

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

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.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Healthy Lifestyles and Prevention America Act” or the
6 “HeLP America Act”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

TITLE I—HEALTHIER KIDS AND SCHOOLS

- Sec. 101. Fruit and vegetable program.
- Sec. 102. School wellness policy; competitive foods.
- Sec. 103. Healthy school nutrition environment incentive grants.
- Sec. 104. Grants for the integration of schools and mental health systems.

TITLE II—HEALTHIER COMMUNITIES AND WORKPLACES

Subtitle A—Incentives for a Healthy Workforce

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

Subtitle B—Healthy Communities

- Sec. 211. Healthy community grants.
- Sec. 212. Living well with a disability and working well with a disability programs.
- Sec. 213. Enhanced standards for roads and intersection controls.
- Sec. 214. Mental health surveillance.

Subtitle C—Family Smoking Prevention and Control

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

CHAPTER 1—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

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

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

- Sec. 241. Cigarette label and advertising warnings.
- Sec. 242. Authority to revise cigarette warning label Statements.
- Sec. 243. State regulation of cigarette advertising and promotion.
- Sec. 244. Smokeless tobacco labels and advertising warnings.
- Sec. 245. Authority to revise smokeless tobacco product warning label Statements.
- Sec. 246. Tar, nicotine, and other smoke constituent disclosure to the public.

CHAPTER 3—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

- Sec. 251. Labeling, recordkeeping, records inspection.
- Sec. 252. Study and report.

TITLE III—RESPONSIBLE MARKETING AND CONSUMER
AWARENESS

Subtitle A—General Provisions

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

Subtitle B—Penalties for Failure to Reduce Teen Smoking

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

TITLE IV—REIMBURSEMENT AND COVERAGE OF PREVENTIVE SERVICES

- Sec. 401. Coverage of substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling.
- Sec. 402. Preventive mental health screenings.
- Sec. 403. Encouragement of cessation of tobacco use.
- Sec. 404. Preventive health services for women.

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

- Sec. 501. HELP (healthy lifestyles and prevention) America Trust Fund.

TITLE VI—RESEARCH

- Sec. 601. Expansion of research regarding obesity.

TITLE VII—PROVISIONS DESIGNED TO CURTAIL TAX SHELTERS

- Sec. 700. Amendment of 1986 Code.
- Sec. 701. Clarification of economic substance doctrine.
- Sec. 702. Penalty for failing to disclose reportable transaction.
- Sec. 703. Accuracy-related penalty for listed transactions and other reportable transactions having a significant tax avoidance purpose.
- Sec. 704. Penalty for understatements attributable to transactions lacking economic substance, etc.
- Sec. 705. Modifications of substantial understatement penalty for nonreportable transactions.
- Sec. 706. Tax shelter exception to confidentiality privileges relating to taxpayer communications.
- Sec. 707. Disclosure of reportable transactions.
- Sec. 708. Modifications to penalty for failure to register tax shelters.
- Sec. 709. Modification of penalty for failure to maintain lists of investors.
- Sec. 710. Modification of actions to enjoin certain conduct related to tax shelters and reportable transactions.
- Sec. 711. Penalty for promoting abusive tax shelters.
- Sec. 712. Statute of limitations for taxable years for which required listed transactions not reported.
- Sec. 713. Denial of deduction for interest on underpayments attributable to nondisclosed reportable and noneconomic substance transactions.
- Sec. 714. Penalty for aiding and abetting the understatement of tax liability.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Health care costs in the United States are
4 rising rapidly. On a per capita basis, the United
5 States spends 40 percent more than any other coun-
6 try on health care as a proportion of our gross do-
7 mestic product.

8 (2) The United States spends over
9 \$1,800,000,000,000 annually on health care, 75 per-
10 cent of which is spent on the treatment of chronic
11 disease.

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

15 (4) The high cost of chronic disease manage-
16 ment and treatment is a major contributing factor
17 to these exploding health care costs.

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

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

24 (7) In 2000, 38.2 percent of all deaths were
25 due to tobacco use, poor nutrition and physical inac-
26 tivity, and alcohol consumption.

1 (8) The economic impact of chronic disease can
2 be seen in the annual costs associated with cardio-
3 vascular disease \$352,000,000,000 obesity
4 \$117,000,000,000, tobacco use \$75,000,000,000
5 and mental illness \$150,000,000,000.

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

10 (10) Health promotion investments by employ-
11 ers on average yield a return \$3 for every \$1 in-
12 vested in a program.

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

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

19 (13) The rates of obesity have doubled in chil-
20 dren and tripled in teens since the 1980's.

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

23 (15) Almost 40 percent of Americans are sed-
24 entary. More than a third of young people in grades

1 9 through 12 do not regularly engage in vigorous-
2 intensity physical activity.

3 (16) Only 1 in 5 young people eat the rec-
4 ommended 5 daily servings of fruits and vegetables.

5 (17) More than \$12,000,000,000 a year is
6 spent on advertising and marketing, mostly
7 unhealthy food to children through television, the in-
8 sert Internet, movies, magazines, in-school mar-
9 keting, kids clubs, toys, coupons, product placement
10 in movies and books.

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

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

20 (20) In 2002, 61,000,000 Americans, 26 per-
21 cent of our population smoked cigarettes.

22 (21) Research consistently shows that smoking
23 cessation services offered as a combination of to-
24 bacco medication therapy and counseling can be one

1 of the most cost-effective health interventions and
2 can reduce smoking-related health care costs.

3 (22) Physical and mental health are inter-
4 connected. Physical conditions often result in mental
5 health complications, likewise, depression can mani-
6 fest itself through physical symptoms.

7 (23) The Surgeon General reported that mental
8 disorders collectively account for 15 percent of the
9 overall burden of disease from all causes, and slight-
10 ly more than the burden associated with all forms of
11 cancer.

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

14 (25) One of every 2 people who need mental
15 health treatment in the United States does not re-
16 ceive it and 30,000 Americans die by suicide each
17 year.

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

22 (27) People with disabilities report substantial
23 disparities in health compared with people without
24 disabilities. These disparities are caused by a num-
25 ber of factors, including less access to health care

1 than individuals without disabilities. People with dis-
 2 abilities report more days of pain, depression, and
 3 anxiety and they have higher rates of obesity.

4 (28) Evidence shows that health promotion pro-
 5 grams with exercise, nutrition, and wellness compo-
 6 nents targeting people with disabilities can signifi-
 7 cantly reduce the incidence of these conditions and
 8 lead to healthy outcomes for people with disabilities,
 9 as well as save money by reducing the frequency of
 10 medical visits.

11 **TITLE I—HEALTHIER KIDS AND** 12 **SCHOOLS**

13 **SEC. 101. FRUIT AND VEGETABLE PROGRAM.**

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

17 “(g) FRUIT AND VEGETABLE PROGRAM.—

18 “(1) IN GENERAL.—For the school year begin-
 19 ning July 2005 and each subsequent school year, the
 20 Secretary shall carry out a program to make free
 21 fresh fruits and vegetables available to each school
 22 that submits a certification of support for participa-
 23 tion in the program that is signed by the school food
 24 manager, the school principal, and the district su-

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

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

7 “(3) NOTICE OF AVAILABILITY.—To be eligible
8 to participate in the fresh fruit and vegetable pro-
9 gram under this subsection, a school shall widely
10 publicize within the school the availability of free
11 fresh fruits and vegetables under the program.

12 “(4) PER STUDENT GRANT.—

13 “(A) IN GENERAL.—For each school year
14 during which a school participates in the pro-
15 gram under this subsection, the Secretary shall
16 provide to the school an amount equal to \$75
17 per student, as adjusted under subparagraph
18 (B), to be used to carry out the program in the
19 school.

20 “(B) ADJUSTMENT.—The amount of the
21 grant for each student under subparagraph (A)
22 shall be adjusted on July 1, 2006, and each
23 subsequent July 1, to reflect changes in the
24 Consumer Price Index of the Bureau of Labor

1 Statistics for fresh fruits and vegetables, with
 2 the adjustment—

3 “(i) rounded down to the nearest dol-
 4 lar increment; and

5 “(ii) based on the unrounded amounts
 6 for the preceding 12-month period.

7 “(5) EVALUATION.—

8 “(A) IN GENERAL.—The Secretary, acting
 9 through the Administrator of the Food and Nu-
 10 trition Service, shall conduct an evaluation of
 11 schools participating in the program under this
 12 subsection.

13 “(B) CONTENT.—The evaluation shall
 14 measure, at a minimum, the impact of partici-
 15 pation in the program and any changes in the
 16 school nutrition environment relating to—

17 “(i) overweight and obesity among
 18 children;

19 “(ii) dietary intake;

20 “(iii) nutrition education and behav-
 21 ior;

22 “(iv) rates of physical activity among
 23 children; and

24 “(v) parental and student attitudes
 25 about—

1 “(I) participation in the program;

2 and

3 “(II) general nutrition, physical

4 activity, and wellness.

