(1) is amended by striking ''this part'' and inserting ''section 6662 or 6663''.

(5) Subsection (b) of section 7525 is amended by striking ''section 6662(d)(2)(C)(iii)'' and inserting ''section 1274(b)(3)(C)''.

(6)(A) The heading for section 6662 is amended to read as follows:

"SEC. 6662. IMPOSITION OF ACCURACY-RELATED PENALTY ON UNDERPAYMENTS.".

(B) The table of sections for part II of subchapter A of chapter 68 is amended by striking the item relating to section 6662 and inserting the following new items:

"Sec. 6662. Imposition of accuracy-related penalty on underpayments.
"Sec. 6662A. Imposition of accuracy-related penalty on understatements with respect to reportable transactions.".

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

SEC. 704. PENALTY FOR UNDERSTATEMENTS ATTRIBUTABLE TO TRANSACTIONS LACKING ECONOMIC SUBSTANCE, ETC.

(a) IN GENERAL.—Subchapter A of chapter 68 is amended by inserting after section 6662A the following new section:

"SEC. 6662B. PENALTY FOR UNDERSTATEMENTS ATTRIBUTABLE TO TRANSACTIONS LACKING ECONOMIC SUBSTANCE, ETC.

"(a) IMPOSITION OF PENALTY.—If a taxpayer has an noneconomic substance transaction understatement for any taxable year, there shall be added to the tax an amount equal to 40 percent of the amount of such understatement.

''(b) REDUCTION OF PENALTY FOR DISCLOSED TRANSACTIONS.—Subsection (a) shall be applied by substituting '20 percent' for '40 percent' with respect to the portion of any noneconomic substance transaction understatement with respect to which the relevant facts affecting the tax treatment of the item are adequately disclosed in the return or a statement attached to the return.

''(c) NONECONOMIC SUBSTANCE TRANSACTION UNDERSTATEMENT.—For purposes of this section—

''(1) IN GENERAL.—The term 'noneconomic substance transaction understatement' means any amount which would be an understatement under section 6662A(b)(1) if section 6662A were applied by taking into account items attributable to noneconomic substance transactions rather than items to which section 6662A would apply without regard to this paragraph.

''(2) NONECONOMIC SUBSTANCE TRANSACTION.—The term 'noneconomic substance transaction' means any transaction if—

''(A) there is a lack of economic substance (within the meaning of section 7701(n)(1)) for the transaction giving rise to the claimed benefit or the transaction was not respected under section 7701(n)(2), or

''(B) the transaction fails to meet the requirements of any similar rule of law.

''(d) RULES APPLICABLE TO COMPROMISE OF PENALTY.—

''(1) IN GENERAL.—If the 1st letter of proposed deficiency which allows the taxpayer an opportunity for administrative review in the Internal Revenue Service Office of Appeals has been sent with respect to a penalty to which this section applies, only the Commissioner of Internal Revenue may compromise all or any portion of such penalty.

''(2) APPLICABLE RULES.—The rules of paragraphs (2), (3), (4), and (5) of section 6707A(d) shall apply for purposes of paragraph (1).

''(e) COORDINATION WITH OTHER PENALTIES.—Except as otherwise provided in this part, the penalty imposed by this section shall be in addition to any other penalty imposed by this title.

''(f) CROSS REFERENCES.—

''(1) For coordination of penalty with understatements under section 6662 and other special rules, see section 6662A(e).

''(2) For reporting of penalty imposed under this section to the Securities and Exchange Commission, see section 6707A(e).''.

(b) CLERICAL AMENDMENT.—The table of sections for part II of subchapter A of chapter 68 is amended by

inserting after the item relating to section 6662A the following new item:

"Sec. 6662B. Penalty for understatements attributable to transactions lacking economic substance, etc.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to transactions entered into after the date of the enactment of this Act.

SEC. 705. MODIFICATIONS OF SUBSTANTIAL UNDERSTATEMENT PENALTY FOR NONREPORTABLE TRANSACTIONS.