5 “(6) HEALTHY COOKING PILOT PROGRAM.—

6 “(A) IN GENERAL.—As part of the pro-
7 gram conducted under this subsection, the Sec-
8 retary shall carry out a pilot program under
9 which the Secretary shall make competitive
10 grants to selected elementary and secondary
11 schools to teach children—

12 “(i) how to eat a nutritious diet;

13 “(ii) how to select foods to make a
14 healthy meal; and

15 “(iii) how to prepare healthy meals.

16 “(B) SELECTION OF SCHOOL.—In select-
17 ing schools to participate in the pilot program,
18 the Secretary shall ensure that—

19 “(i) only schools participating in the
20 fruit and vegetable program under this
21 subsection are eligible to receive funds
22 under this paragraph;

23 “(ii) to the maximum extent prac-
24 ticable, at least 75 percent of schools se-
25 lected are schools in which at least 50 per-

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

4 “(iii) there is appropriate representa-
5 tion, as determined by the Secretary, of—

6 “(I) rural, urban, and suburban
7 schools; and

8 “(II) elementary, middle, and
9 secondary schools.

10 “(C) PRIORITY CONSIDERATION.—In
11 awarding competitive grants under this para-
12 graph, the Secretary shall give priority consid-
13 eration to schools that submit an application
14 that includes the participation of the parents or
15 families of the children enrolled in the school.

16 “(7) AUTHORIZATION OF APPROPRIATIONS.—

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

21 “(B) INSUFFICIENT FUNDS.—If the funds
22 appropriated under subparagraph (A) are insuf-
23 ficient to carry out the program under this sub-
24 section in all schools that meet the require-
25 ments of paragraph (1), the Secretary shall give

1 priority to schools that have the highest per-
 2 centage of students enrolled that are eligible for
 3 free or reduced price meals under this Act.”.

4 **SEC. 102. SCHOOL WELLNESS POLICY; COMPETITIVE**
 5 **FOODS.**

6 (a) SCHOOL WELLNESS POLICIES.—

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

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

20 (B) includes nutrition guidelines that—

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

24 (ii) are applicable to all foods avail-
 25 able during the school day; and

1 (iii) have as objectives—

2 (I) promotion of sound nutrition;

3 (II) improvement of student
4 health; and

5 (III) reduction in childhood obe-
6 sity;

7 (C) ensures that meals and supplements
8 provided in accordance with the Richard B.
9 Russell National School Lunch Act (42 U.S.C.
10 1751 et seq.) and the Child Nutrition Act of
11 1966 (42 U.S.C. 1771 et seq.) conform with
12 nutritional guidelines contained in regulations
13 promulgated by the Secretary of Agriculture
14 (referred to in this section as the “Secretary”)
15 in accordance with the programs authorized
16 under those Acts;

17 (D) establishes a plan for ensuring imple-
18 mentation of the local wellness policy, including
19 designation of 1 or more individuals within the
20 local educational agency charged with oper-
21 ational responsibility for ensuring that the re-
22 quirements of the school wellness plan are car-
23 ried out; and

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

1 board, school administrators, physical activity
 2 professionals, medical and nutrition profes-
 3 sionals, and the public in the development of the
 4 school wellness policy.

5 (2) TECHNICAL ASSISTANCE AND BEST PRAC-
 6 TICES TO SCHOOLS AND STATES.—

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

12 (i) carrying out paragraph (1); and

13 (ii) otherwise—

14 (I) establishing healthy school
 15 food environments;

16 (II) reducing childhood obesity;

17 and

18 (III) preventing diet-related
 19 chronic diseases.

20 (B) CONTENT.—The guidance and tech-
 21 nical assistance shall include, at a minimum—

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

1 triets that have done so without experi-
2 encing adverse effects on revenue from
3 sales of competitive foods;

4 (ii) recommended nutritional guide-
5 lines regarding appropriate standards for
6 the availability, sale, and service of foods
7 of any kind throughout the school day, as
8 provided by the Institute of Medicine
9 under subsection (b)(3) of section 10 of
10 the Child Nutrition Act of 1966 (42
11 U.S.C. 1779) (as amended by subsection
12 (b)); and

13 (iii) such other technical assistance as
14 is required to carry out the goals of pro-
15 moting sound nutrition and establishing
16 healthy school food environments.

17 (C) GUIDANCE ONLY.—The recommenda-
18 tions of the Institute of Medicine under sub-
19 section (b)(3) of section 10 of the Child Nutri-
20 tion Act of 1966 (42 U.S.C. 1779) (as amended
21 by subsection (b))—

22 (i) are solely for the purpose of pro-
23 viding guidance to schools to develop
24 school wellness policies in accordance with
25 paragraph (1); and

1 (ii) shall not be construed as a man-
 2 date to local educational agencies, school
 3 food authorities, or schools.

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

7 (1) in subsection (a), by striking “, including”
 8 and all that follows through “Lunch Act”; and

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

11 “(b) COMPETITIVE FOODS IN SCHOOLS.—

12 “(1) IN GENERAL.—The regulations under sub-
 13 section (a) may include provisions that regulate the
 14 service of food in participating schools and service
 15 institutions in competition with the programs au-
 16 thorized under this Act and the Richard B. Russell
 17 National School Lunch Act (42 U.S.C. 1751 et seq.)
 18 (referred to in this subsection as ‘competitive
 19 foods’).

20 “(2) REGULATIONS.—The regulations promul-
 21 gated under paragraph (1)—

22 “(A) shall apply to all school grounds dur-
 23 ing the duration of the school day;

24 “(B) shall not supersede or otherwise af-
 25 fect State and local regulations on competitive

1 foods that, as determined by the Secretary, con-
 2 form to the nutritional goals of the regulations
 3 promulgated by the Secretary;

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

9 “(D) shall take into account the differing
 10 needs of—

11 “(i) elementary schools;

12 “(ii) middle schools and junior high
 13 schools; and

14 “(iii) high schools; and

15 “(E) shall implement the recommendations
 16 of the Institute of Medicine made under para-
 17 graph (3).

18 “(3) INSTITUTE OF MEDICINE RECOMMENDA-
 19 TIONS.—

20 “(A) IN GENERAL.—The Secretary shall
 21 offer to enter into an agreement with the Insti-
 22 tute of Medicine of the National Academy of
 23 Sciences under which the Institute of Medicine,
 24 based on sound nutritional science, shall make
 25 recommendations to the Secretary regarding—

1 “(i) the regulation of competitive
2 foods; and

3 “(ii) appropriate nutritional guidelines
4 for competitive foods offered in schools.

5 “(B) REGULATIONS.—Not later than 1
6 year after the date of receipt of final rec-
7 ommendations from the Institute of Medicine,
8 the Secretary shall promulgate regulations to
9 carry out this subsection in accordance with the
10 recommendations of the Institute of Medicine.

11 “(C) REPORT.—Not later than 1 year
12 after the date of receipt of final recommenda-
13 tions from the Institute of Medicine, the Sec-
14 retary shall submit to the Committee on Edu-
15 cation and the Workforce of the House of Rep-
16 resentatives and the Committee on Agriculture,
17 Nutrition, and Forestry of the Senate a report
18 that describes the actions of the Secretary
19 under subparagraph (B).”.

20 (c) APPLICABILITY.—This section and the amend-
21 ments made by this section apply only to schools partici-
22 pating in a program authorized under the Richard B. Rus-
23 sell National School Lunch Act (42 U.S.C. 1751 et seq.)
24 or the Child Nutrition Act of 1966 (42 U.S.C. 1771 et
25 seq.).

1 **SEC. 103. HEALTHY SCHOOL NUTRITION ENVIRONMENT IN-**
2 **CENTIVE GRANTS.**

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

6 “(h) HEALTHY SCHOOL NUTRITION ENVIRONMENT
7 INCENTIVE GRANTS.—

8 “(1) IN GENERAL.—The Secretary shall estab-
9 lish a program under which the Secretary shall make
10 competitive grants to selected elementary and sec-
11 ondary schools—

12 “(A) to create healthy school nutrition en-
13 vironments; and

14 “(B) to assess the impact of the environ-
15 ments on the health and well-being of children
16 enrolled in the schools.

17 “(2) SELECTION OF SCHOOLS.—In selecting
18 schools to receive incentive grants under this sub-
19 section, the Secretary shall—

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

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

5 “(C) ensure that, of the schools selected to
6 participate in the program, there is appropriate
7 representation of elementary, middle, and sec-
8 ondary schools, as determined by the Secretary;

9 “(D) ensure that schools selected to receive
10 a grant under this subsection meet the require-
11 ments of paragraph (3);

12 “(E) give priority to schools that develop
13 comprehensive plans that include the involve-
14 ment of a broad range of community stake-
15 holders in achieving healthy school nutrition en-
16 vironments; and

17 “(F) give priority to schools that develop
18 comprehensive plans that include a strategy for
19 maintaining healthy school nutrition environ-
20 ments in the years following the fiscal years for
21 which the schools receive grants under this sub-
22 section.

23 “(3) REQUIREMENTS.—

24 “(A) INPUT.—Prior to the solicitation of
25 proposals for grants under this subsection, the

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

5 “(B) CRITERIA FOR HEALTHY SCHOOL EN-
6 VIRONMENTS.—The Secretary shall, taking into
7 account input received under subparagraph (A),
8 establish criteria for defining a healthy school
9 environment, including criteria that—

10 “(i) provide program meals that meet
11 nutritional standards for breakfasts and
12 lunches established by the Secretary;

13 “(ii) ensure that all food served (in-
14 cluding food served in participating schools
15 and service institutions in competition with
16 the programs authorized under this Act
17 and the Child Nutrition Act of 1966 (42
18 U.S.C. 1771 et seq.)) on school grounds
19 during regular school hours is consistent
20 with the nutritional standards for break-
21 fasts and lunches established by the Sec-
22 retary;

23 “(iii) promote the consumption of
24 fruits and vegetables;

1 “(iv) promote physical education and
 2 provide nutrition education to students and
 3 staff;

4 “(v) ensure that all children are in-
 5 cluded in physical education and nutrition
 6 activities, including children with disabil-
 7 ities and children with limited English pro-
 8 ficiency;

9 “(vi) ban foods of minimal nutritional
 10 value, as that term is defined in section
 11 210.11 of title 7, Code of Federal Regula-
 12 tions (or any successor regulation), and the
 13 marketing and advertising in schools of
 14 foods of minimal nutritional value;

15 “(vii) integrate general wellness goals
 16 into the school curriculum; and

17 “(viii) meet other criteria established
 18 by the Secretary.

19 “(C) PLANS.—To be eligible to receive a
 20 grant under this subsection, a school shall—

21 “(i) submit to the Secretary a healthy
 22 school nutrition environment plan that de-
 23 scribes the actions the school will take to
 24 meet the criteria established under sub-
 25 paragraph (B); and

1 “(ii) take the actions described in the
2 plan.

3 “(4) GRANTS.—For each of fiscal years 2006
4 through 2010, the Secretary shall make a grant to
5 each school selected under paragraph (2).

6 “(5) EVALUATIONS.—

7 “(A) IN GENERAL.—The Secretary, acting
8 through the Administrator of the Food and Nu-
9 trition Service, shall conduct an evaluation of a
10 representative sample of schools that receive
11 grants under this subsection.

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

15 “(i) overweight children and obesity;

16 “(ii) dietary intake;

17 “(iii) nutrition education and behav-
18 ior;

19 “(iv) the adequacy of time to eat;

20 “(v) physical activities;

21 “(vi) parental and student attitudes
22 and participation; and

23 “(vii) related funding issues, including
24 the cost of maintaining a healthy school
25 nutrition environment.

1 “(C) REPORTS.—The Secretary shall sub-
2 mit to the Committee on Education and the
3 Workforce of the House of Representatives and
4 the Committee on Agriculture, Nutrition, and
5 Forestry of the Senate—

6 “(i) an interim report on the activities
7 of schools evaluated under this subsection;
8 and

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

11 “(6) FUNDING.—

12 “(A) IN GENERAL.—On October 1, 2004,
13 and each October 1 thereafter on which this
14 program is authorized, out of any funds in the
15 Treasury not otherwise appropriated, the Sec-
16 retary of the Treasury shall transfer to the Sec-
17 retary of Agriculture to carry out this sub-
18 section \$100,000,000.

19 “(B) RECEIPT AND ACCEPTANCE.—The
20 Secretary shall be entitled to receive, shall ac-
21 cept, and shall use to carry out this section the
22 funds transferred under subparagraph (A),
23 without further appropriation.

1 “(C) AVAILABILITY OF FUNDS.—Funds
2 transferred under subparagraph (A) shall re-
3 main available until expended.

4 “(D) EVALUATIONS.—Of the funds made
5 available under this paragraph, the Secretary
6 shall use not more than \$5,000,000 to conduct
7 evaluations under paragraph (5).”.

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

10 Section 5541 of the Elementary and Secondary Edu-
11 cation Act of 1965 (20 U.S.C. 7269) is amended—

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

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

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

23 (2) in subsection (d)—

24 (A) in paragraph (4)—

1 (i) in subparagraph (C), by striking
2 “and” after the semicolon;

3 (ii) in subparagraph (D), by striking
4 the period and inserting “; and”; and

5 (iii) by adding at the end the fol-
6 lowing:

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

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

11 “(7) An explanation of how the applicant will
12 carry out public education programs in support of
13 mental health promotion and prevention by collabo-
14 rating with—

15 “(A) an institution of higher education (in-
16 cluding a graduate program in psychology, so-
17 cial work, or education at an institution of
18 higher education); and

19 “(B) private nonprofit community-based
20 organizations that have experience in public
21 education programs relating to mental health
22 promotion and prevention.”.

1 **TITLE II—HEALTHIER COMMU-**
 2 **NITIES AND WORKPLACES**
 3 **Subtitle A—Incentives for a**
 4 **Healthy Workforce**

5 **SEC. 201. SHORT TITLE.**

6 This subtitle may be cited as the “Healthy Workforce
 7 Act of 2004”.

8 **SEC. 202. TAX CREDIT TO EMPLOYERS FOR COSTS OF IM-**
 9 **PLEMENTING WELLNESS PROGRAMS.**

10 (a) IN GENERAL.—Subpart D of part IV of sub-
 11 chapter A of chapter 1 of the Internal Revenue Code of
 12 1986 (relating to business related credits) is amended by
 13 adding at the end the following:

14 **“SEC. 45G. WELLNESS PROGRAM CREDIT.**

15 **“(a) ALLOWANCE OF CREDIT.—**

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

19 **“(A) in the case of a small business em-**
 20 **ployer, an amount equal to 50 percent of the**
 21 **costs paid or incurred by the small business em-**
 22 **ployer in connection with a qualified small busi-**
 23 **ness wellness program during the taxable year,**
 24 **and**

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

6 “(2) LIMITATION.—The amount of credit al-
 7 lowed under paragraph (1) for any taxable year shall
 8 not exceed the product of \$200 and the number of
 9 employees of the employer or small business em-
 10 ployer, as the case may be.

11 “(b) QUALIFIED WELLNESS PROGRAM; QUALIFIED
 12 SMALL BUSINESS WELLNESS PROGRAM.—For purposes
 13 of this section—

14 “(1) QUALIFIED WELLNESS PROGRAM.—The
 15 term ‘qualified wellness program’ means a program
 16 which consists of all of the wellness program compo-
 17 nents described in subsection (c) and which is cer-
 18 tified by the Secretary of Health and Human Serv-
 19 ices, in consultation with persons who have expertise
 20 in employer health promotion and wellness pro-
 21 grams, as a qualified wellness program under this
 22 section.

23 “(2) QUALIFIED SMALL BUSINESS WELLNESS
 24 PROGRAM.—The term ‘qualified small business
 25 wellness program’ means a program which consists

1 of any 2 of the components described in subsection
2 (c) and which is certified by the Secretary of Health
3 and Human Services, in consultation with persons
4 who have expertise in employer health promotion and
5 wellness programs, as a qualified small business
6 wellness program under this section.

7 “(c) WELLNESS PROGRAM COMPONENTS.—For pur-
8 poses of this section, the wellness program components de-
9 scribed in this subsection are the following:

10 “(1) HEALTH AWARENESS COMPONENT.—A
11 health awareness component which provides for the
12 following:

13 “(A) HEALTH EDUCATION.—The dissemi-
14 nation of health information which addresses
15 the specific needs and health risks of employees.

16 “(B) HEALTH SCREENINGS.—The oppor-
17 tunity for periodic screenings for health prob-
18 lems and referrals for appropriate follow up
19 measures.

20 “(2) BEHAVIORAL CHANGE COMPONENT.—A
21 behavioral change component which provides for al-
22 tering employee lifestyles to encourage healthy living
23 through counseling, seminars, on-line programs, or
24 self-help materials. Such component shall include
25 programs relating to—

- 1 “(A) smoking,
- 2 “(B) obesity,
- 3 “(C) stress management,
- 4 “(D) physical fitness,
- 5 “(E) nutrition,
- 6 “(F) substance abuse, and
- 7 “(G) depression.

8 “(3) SUPPORTIVE ENVIRONMENT COMPO-
 9 NENT.—A supportive environment component which
 10 includes the following:

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

14 “(i) smoking at the worksite,

15 “(ii) the nutrition of food available at
 16 the worksite through cafeterias and vend-
 17 ing options,

18 “(iii) minimizing stress in the work-
 19 place,

20 “(iv) where applicable, accessible and
 21 attractive stairs, and

22 “(v) the encouragement of physical
 23 activity during work hours.

24 “(B) PARTICIPATION INCENTIVES.—

1 “(i) IN GENERAL.—Qualified incentive
 2 benefits for each employee who participates
 3 in the health screenings described in para-
 4 graph (1)(B) or the behavioral change pro-
 5 grams described in paragraph (2).