(a) SUBSTANTIAL UNDERSTATEMENT OF CORPORATIONS.—Section 6662(d)(1)(B) (relating to special rule for corporations) is amended to read as follows:

"(B) SPECIAL RULE FOR CORPORATIONS.—In the case of a corporation other than an S corporation or a personal holding company (as defined in section 542), there is a substantial understatement of income tax for any taxable year if the amount of the understatement for the taxable year exceeds the lesser of—

"(i) 10 percent of the tax required to be shown on the return for the taxable year (or, if greater, $10,000), or

"(ii) $10,000,000.".

(b) REDUCTION FOR UNDERSTATEMENT OF TAXPAYER DUE TO POSITION OF TAXPAYER OR DISCLOSED ITEM.—

(1) IN GENERAL.—Section 6662(d)(2)(B)(i) (relating to substantial authority) is amended to read as follows:

"(i) the tax treatment of any item by the taxpayer if the taxpayer had reasonable belief that the tax treatment was more likely than not the proper treatment, or".

(2) CONFORMING AMENDMENT.—Section 6662(d) is amended by adding at the end the following new paragraph:

"(3) SECRETARIAL LIST.—For purposes of this subsection, section 6664(d)(2), and section 6694(a)(1), the Secretary may prescribe a list of positions for which the Secretary believes there is not substantial authority or there is no reasonable belief that the tax treatment is more likely than not the proper tax treatment. Such list (and any revisions thereof) shall be published in the Federal Register or the Internal Revenue Bulletin.".

(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. 706. TAX SHELTER EXCEPTION TO CONFIDENTIALITY PRIVILEGES RELATING TO TAXPAYER COMMUNICATIONS.

(a) IN GENERAL.—Section 7525(b) (relating to section not to apply to communications regarding corporate tax shelters) is amended to read as follows:

''(b) SECTION NOT TO APPLY TO COMMUNICATIONS REGARDING TAX SHELTERS.—The privilege under subsection (a) shall not apply to any written communication which is—

''(1) between a federally authorized tax practitioner and—

''(A) any person,

''(B) any director, officer, employee, agent, or representative of the person, or

''(C) any other person holding a capital or profits interest in the person, and

''(2) in connection with the promotion of the direct or indirect participation of the person in any tax shelter (as defined in section 1274(b)(3)(C)).''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to communications made on or after the date of the enactment of this Act.

SEC. 707. DISCLOSURE OF REPORTABLE TRANSACTIONS.

(a) IN GENERAL.—Section 6111 (relating to registration of tax shelters) is amended to read as follows:

"SEC. 6111. DISCLOSURE OF REPORTABLE TRANSACTIONS.

''(a) IN GENERAL.—Each material advisor with respect to any reportable transaction shall make a return (in such form as the Secretary may prescribe) setting forth—

''(1) information identifying and describing the transaction,

''(2) information describing any potential tax benefits expected to result from the transaction, and

''(3) such other information as the Secretary may prescribe.

Such return shall be filed not later than the date specified by the Secretary.

''(b) DEFINITIONS.—For purposes of this section—

''(1) MATERIAL ADVISOR.—

''(A) IN GENERAL.—The term 'material advisor' means any person—

''(i) who provides any material aid, assistance, or advice with respect to organizing, managing, promoting, selling, implementing, insuring, or carrying out any reportable transaction, and

''(ii) who directly or indirectly derives gross income in excess of the threshold amount for such aid, assistance, or advice.

''(B) THRESHOLD AMOUNT.—For purposes of subparagraph (A), the threshold amount is—

''(i) $50,000 in the case of a reportable transaction substantially all of the tax benefits from which are provided to natural persons, and

''(ii) $250,000 in any other case.

''(2) REPORTABLE TRANSACTION.—The term 'reportable transaction' has the meaning given to such term by section 6707A(c).

''(c) REGULATIONS.—The Secretary may prescribe regulations which provide—

''(1) that only 1 person shall be required to meet the requirements of subsection (a) in cases in which 2 or more persons would otherwise be required to meet such requirements,

''(2) exemptions from the requirements of this section, and

''(3) such rules as may be necessary or appropriate to carry out the purposes of this section.''.

(b) CONFORMING AMENDMENTS.—

(1) The item relating to section 6111 in the table of sections for subchapter B of chapter 61 is amended to read as follows:

''Sec. 6111. Disclosure of reportable transactions.''.