6 “(ii) QUALIFIED INCENTIVE BEN-
 7 EFIT.—For purposes of clause (i), the
 8 term ‘qualified incentive benefit’ means
 9 any benefit which is approved by the Sec-
 10 retary of Health and Human Services.
 11 Such benefit may include an adjustment in
 12 health insurance premiums or co-pays.

13 “(C) EMPLOYEE INPUT.—The opportunity
 14 for employees to participate in the management
 15 of any qualified wellness program or qualified
 16 small business wellness program to which this
 17 section applies.

18 “(d) PARTICIPATION REQUIREMENT.—

19 “(1) IN GENERAL.—No credit shall be allowed
 20 under subsection (a) unless the Secretary of Health
 21 and Human Services certifies, as a part of any cer-
 22 tification described in subsection (b), that each
 23 wellness program component of the qualified
 24 wellness program or qualified small business

1 wellness program applies to all qualified employees
2 of the employer.

3 “(2) QUALIFIED EMPLOYEE.—For purposes of
4 paragraph (1), the term ‘qualified employee’ means
5 an employee who works an average of not less than
6 25 hours per week during the taxable year.

7 “(e) OTHER DEFINITIONS AND SPECIAL RULES.—
8 For purposes of this section—

9 “(1) EMPLOYEE AND EMPLOYER.—

10 “(A) PARTNERS AND PARTNERSHIPS.—
11 The term ‘employee’ includes a partner and the
12 term ‘employer’ includes a partnership.

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

15 “(2) SMALL BUSINESS EMPLOYER.—

16 “(A) IN GENERAL.—The term ‘small busi-
17 ness employer’ means, with respect to any tax-
18 able year, an employer who employed an aver-
19 age of 200 or fewer employees on business days
20 during such taxable year.

21 “(B) CONTROLLED GROUPS.—For pur-
22 poses of subparagraph (A), all persons treated
23 as a single employer under subsection (b), (c),
24 (m), or (o) of section 414 shall be treated as a
25 single employer.

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

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

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

11 (b) TREATMENT AS GENERAL BUSINESS CREDIT.—

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

18 “(16) the wellness program credit determined
19 under section 45G.”.

20 (2) TRANSITIONAL RULE FOR CARRYBACKS.—

21 Subsection (d) of section 39 of such Code (relating
22 to transitional rules) is amended by adding at the
23 end the following:

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

1 used business credit for any taxable year which is
 2 attributable to the wellness program credit deter-
 3 mined under section 45G may be carried back to a
 4 taxable year beginning before January 1, 2005.”.

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

9 “(d) WELLNESS PROGRAM CREDIT.—

10 “(1) IN GENERAL.—No deduction shall be al-
 11 lowed for that portion of the costs paid or incurred
 12 for a qualified wellness program (within the meaning
 13 of section 45G) or a qualified small business
 14 wellness program (within the meaning of such sec-
 15 tion) allowable as a deduction for the taxable year
 16 which is equal to the amount of the credit allowable
 17 for the taxable year under section 45G.

18 “(2) SIMILAR RULE WHERE TAXPAYER CAP-
 19 ITALIZES RATHER THAN DEDUCTS EXPENSES.—If—

20 “(A) the amount of the credit determined
 21 for the taxable year under section 45G, exceeds

22 “(B) the amount allowable as a deduction
 23 for such taxable year for a qualified wellness
 24 program or a qualified small business wellness
 25 program,

1 the amount chargeable to capital account for the
 2 taxable year for such expenses shall be reduced by
 3 the amount of such excess.

4 “(3) CONTROLLED GROUPS.—In the case of a
 5 corporation which is a member of a controlled group
 6 of corporations (within the meaning of section
 7 41(f)(5)) or a trade or business which is treated as
 8 being under common control with other trades or
 9 business (within the meaning of section
 10 41(f)(1)(B)), this subsection shall be applied under
 11 rules prescribed by the Secretary similar to the rules
 12 applicable under subparagraphs (A) and (B) of sec-
 13 tion 41(f)(1).”.

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

“Sec. 45G. Wellness program credit.”.

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

21 (f) OUTREACH.—

22 (1) IN GENERAL.—The Secretary of the Treas-
 23 ury, in conjunction with the Director of the Centers
 24 for Disease Control and members of the business
 25 community, shall institute an outreach program to

1 inform businesses about the availability of the
 2 wellness program credit under section 45G of the In-
 3 ternal Revenue Code of 1986.

4 (2) AUTHORIZATION OF APPROPRIATIONS.—

5 There are authorized to be appropriated such sums
 6 as are necessary to carry out the outreach program
 7 described in paragraph (1).

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

10 (a) TREATMENT AS FRINGE BENEFIT.—Subpara-
 11 graph (A) of section 132(j)(4) of the Internal Revenue
 12 Code of 1986 (relating to on-premises gyms and other ath-
 13 letic facilities) is amended to read as follows:

14 “(A) IN GENERAL.—Gross income shall
 15 not include—

16 “(i) the value of any on-premises ath-
 17 letic facility provided by an employer to its
 18 employees, and

19 “(ii) fees or membership expenses
 20 paid by an employer to an athletic or fit-
 21 ness facility described in subparagraph (C)
 22 on behalf of its employees, but only to the
 23 extent that such fees or expenses do not
 24 exceed \$900.

1 The preceding sentence shall apply with respect
 2 to any highly compensated employee only if ac-
 3 cess to the facility is available on substantially
 4 the same terms to each member of a group of
 5 employees which is defined under a reasonable
 6 classification set up by the employer which does
 7 not discriminate in favor of highly compensated
 8 employees.”.

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

12 “(C) CERTAIN ATHLETIC OR FITNESS FA-
 13 CILITIES DESCRIBED.—For purposes of sub-
 14 paragraph (A)(ii), an athletic or fitness facility
 15 described in this subparagraph is a facility—

16 “(i) providing instruction in a pro-
 17 gram of physical exercise or offering facili-
 18 ties for the preservation, maintenance, en-
 19 couragement, or development of physical
 20 fitness,

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

23 “(iii) which does not offer golf, hunt-
 24 ing, sailing, or riding facilities,

1 “(iv) whose health or fitness facility is
 2 not incidental to its overall function and
 3 purpose, and

4 “(v) which is fully compliant with the
 5 State of jurisdiction and Federal anti-dis-
 6 criminations laws.”.

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

9 (1) IN GENERAL.—Paragraph (3) of section
 10 274(a) of such Code (relating to denial of deduction
 11 for club dues) is amended—

12 (A) by striking “Notwithstanding” and in-
 13 serting the following:

14 “(A) IN GENERAL.—Notwithstanding”,
 15 and

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

18 “(B) EXCEPTION FOR ATHLETIC FACILI-
 19 TIES.—This paragraph shall not apply to fees
 20 or dues paid to athletic or fitness facilities
 21 (within the meaning of section 132(j)(4)(C)) to
 22 the extent that such fees or dues do not exceed
 23 \$900 for any membership.”.

24 (2) CONFORMING AMENDMENT.—Section
 25 274(e)(4) of such Code is amended by striking “sub-

1 section (a)(3)” and by inserting “subsection
2 (a)(3)(A)”.

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

6 **SEC. 204. CDC AND EMPLOYER-BASED WELLNESS PRO-**
7 **GRAMS.**

8 (a) AMENDMENT TO PUBLIC HEALTH SERVICE
9 ACT.—Title III of the Public Health Service Act (42
10 U.S.C. 241 et seq.) is amended by adding at the end the
11 following:

12 **“PART R—CDC AND EMPLOYER-BASED**
13 **WELLNESS PROGRAMS**

14 **“SEC. 399Z-1. EMPLOYER-BASED WELLNESS BEST PRAC-**
15 **TICES.**

16 “(a) IN GENERAL.—The Director of the Centers for
17 Disease Control and Prevention shall conduct a study that
18 analyzes employer-based wellness programs and deter-
19 mines—

20 “(1) best practices of such programs that im-
21 pact and sustain behavior change in employees;

22 “(2) the impact that such programs have on re-
23 ducing health risk prevalence and improving absen-
24 teeism of employees; and

1 “(3) the return to employers on the investment
2 made by such employers in such programs.

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

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

9 “(2) an Employer Wellness Model that is sup-
10 ported by the Centers for Disease Control and Pre-
11 vention.

12 **“SEC. 399Z-2. WORKPLACE WELLNESS EDUCATION CAM-**
13 **PAIGN FOR EMPLOYERS.**

14 “The Director of the Centers for Disease Control and
15 Prevention, in coordination with relevant worksite health
16 promotion organizations, shall conduct an educational
17 campaign to make employers, employer groups, and other
18 interested parties aware of the benefits of employer-based
19 wellness programs. Such campaign shall include informa-
20 tion about the Employer Wellness Model described in sec-
21 tion 399Z-1(b)(2) and information on developing, imple-
22 menting, and maintaining a program based on such model.

1 **“SEC. 399Z-3. EVALUATION OF EMPLOYER-BASED**
2 **WELLNESS PROGRAMS.**

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

5 “(1) provide employers with technical assistance
6 in evaluating such employers’ employer-based
7 wellness programs; and

8 “(2) train employers on how to evaluate such
9 employers’ employer-based wellness programs.

10 **“SEC. 399Z-4. REQUIREMENTS BASED ON APPROPRIATED**
11 **FUNDS.**

12 “The Director of the Centers for Disease Control and
13 Prevention shall be required to carry out the activities in
14 sections 399Z-1, 399Z-2, and 399Z-3 only if funds are
15 appropriated to carry out such sections.”.

16 (b) GRANTS TO HELP SMALL BUSINESSES.—

17 (1) WELLNESS PROGRAMS.—

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

1 (B) CRITERIA FOR PROGRAMS.—The
 2 wellness programs implemented pursuant to
 3 subparagraph (A) shall be certified by the Sec-
 4 retary of Human Services, in the same manner
 5 as required under section 45G of the Internal
 6 Revenue Code of 1986, as a qualified wellness
 7 program (within the meaning of such section)
 8 or as a qualified small business wellness pro-
 9 gram (within the meaning of such section).

10 (2) QUALIFYING EMPLOYER.—In this sub-
 11 section, the term “qualifying employer” means a
 12 business—

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

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

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

17 or

18 (iii) that is exempt from tax under section
 19 501 of the Internal Revenue Code of 1986.

20 (3) REQUIREMENTS BASED ON APPROPRIATED
 21 FUNDS.—The Director of the Centers for Disease
 22 Control and Prevention shall be required to award
 23 grants under this subsection only if funds are appro-
 24 priated to carry out this subsection.

1 **Subtitle B—Healthy Communities**

2 **SEC. 211. HEALTHY COMMUNITY GRANTS.**

3 Part P of title III of the Public Health Service Act
4 (42 U.S.C. 280g et seq.) is amended by adding at the end
5 the following:

6 **“SEC. 399P. HEALTHY COMMUNITY GRANTS.**

7 “(a) ESTABLISHMENT.—The Secretary, acting
8 through the Director of the Centers for Disease Control
9 and Prevention and in coordination with the Directors of
10 other appropriate Federal agencies, shall award competi-
11 tive grants to eligible entities for the purpose of planning
12 and implementing programs that seek to promote indi-
13 vidual and community health and to prevent the incidence
14 of chronic disease.

15 “(b) ELIGIBILITY.—

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

18 “(A) be—

19 “(i) a city, county, or Indian tribe;

20 “(ii) a local or tribal educational
21 agency;

22 “(iii) an accredited university, college,
23 or community college;

24 “(iv) a federally qualified health cen-
25 ter;

1 “(v) a local health department;

2 “(vi) a health care provider;

3 “(vii) a community-based organiza-
4 tion; or

5 “(viii) any other entity determined ap-
6 propriate by the Secretary, including a
7 consortia or partnership of entities de-
8 scribed in any of clauses (i) through (vii);

9 “(B) prepare and submit an application in
10 accordance with paragraph (2); and

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

15 “(2) APPLICATION.—

16 “(A) IN GENERAL.—An entity desiring a
17 grant under this section shall submit an appli-
18 cation to the Secretary at such time, in such
19 manner, and containing such information as the
20 Secretary may require, including a plan that
21 meets the requirements of subparagraph (B).

22 “(B) PLAN.—A plan meets the require-
23 ments of this subparagraph if such plan, at a
24 minimum, includes information regarding—

1 “(i)(I) programs or community-based
 2 activities that the applicant proposes to
 3 carry out with funds received under this
 4 section and which seek to prevent and re-
 5 duce the incidence of—

6 “(aa) overweight and obesity, or
 7 chronic diseases associated with over-
 8 weight and obesity;

9 “(bb) tobacco use; or

10 “(cc) mental illness; or

11 “(II) other such activities, as deter-
 12 mined appropriate by the Secretary, that
 13 are consistent with the goals of promoting
 14 individual and community health and pre-
 15 venting chronic disease; and

16 “(ii) the manner in which the appli-
 17 cant will evaluate the effectiveness of the
 18 program or activities carried out under this
 19 section.

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

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

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

9 “(A) being overweight or obese;

10 “(B) tobacco use; or

11 “(C) mental illness; or

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

15 “(d) PRIORITY.—In awarding grants under sub-
16 section (a), the Secretary shall give priority to—

17 “(1) entities that demonstrate that they have
18 previously applied successfully for funds to carry out
19 activities that seek to promote individual and com-
20 munity health and to prevent the incidence of chron-
21 ic disease and that can cite published and peer-re-
22 viewed research demonstrating that the activities
23 that the entity proposes to carry out under this sub-
24 section are effective;

1 “(2) entities that will carry out programs or ac-
 2 tivities that seek to accomplish a goal or goals set
 3 by the State in the Healthy People 2010 plan of the
 4 State;

5 “(3) entities that provide non-Federal contribu-
 6 tions, either in cash or in kind, to the costs of fund-
 7 ing activities under the grant;

8 “(4) entities that develop comprehensive plans
 9 that include a strategy for extending program activi-
 10 ties developed under this section in the years fol-
 11 lowing the fiscal years for which they receive grants
 12 under this section;

13 “(5) entities located in communities that are
 14 medically underserved, as determined by the Sec-
 15 retary;

16 “(6) entities located in areas where the average
 17 poverty rate is 150 or higher than the average pov-
 18 erty rate in the State involved, as determined by the
 19 Secretary; and

20 “(7) entities that submit plans that exhibit
 21 multisectoral, cooperative conduct that includes the
 22 involvement of a broad range of stakeholders, includ-
 23 ing—

24 “(A) community-based organizations;

25 “(B) local governments;

- 1 “(C) local educational agencies;
- 2 “(D) the private sector;
- 3 “(E) State or local departments of health;
- 4 “(F) accredited colleges, universities, and
- 5 community colleges;
- 6 “(G) health care providers;
- 7 “(H) State and local departments of trans-
- 8 portation and city planning; and
- 9 “(I) other entities determined appropriate
- 10 by the Secretary.

11 “(e) TECHNICAL ASSISTANCE.—From amounts ap-
12 propriated to carry out this section, the Secretary may re-
13 serve not more than 10 percent for each fiscal year to pro-
14 vide entities receiving grants under this section with tech-
15 nical assistance in the implementation of the plans re-
16 quired under subsection (b)(2)(B).

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

1 Senate and the Committee on Appropriations of the House
2 of Representatives.

3 “(g) LIMITATION ON ADMINISTRATIVE COSTS.—An
4 entity may not use more than 10 percent of amounts re-
5 ceived under a grant under this section for administrative
6 expenses.

7 “(h) SUPPLEMENT NOT SUPPLANT.—Amounts pro-
8 vided under a grant under this section shall be used to
9 supplement, and not supplant, other amounts provided for
10 activities of the type to be carried out under this section.

11 “(i) AUTHORIZATION OF APPROPRIATIONS.—There is
12 authorized to be appropriated such sums as may be nec-
13 essary to carry out this section.”.

14 **SEC. 212. LIVING WELL WITH A DISABILITY AND WORKING**
15 **WELL WITH A DISABILITY PROGRAMS.**

16 Part P of title III of the Public Health Service Act
17 (42 U.S.C. 280g et seq.), as amended by section 211, is
18 further amended by adding at the end the following:

19 **“SEC. 399Q. LIVING WELL WITH A DISABILITY PROGRAMS.**

20 “(a) DEFINITIONS.—In this section:

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

1 “(2) DISABILITY.—The term ‘disability’ has the
2 meaning given the term in section 3 of the Ameri-
3 cans with Disabilities Act of 1990 (42 U.S.C.
4 12102).

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

9 “(b) GRANTS.—The Secretary, acting through the
10 Director of the Centers for Disease Control and Preven-
11 tion, may make grants to eligible entities on a competitive
12 basis, to assist the entities in implementing Living Well
13 With a Disability Programs, designed—

14 “(1) to increase health-promoting behavior,
15 such as engaging in exercise, eating nutritious food,
16 and using stress management techniques, among in-
17 dividuals with disabilities; and

18 “(2) to reduce the limitations of secondary con-
19 ditions for such individuals.

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

22 “(1) shall be a nonprofit organization that
23 serves individuals with disabilities;

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

4 “(3) may be a center for independent living.

5 “(d) APPLICATION.—To be eligible to receive a grant
 6 under this section for a program, an entity shall submit
 7 an application to the Secretary at such time, in such man-
 8 ner, and containing such information as the Secretary may
 9 require, including information on—

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

12 “(2) the entity’s capacity to collect data and in-
 13 formation on outcomes of the program; and

14 “(3) the entity’s experience implementing simi-
 15 lar training programs.