(2)(A) So much of section 6112 as precedes subsection (c) thereof is amended to read as follows:

"SEC. 6112. MATERIAL ADVISORS OF REPORTABLE TRANSACTIONS MUST KEEP LISTS OF ADVISEES.

"(a) IN GENERAL.—Each material advisor (as defined in section 6111) with respect to any reportable transaction (as defined in section 6707A(c)) shall maintain, in such manner as the Secretary may by regulations prescribe, a list—

"(1) identifying each person with respect to whom such advisor acted as such a material advisor with respect to such transaction, and

"(2) containing such other information as the Secretary may by regulations require.

This section shall apply without regard to whether a material advisor is required to file a return under section 6111 with respect to such transaction.".

(B) Section 6112 is amended by redesignating subsection (c) as subsection (b).

(C) Section 6112(b), as redesignated by subparagraph (B), is amended—

(i) by inserting "written" before "request" in paragraph (1)(A), and

(ii) by striking "shall prescribe" in paragraph (2) and inserting "may prescribe".

(D) The item relating to section 6112 in the table of sections for subchapter B of chapter 61 is amended to read as follows:

''Sec. 6112. Material advisors of reportable transactions must keep lists of advisees.''.

(3)(A) The heading for section 6708 is amended to read as follows:

''SEC. 6708. FAILURE TO MAINTAIN LISTS OF ADVISEES WITH RESPECT TO REPORTABLE TRANSACTIONS.''.

(B) The item relating to section 6708 in the table of sections for part I of subchapter B of chapter 68 is amended to read as follows:

''Sec. 6708. Failure to maintain lists of advisees with respect to reportable transactions.''.

(c) REQUIRED DISCLOSURE NOT SUBJECT TO CLAIM OF CONFIDENTIALITY.—Subparagraph (A) of section 6112(b)(1), as redesignated by subsection (b)(2)(B), is amended by adding at the end the following new flush sentence:

''For purposes of this section, the identity of any person on such list shall not be privileged.''.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall apply to transactions with respect to which material aid, assistance, or advice referred to in section

6111(b)(1)(A)(i) of the Internal Revenue Code of 1986 (as added by this section) is provided after the date of the enactment of this Act.

(2) NO CLAIM OF CONFIDENTIALITY AGAINST DISCLOSURE.—The amendment made by subsection (c) shall take effect as if included in the amendments made by section 142 of the Deficit Reduction Act of 1984.

SEC. 708. MODIFICATIONS TO PENALTY FOR FAILURE TO REGISTER TAX SHELTERS.

(a) IN GENERAL.—Section 6707 (relating to failure to furnish information regarding tax shelters) is amended to read as follows:

"SEC. 6707. FAILURE TO FURNISH INFORMATION REGARDING REPORTABLE TRANSACTIONS.

''(a) IN GENERAL.—If a person who is required to file a return under section 6111(a) with respect to any reportable transaction—

''(1) fails to file such return on or before the date prescribed therefor, or

''(2) files false or incomplete information with the Secretary with respect to such transaction,

such person shall pay a penalty with respect to such return in the amount determined under subsection (b).

''(b) AMOUNT OF PENALTY.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the penalty imposed under subsection (a) with respect to any failure shall be $50,000.

''(2) LISTED TRANSACTIONS.—The penalty imposed under subsection (a) with respect to any listed transaction shall be an amount equal to the greater of—

''(A) $200,000, or

''(B) 50 percent of the gross income derived by such person with respect to aid, assistance, or advice which is provided with respect to the listed transaction before the date the return including the transaction is filed under section 6111.

Subparagraph (B) shall be applied by substituting '75 percent' for '50 percent' in the case of an intentional failure or act described in subsection (a).

''(c) CERTAIN RULES TO APPLY.—The provisions of section 6707A(d) shall apply to any penalty imposed under this section.

''(d) REPORTABLE AND LISTED TRANSACTIONS.—The terms 'reportable transaction' and 'listed transaction' have the respective meanings given to such terms by section 6707A(c).''.

(b) CLERICAL AMENDMENT.—The item relating to section 6707 in the table of sections for part I of subchapter B of chapter 68 is amended by striking ''tax shelters'' and inserting ''reportable transactions''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to returns the due date for which is after the date of the enactment of this Act.