16 “(e) PREFERENCE AND DISTRIBUTION.—

17 “(1) PREFERENCE.—In making grants under
 18 this section, the Secretary shall give preference to el-
 19 igible entities who—

20 “(A) are currently (as of the date of sub-
 21 mission of the application) serving individuals
 22 with disabilities and implementing training and
 23 peer support programs;

4 “(C) have not previously provided training
5 through a Living Well With a Disability Pro-
6 gram.

7 “(2) DISTRIBUTION.—In making grants under
8 this section, the Secretary shall, to the extent prac-
9 ticable, ensure an equitable geographic distribution
10 of the grants.

“(f) CURRICULUM, TRAINING, AND TECHNICAL AS-
SISTANCE.—An entity that receives a grant under this sec-
tion 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.

18 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
19 are authorized to be appropriated to carry out this section
20 \$2,000,000 for each of fiscal years 2005 through 2009.

21 “SEC. 399R. WORKING WELL WITH A DISABILITY PRO-
22 GRAMS.

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1 living services' have the meanings given the terms in sec-
2 tion 399O.

3 “(b) AUTHORIZATION.—The Secretary, acting
4 through the Director of the Centers for Disease Control
5 and Prevention, may establish a demonstration program
6 promoting the health and wellness of individuals with dis-
7 abilities in the workplace.

8 “(c) GRANTS.—In carrying out the program, the Sec-
9 retary shall make grants to an eligible entity, to assist the
10 entity in preparing for the implementation of, or imple-
11 menting, Working Well With a Disability Programs, which
12 may include—

13 “(1) gathering data on the positive effects of
14 healthy behaviors on retention and productivity of
15 individuals with disabilities who are employees or po-
16 tential employees;

17 “(2) building relationships between vocational
18 rehabilitation programs and health promotion pro-
19 grams;

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

23 “(4) training individuals in methods of imple-
24 menting the program;

25 “(5) implementing the program; and

1 “(6) measuring the impact of the program on
2 health and employment outcomes.

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

5 “(1) have experience in implementing a Living
6 Well With a Disability Program; and

7 “(2) demonstrate that the entity is qualified
8 and able to adapt the program to establish a Work-
9 ing Well With a Disability Program, and implement
10 the program.

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

15 “(1) shall be nonprofit organizations that serve
16 individuals with disabilities;

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

20 “(3) may be centers for independent living.

21 “(f) APPLICATION.—To be eligible to receive a grant
22 under this section for a program, an entity shall submit
23 an application to the Secretary at such time, in such man-
24 ner, and containing such information as the Secretary may
25 require.

1 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
 2 are authorized to be appropriated to carry out this section
 3 \$1,000,000 for the period of fiscal years 2005 through
 4 2007.”.

5 **SEC. 213. ENHANCED STANDARDS FOR ROADS AND INTER-**
 6 **SECTION CONTROLS.**

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

9 “(g) ENHANCED STANDARDS FOR ROADS AND
 10 INTERSECTION CONTROLS.—

11 “(1) IN GENERAL.—Not later than 18 months
 12 after the date of enactment of this subsection, the
 13 Secretary, in coordination with the American Asso-
 14 ciation of State Highway and Transportation Offi-
 15 cials and the Institute of Transportation Engineers,
 16 shall develop recommended enhanced standards for
 17 the design of roads and intersection controls (includ-
 18 ing associated bicycle paths, bicycle lanes, and walk-
 19 ways) to improve pedestrian and bicycle safety.

20 “(2) ACCOMMODATION OF BICYCLES AND PE-
 21 DESTRIANS.—The standards under paragraph (1)
 22 shall—

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

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

3 “(B) specify that generally, when the in-
4 creased cost is not excessive, as an element of
5 good highway design for new construction or re-
6 construction facilities on which bicycles or pe-
7 destrians are permitted, the design shall include
8 appropriate provisions to accommodate bicycles
9 or pedestrians.

10 “(3) INCREASED APPORTIONMENT.—

11 “(A) IN GENERAL.—Beginning with the
12 first fiscal year that begins after the date that
13 is 2 years after the date of enactment of this
14 subsection, if a State accepts the recommended
15 enhanced standards for the State and local
16 units of government to meet, the State shall re-
17 ceive a 4 percent increase in the amount of
18 funds made available to the State under this
19 section for each fiscal year, if, at least 10 days
20 before the beginning of the fiscal year, the
21 State—

22 “(i) agrees to follow the enhanced
23 standards; or

1 “(ii) establishes an alternative en-
 2 hanced standard that the Secretary ap-
 3 proves.

4 “(B) SIGNIFICANT COMMITMENT.—In de-
 5 termining the significance of the required com-
 6 mitment of funds under subparagraph (A), the
 7 Secretary shall take into consideration the ef-
 8 fectiveness of the criteria required and an esti-
 9 mation of increased costs.

10 “(4) CONSTRUCTION REQUIREMENTS.—The
 11 Secretary and a State may establish differing re-
 12 quirements for the construction of new facilities, for
 13 the rehabilitation of facilities, and for modifications
 14 specifically to improve safety and for facilities based
 15 on the level of expected pedestrian and bicycle traf-
 16 fic.”.

17 **SEC. 214. MENTAL HEALTH SURVEILLANCE.**

18 Title V of the Public Health Service Act (42 U.S.C.
 19 290aa et seq.) is amended by inserting after section 506B
 20 (42 U.S.C. 290aa-5b) the following:

21 **“SEC. 506C. MENTAL HEALTH SURVEILLANCE.**

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

1 plement public health surveillance measures to address the
2 mental and behavioral health needs of the population of
3 the United States and other populations served by the Ad-
4 ministration, that include—

5 “(1) monitoring the mental health status of the
6 population;

7 “(2) monitoring mental and behavioral health
8 risks;

9 “(3) enhancing existing public health surveil-
10 lance systems to include data on mental and behav-
11 ioral health status and risks; and

12 “(4) monitoring the immediate and long-term
13 impact of emergencies on population mental health
14 and behavior.

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

20 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
21 is authorized to be appropriated \$5,000,000 for fiscal year
22 2005 and \$15,000,000 for each of the following fiscal
23 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-

1 prehensive restrictions on the sale, promotion, and
2 distribution of such products are needed.

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

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

12 (9) Under article I, section 8 of the Constitu-
13 tion, the Congress is vested with the responsibility
14 for regulating interstate commerce and commerce
15 with Indian tribes.

16 (10) The sale, distribution, marketing, adver-
17 tising, and use of tobacco products are activities in
18 and substantially affecting interstate commerce be-
19 cause they are sold, marketed, advertised, and dis-
20 tributed in interstate commerce on a nationwide
21 basis, and have a substantial effect on the Nation's
22 economy.

23 (11) The sale, distribution, marketing, adver-
24 tising, and use of such products substantially affect
25 interstate commerce through the health care and

1 other costs attributable to the use of tobacco prod-
2 ucts.

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

10 (13) Tobacco use is the foremost preventable
11 cause of premature death in America. It causes over
12 400,000 deaths in the United States each year and
13 approximately 8,600,000 Americans have chronic ill-
14 nesses related to smoking.

15 (14) Reducing the use of tobacco by minors by
16 50 percent would prevent well over 6,500,000 of to-
17 day's children from becoming regular, daily smokers,
18 saving over 2,000,000 of them from premature
19 death due to tobacco induced disease. Such a reduc-
20 tion in youth smoking would also result in approxi-
21 mately \$75,000,000,000 in savings attributable to
22 reduced health care costs.

23 (15) Advertising, marketing, and promotion of
24 tobacco products have been especially directed to at-
25 tract young persons to use tobacco products and

1 these efforts have resulted in increased use of such
2 products by youth. Past efforts to oversee these ac-
3 tivities have not been successful in adequately pre-
4 venting such increased use.

5 (16) In 2001, the tobacco industry spent more
6 than \$11,000,000,000 to attract new users, retain
7 current users, increase current consumption, and
8 generate favorable long-term attitudes toward smok-
9 ing and tobacco use.

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

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

17 (19) Through advertisements during and spon-
18 sorship of sporting events, tobacco has become
19 strongly associated with sports and has become por-
20 trayed as an integral part of sports and the healthy
21 lifestyle associated with rigorous sporting activity.

22 (20) Children are exposed to substantial and
23 unavoidable tobacco advertising that leads to favor-
24 able beliefs about tobacco use, plays a role in leading
25 young people to overestimate the prevalence of to-

1 bacco use, and increases the number of young people
2 who begin to use tobacco.

3 (21) The use of tobacco products in motion pic-
4 tures and other mass media glamorizes its use for
5 young people and encourages them to use tobacco
6 products.

7 (22) Tobacco advertising expands the size of
8 the tobacco market by increasing consumption of to-
9 bacco products including tobacco use by young peo-
10 ple.

11 (23) Children are more influenced by tobacco
12 advertising than adults, they smoke the most adver-
13 tised brands.

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

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

23 (26) Restrictions on advertising are necessary
24 to prevent unrestricted tobacco advertising from un-
25 dermining legislation prohibiting access to young

1 people and providing for education about tobacco
2 use.

3 (27) International experience shows that adver-
4 tising regulations that are stringent and comprehen-
5 sive have a greater impact on overall tobacco use
6 and young people's use than weaker or less com-
7 prehensive ones.

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

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

15 (30) The final regulations promulgated by the
16 Secretary of Health and Human Services in the Au-
17 gust 28, 1996, issue of the Federal Register (61
18 Fed. Reg. 44615–44618) for inclusion as part 897
19 of title 21, Code of Federal Regulations, are con-
20 sistent with the First Amendment to the United
21 States Constitution and with the standards set forth
22 in the amendments made by this subtitle for the reg-
23 ulation of tobacco products by the Food and Drug
24 Administration and the restriction on the sale and
25 distribution, including access to and the advertising

1 and promotion of, tobacco products contained in
2 such regulations are substantially related to accom-
3 plishing the public health goals of this subtitle.

4 (31) The regulations described in paragraph
5 (30) will directly and materially advance the Federal
6 Government's substantial interest in reducing the
7 number of children and adolescents who use ciga-
8 rettes and smokeless tobacco and in preventing the
9 life-threatening health consequences associated with
10 tobacco use. An overwhelming majority of Americans
11 who use tobacco products begin using such products
12 while they are minors and become addicted to the
13 nicotine in those products before reaching the age of
14 18. Tobacco advertising and promotion plays a cru-
15 cial role in the decision of these minors to begin
16 using tobacco products. Less restrictive and less
17 comprehensive approaches have not and will not be
18 effective in reducing the problems addressed by such
19 regulations. The reasonable restrictions on the ad-
20 vertising and promotion of tobacco products con-
21 tained in such regulations will lead to a significant
22 decrease in the number of minors using and becom-
23 ing addicted to those products.

24 (32) The regulations described in paragraph
25 (30) impose no more extensive restrictions on com-

1 munication by tobacco manufacturers and sellers
2 than are necessary to reduce the number of children
3 and adolescents who use cigarettes and smokeless to-
4 bacco and to prevent the life-threatening health con-
5 sequences associated with tobacco use. Such regula-
6 tions are narrowly tailored to restrict those adver-
7 tising and promotional practices which are most like-
8 ly to be seen or heard by youth and most likely to
9 entice them into tobacco use, while affording tobacco
10 manufacturers and sellers ample opportunity to con-
11 vey information about their products to adult con-
12 sumers.

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

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

19 (35) Tobacco products have been used to facili-
20 tate and finance criminal activities both domestically
21 and internationally. Illicit trade of tobacco products
22 has been linked to organized crime and terrorist
23 groups.

24 (36) It is essential that the Food and Drug Ad-
25 ministration review products sold or distributed for

1 use to reduce risks or exposures associated with to-
2 bacco products and that it be empowered to review
3 any advertising and labeling for such products. It is
4 also essential that manufacturers, prior to marketing
5 such products, be required to demonstrate that such
6 products will meet a series of rigorous criteria, and
7 will benefit the health of the population as a whole,
8 taking into account both users of tobacco products
9 and persons who do not currently use tobacco prod-
10 ucts.

11 (37) Unless tobacco products that purport to
12 reduce the risks to the public of tobacco use actually
13 reduce such risks, those products can cause substan-
14 tial harm to the public health to the extent that the
15 individuals, who would otherwise not consume to-
16 bacco products or would consume such products less,
17 use tobacco products purporting to reduce risk.
18 Those who use products sold or distributed as modi-
19 fied risk products that do not in fact reduce risk,
20 rather than quitting or reducing their use of tobacco
21 products, have a substantially increased likelihood of
22 suffering disability and premature death. The costs
23 to society of the widespread use of products sold or
24 distributed as modified risk products that do not in
25 fact reduce risk or that increase risk include thou-

1 sands of unnecessary deaths and injuries and huge
2 costs to our health care system.

3 (38) As the National Cancer Institute has
4 found, many smokers mistakenly believe that “low
5 tar” and “light” cigarettes cause fewer health prob-
6 lems than other cigarettes. As the National Cancer
7 Institute has also found, mistaken beliefs about the
8 health consequences of smoking “low tar” and
9 “light” cigarettes can reduce the motivation to quit
10 smoking entirely and thereby lead to disease and
11 death.

12 (39) Recent studies have demonstrated that
13 there has been no reduction in risk on a population-
14 wide basis from “low tar” and “light” cigarettes and
15 such products may actually increase the risk of to-
16 bacco use.

17 (40) The dangers of products sold or distrib-
18 uted as modified risk tobacco products that do not
19 in fact reduce risk are so high that there is a com-
20 pelling governmental interest in insuring that state-
21 ments about modified risk tobacco products are com-
22 plete, accurate, and relate to the overall disease risk
23 of the product.

24 (41) As the Federal Trade Commission has
25 found, consumers have misinterpreted advertise-

1 ments in which one product is claimed to be less
2 harmful than a comparable product, even in the
3 presence of disclosures and advisories intended to
4 provide clarification.

5 (42) Permitting manufacturers to make unsub-
6 stantiated statements concerning modified risk to-
7 bacco products, whether express or implied, even if
8 accompanied by disclaimers would be detrimental to
9 the public health.

10 (43) The only way to effectively protect the
11 public health from the dangers of unsubstantiated
12 modified risk tobacco products is to empower the
13 Food and Drug Administration to require that prod-
14 ucts that tobacco manufacturers sold or distributed
15 for risk reduction be approved in advance of mar-
16 keting, and to require that the evidence relied on to
17 support approval of these products is rigorous.

18 **SEC. 223. PURPOSE.**

19 The purposes of this subtitle are—

20 (1) to provide authority to the Food and Drug
21 Administration to regulate tobacco products under
22 the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 301 et seq.), by recognizing it as the primary
24 Federal regulatory authority with respect to the

1 manufacture, marketing, and distribution of tobacco
2 products;

3 (2) to ensure that the Food and Drug Adminis-
4 tration has the authority to address issues of par-
5 ticular concern to public health officials, especially
6 the use of tobacco by young people and dependence
7 on tobacco;

8 (3) to authorize the Food and Drug Adminis-
9 tration to set national standards controlling the
10 manufacture of tobacco products and the identity,
11 public disclosure, and amount of ingredients used in
12 such products;

13 (4) to provide new and flexible enforcement au-
14 thority to ensure that there is effective oversight of
15 the tobacco industry's efforts to develop, introduce,
16 and promote less harmful tobacco products;

17 (5) to vest the Food and Drug Administration
18 with the authority to regulate the levels of tar, nico-
19 tine, and other harmful components of tobacco prod-
20 ucts;

21 (6) in order to ensure that consumers are better
22 informed, to require tobacco product manufacturers
23 to disclose research which has not previously been
24 made available, as well as research generated in the

1 future, relating to the health and dependency effects
2 or safety of tobacco products;

3 (7) to continue to permit the sale of tobacco
4 products to adults in conjunction with measures to
5 ensure that they are not sold or accessible to under-
6 age purchasers;

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

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

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

14 **SEC. 224. SCOPE AND EFFECT.**

15 (a) INTENDED EFFECT.—Nothing in this subtitle (or
16 an amendment made by this subtitle) shall be construed
17 to—

18 (1) establish a precedent with regard to any
19 other industry, situation, circumstance, or legal ac-
20 tion; or

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

24 (b) AGRICULTURAL ACTIVITIES.—The provisions of
25 this subtitle (or an amendment made by this subtitle)

1 which authorize the Secretary to take certain actions with
 2 regard to tobacco and tobacco products shall not be con-
 3 strued to affect any authority of the Secretary of Agri-
 4 culture under existing law regarding the growing, cultiva-
 5 tion, or curing of raw tobacco.

6 **SEC. 225. SEVERABILITY.**

7 If any provision of this subtitle, the amendments
 8 made by this subtitle, or the application of any provision
 9 of this subtitle to any person or circumstance is held to
 10 be invalid, the remainder of this subtitle, the amendments
 11 made by this subtitle, and the application of the provisions
 12 of this subtitle to any other person or circumstance shall
 13 not be affected and shall continue to be enforced to the
 14 fullest extent possible.

15 **CHAPTER 1—AUTHORITY OF THE FOOD**
 16 **AND DRUG ADMINISTRATION**

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

19 (a) DEFINITION OF TOBACCO PRODUCTS.—Section
 20 201 of the Federal Food, Drug, and Cosmetic Act (21
 21 U.S.C. 321) is amended by adding at the end the fol-
 22 lowing:

23 “(nn)(1) The term ‘tobacco product’ means any prod-
 24 uct made or derived from tobacco that is intended for
 25 human consumption, including any component, part, or

1 accessory of a tobacco product (except for raw materials
 2 other than tobacco used in manufacturing a component,
 3 part, or accessory of a tobacco product).