SEC. 709. MODIFICATION OF PENALTY FOR FAILURE TO MAINTAIN LISTS OF INVESTORS.

(a) IN GENERAL.—Subsection (a) of section 6708 is amended to read as follows:

''(a) IMPOSITION OF PENALTY.—

''(1) IN GENERAL.—If any person who is required to maintain a list under section 6112(a) fails to make such list available upon written request to the Secretary in accordance with section 6112(b)(1)(A) within 20 business days after the date of the Secretary's request, such person shall pay a penalty of $10,000 for each day of such failure after such 20th day.

''(2) REASONABLE CAUSE EXCEPTION.—No penalty shall be imposed by paragraph (1) with respect to the failure on any day if such failure is due to reasonable cause.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to requests made after the date of the enactment of this Act.

SEC. 710. MODIFICATION OF ACTIONS TO ENJOIN CERTAIN CONDUCT RELATED TO TAX SHELTERS AND REPORTABLE TRANSACTIONS.

(a) IN GENERAL.—Section 7408 (relating to action to enjoin promoters of abusive tax shelters, etc.) is amended by redesignating subsection (c) as subsection (d) and by striking subsections (a) and (b) and inserting the following new subsections:

''(a) AUTHORITY TO SEEK INJUNCTION.—A civil action in the name of the United States to enjoin any person from further engaging in specified conduct may be commenced at the request of the Secretary. Any action under this section shall be brought in the district court of the United States for the district in which such person resides, has his principal place of business, or has engaged in specified conduct. The court may exercise its jurisdiction over such action (as provided in section 7402(a)) separate and apart from any other action brought by the United States against such person.

''(b) ADJUDICATION AND DECREE.—In any action under subsection (a), if the court finds—

''(1) that the person has engaged in any specified conduct, and

''(2) that injunctive relief is appropriate to prevent recurrence of such conduct,

the court may enjoin such person from engaging in such conduct or in any other activity subject to penalty under this title.

''(c) SPECIFIED CONDUCT.—For purposes of this section, the term 'specified conduct' means any action, or failure to take action, which is—

''(1) subject to penalty under section 6700, 6701, 6707, or 6708, or

''(2) in violation of any requirement under regulations issued under section 320 of title 31, United States Code.''.

(b) CONFORMING AMENDMENTS.—

(1) The heading for section 7408 is amended to read as follows:

''SEC. 7408. ACTIONS TO ENJOIN SPECIFIED CONDUCT RELATED TO TAX SHELTERS AND REPORTABLE TRANSACTIONS.''.

(2) The table of sections for subchapter A of chapter 67 is amended by striking the item relating to section 7408 and inserting the following new item:

''Sec. 7408. Actions to enjoin specified conduct related to tax shelters and reportable transactions.''.

(c) EFFECTIVE DATE.—The amendment made by this section shall take effect on the day after the date of the enactment of this Act.

SEC. 711. PENALTY FOR PROMOTING ABUSIVE TAX SHELTERS.

(a) PENALTY FOR PROMOTING ABUSIVE TAX SHELTERS.—Section 6700 (relating to promoting abusive tax shelters, etc.) is amended—

(1) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively,

(2) by striking ''a penalty'' and all that follows through the period in the first sentence of subsection (a) and inserting ''a penalty determined under subsection (b)'', and

(3) by inserting after subsection (a) the following new subsections:

''(b) AMOUNT OF PENALTY; CALCULATION OF PENALTY; LIABILITY FOR PENALTY.—

''(1) AMOUNT OF PENALTY.—The amount of the penalty imposed by subsection (a) shall not exceed 100 percent of the gross income derived (or to be derived) from such activity by the person or persons subject to such penalty.

''(2) CALCULATION OF PENALTY.—The penalty amount determined under paragraph (1) shall be calculated with respect to each instance of an activity described in subsection (a), each instance in which income was derived by the person or persons subject to such penalty, and each person who participated in such an activity.

''(3) LIABILITY FOR PENALTY.—If more than 1 person is liable under subsection (a) with respect to such activity, all such persons shall be jointly and severally liable for the penalty under such subsection.

''(c) PENALTY NOT DEDUCTIBLE.—The payment of any penalty imposed under this section or the payment of any amount to settle or avoid the imposition of such penalty shall not be deductible by the person who is subject to such penalty or who makes such payment.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to activities after the date of the enactment of this Act.

SEC. 712. STATUTE OF LIMITATIONS FOR TAXABLE YEARS FOR WHICH REQUIRED LISTED TRANSACTIONS NOT REPORTED.

(a) IN GENERAL.—Section 6501(c) (relating to exceptions) is amended by adding at the end the following new paragraph:

''(10) LISTED TRANSACTIONS.—If a taxpayer fails to include on any return or statement for any taxable year any information with respect to a listed transaction (as defined in section 6707A(c)(2)) which is required under section 6011 to be included with such return or statement, the time for assessment of any tax imposed by this title with respect to such transaction shall not expire before the date which is 1 year after the earlier of—

''(A) the date on which the Secretary is furnished the information so required; or

''(B) the date that a material advisor (as defined in section 6111) meets the requirements of section 6112 with respect to a request by the Secretary under section 6112(b) relating to such transaction with respect to such taxpayer.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years with respect to

which the period for assessing a deficiency did not expire before the date of the enactment of this Act.

SEC. 713. DENIAL OF DEDUCTION FOR INTEREST ON UNDERPAYMENTS ATTRIBUTABLE TO NONDISCLOSED REPORTABLE AND NONECONOMIC SUBSTANCE TRANSACTIONS.

(a) IN GENERAL.—Section 163 (relating to deduction for interest) is amended by redesignating subsection (m) as subsection (n) and by inserting after subsection (l) the following new subsection:

''(m) INTEREST ON UNPAID TAXES ATTRIBUTABLE TO NONDISCLOSED REPORTABLE TRANSACTIONS AND NONECONOMIC SUBSTANCE TRANSACTIONS.—No deduction shall be allowed under this chapter for any interest paid or accrued under section 6601 on any underpayment of tax which is attributable to—

''(1) the portion of any reportable transaction understatement (as defined in section 6662A(b)) with respect to which the requirement of section 6664(d)(2)(A) is not met, or

''(2) any noneconomic substance transaction understatement (as defined in section 6662B(c)).''.

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

SEC. 714. PENALTY FOR AIDING AND ABETTING THE UNDERSTATEMENT OF TAX LIABILITY.

(a) IN GENERAL.—Section 6701(a) (relating to imposition of penalty) is amended—

(1) by inserting ''the tax liability or'' after ''respect to,'' in paragraph (1),

(2) by inserting ''aid, assistance, procurement, or advice with respect to such'' before ''portion'' both places it appears in paragraphs (2) and (3), and

(3) by inserting ''instance of aid, assistance, procurement, or advice or each such'' before ''document'' in the matter following paragraph (3).

(b) AMOUNT OF PENALTY.—Subsection (b) of section 6701 (relating to penalties for aiding and abetting understatement of tax liability) is amended to read as follows:

''(b) AMOUNT OF PENALTY; CALCULATION OF PENALTY; LIABILITY FOR PENALTY.—

''(1) AMOUNT OF PENALTY.—The amount of the penalty imposed by subsection (a) shall not exceed 100 percent of the gross income derived (or to be derived) from such aid, assistance, procurement, or advice provided by the person or persons subject to such penalty.

''(2) CALCULATION OF PENALTY.—The penalty amount determined under paragraph (1) shall be

calculated with respect to each instance of aid, assistance, procurement, or advice described in subsection (a), each instance in which income was derived by the person or persons subject to such penalty, and each person who made such an understatement of the liability for tax.

''(3) LIABILITY FOR PENALTY.—If more than 1 person is liable under subsection (a) with respect to providing such aid, assistance, procurement, or advice, all such persons shall be jointly and severally liable for the penalty under such subsection.''.

(c) PENALTY NOT DEDUCTIBLE.—Section 6701 is amended by adding at the end the following new subsection:

''(g) PENALTY NOT DEDUCTIBLE.—The payment of any penalty imposed under this section or the payment of any amount to settle or avoid the imposition of such penalty shall not be deductible by the person who is subject to such penalty or who makes such payment.''.

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

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