4 “(2) The term ‘tobacco product’ does not mean—

5 “(A) a product in the form of conventional food
 6 (including water and chewing gum), a product rep-
 7 resented for use as or for use in a conventional food,
 8 or a product that is intended for ingestion in cap-
 9 sule, tablet, softgel, or liquid form; or

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

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

16 “(4) A tobacco product may not be marketed in com-
 17 bination with any other article or product regulated under
 18 this Act (including a drug, biologic, food, cosmetics, med-
 19 ical device, or a dietary supplement).”.

20 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—

21 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 22 301 et seq.) is amended—

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

24 (2) by redesignating sections 901 through 907

25 as sections 1001 through 1007; and

1 (3) by inserting after section 803 the following:

2 **“CHAPTER IX—TOBACCO**
3 **PRODUCTS**

4 **“SEC. 900. DEFINITIONS.**

5 “In this chapter:

6 “(1) ADDITIVE.—The term ‘additive’ means
7 any substance the intended use of which results or
8 may reasonably be expected to result, directly or in-
9 directly, in its becoming a component or otherwise
10 affecting the characteristic of any tobacco product
11 (including any substances intended for use as a fla-
12 voring, coloring or in producing, manufacturing,
13 packing, processing, preparing, treating, packaging,
14 transporting, or holding), except that such term does
15 not include tobacco or a pesticide chemical residue
16 in or on raw tobacco or a pesticide chemical.

17 “(2) BRAND.—The term ‘brand’ means a vari-
18 ety of tobacco product distinguished by the tobacco
19 used, tar content, nicotine content, flavoring used,
20 size, filtration, or packaging, logo, registered trade-
21 mark or brand name, identifiable pattern of colors,
22 or any combination of such attributes.

23 “(3) CIGARETTE.—The term ‘cigarette’ has the
24 meaning given that term by section 3(1) of the Fed-
25 eral Cigarette Labeling and Advertising Act (15

1 U.S.C. 1332(1)), but also includes tobacco, in any
2 form, that is functional in the product, which, be-
3 cause of its appearance, the type of tobacco used in
4 the filler, or its packaging and labeling, is likely to
5 be offered to, or purchased by, consumers as a ciga-
6 rette or as roll-your-own tobacco.

7 “(4) CIGARETTE TOBACCO.—The term ‘ciga-
8 rette tobacco’ means any product that consists of
9 loose tobacco that is intended for use by consumers
10 in a cigarette. Unless otherwise stated, the require-
11 ments for cigarettes shall also apply to cigarette to-
12 bacco.

13 “(5) COMMERCE.—The term ‘commerce’ has
14 the meaning given that term by section 3(2) of the
15 Federal Cigarette Labeling and Advertising Act (15
16 U.S.C. 1332(2)).

17 “(6) COUNTERFEIT TOBACCO PRODUCT.—The
18 term ‘counterfeit tobacco product’ means a tobacco
19 product (or the container or labeling of such a prod-
20 uct) that, without authorization, bears the trade-
21 mark, trade name, or other identifying mark, im-
22 print or device, or any likeness thereof, of a tobacco
23 product listed in a registration under section
24 905(i)(1).

1 “(7) DISTRIBUTOR.—The term ‘distributor’ as
2 regards a tobacco product means any person who
3 furthers the distribution of a tobacco product,
4 whether domestic or imported, at any point from the
5 original place of manufacture to the person who sells
6 or distributes the product to individuals for personal
7 consumption. Common carriers are not considered
8 distributors for purposes of this chapter.

9 “(8) ILLICIT TRADE.—The term ‘illicit trade’
10 means any practice or conduct prohibited by law
11 which relates to production, shipment, receipt, pos-
12 session, distribution, sale, or purchase of tobacco
13 products including any practice or conduct intended
14 to facilitate such activity.

15 “(9) INDIAN TRIBE.—The term ‘Indian tribe’
16 has the meaning given such term in section 4(e) of
17 the Indian Self Determination and Education Assist-
18 ance Act (25 U.S.C. 450b(e)).

19 “(10) LITTLE CIGAR.—The term ‘little cigar’
20 has the meaning given that term by section 3(7) of
21 the Federal Cigarette Labeling and Advertising Act
22 (15 U.S.C. 1332(7)).

23 “(11) NICOTINE.—The term ‘nicotine’ means
24 the chemical substance named 3-(1-Methyl-2-

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

3 “(12) PACKAGE.—The term ‘package’ means a
4 pack, box, carton, or container of any kind or, if no
5 other container, any wrapping (including cello-
6 phane), in which a tobacco product is offered for
7 sale, sold, or otherwise distributed to consumers.

8 “(13) RETAILER.—The term ‘retailer’ means
9 any person who sells tobacco products to individuals
10 for personal consumption, or who operates a facility
11 where self-service displays of tobacco products are
12 permitted.

13 “(14) ROLL-YOUR-OWN TOBACCO.—The term
14 ‘roll-your-own tobacco’ means any tobacco which, be-
15 cause of its appearance, type, packaging, or labeling,
16 is suitable for use and likely to be offered to, or pur-
17 chased by, consumers as tobacco for making ciga-
18 rettes.

19 “(15) SMOKE CONSTITUENT.—The term ‘smoke
20 constituent’ means any chemical or chemical com-
21 pound in mainstream or sidestream tobacco smoke
22 that either transfers from any component of the cig-
23 arette to the smoke or that is formed by the combus-
24 tion or heating of tobacco, additives, or other compo-
25 nent of the tobacco product.

1 “(16) SMOKELESS TOBACCO.—The term
2 ‘smokeless tobacco’ means any tobacco product that
3 consists of cut, ground, powdered, or leaf tobacco
4 and that is intended to be placed in the oral or nasal
5 cavity.

6 “(17) STATE.—The term ‘State’ means any
7 State of the United States and, for purposes of this
8 chapter, includes the District of Columbia, the Com-
9 monwealth of Puerto Rico, Guam, the Virgin Is-
10 lands, American Samoa, Wake Island, Midway Is-
11 lands, Kingman Reef, Johnston Atoll, the Northern
12 Mariana Islands, and any other trust territory or
13 possession of the United States.

14 “(18) TOBACCO PRODUCT MANUFACTURER.—
15 Term ‘tobacco product manufacturer’ means any
16 person, including any repacker or relabeler, who—

17 “(A) manufactures, fabricates, assembles,
18 processes, or labels a tobacco product; or

19 “(B) imports a finished cigarette or
20 smokeless tobacco product for sale or distribu-
21 tion in the United States.

22 “(19) UNITED STATES.—The term ‘United
23 States’ means the 50 States of the United States of
24 America and the District of Columbia, the Common-
25 wealth of Puerto Rico, Guam, the Virgin Islands,

1 American Samoa, Wake Island, Midway Islands,
 2 Kingman Reef, Johnston Atoll, the Northern Mar-
 3 iana Islands, and any other trust territory or posses-
 4 sion of the United States.

5 **“SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.**

6 “(a) IN GENERAL.—Tobacco products shall be regu-
 7 lated by the Secretary under this chapter and shall not
 8 be subject to the provisions of chapter V, unless—

9 “(1) such products are intended for use in the
 10 diagnosis, cure, mitigation, treatment, or prevention
 11 of disease (within the meaning of section
 12 201(g)(1)(B) or section 201(h)(2)); or

13 “(2) a claim is made for such products under
 14 section 201(g)(1)(C) or 201(h)(3);
 15 other than modified risk tobacco products approved
 16 in accordance with section 911.

17 “(b) APPLICABILITY.—This chapter shall apply to all
 18 tobacco products subject to the regulations referred to in
 19 section 232 of the Family Smoking Prevention and To-
 20 bacco Control Act, and to any other tobacco products that
 21 the Secretary by regulation deems to be subject to this
 22 chapter.

23 “(c) SCOPE.—

24 “(1) IN GENERAL.—Nothing in this chapter, or
 25 any policy issued or regulation promulgated there-

1 under, or the Family Smoking Prevention and To-
 2 bacco Control Act, shall be construed to affect the
 3 Secretary's authority over, or the regulation of,
 4 products under this Act that are not tobacco prod-
 5 ucts under chapter V or any other chapter.

6 “(2) LIMITATION OF AUTHORITY.—

7 “(A) IN GENERAL.—The provisions of this
 8 chapter shall not apply to tobacco leaf that is
 9 not in the possession of a manufacturer of to-
 10 bacco products, or to the producers of tobacco
 11 leaf, including tobacco growers, tobacco ware-
 12 houses, and tobacco grower cooperatives, nor
 13 shall any employee of the Food and Drug Ad-
 14 ministration have any authority to enter onto a
 15 farm owned by a producer of tobacco leaf with-
 16 out the written consent of such producer.

17 “(B) EXCEPTION.—Notwithstanding any
 18 other provision of this subparagraph, if a pro-
 19 ducer of tobacco leaf is also a tobacco product
 20 manufacturer or controlled by a tobacco prod-
 21 uct manufacturer, the producer shall be subject
 22 to this chapter in the producer's capacity as a
 23 manufacturer.

24 “(C) RULE OF CONSTRUCTION.—Nothing
 25 in this chapter shall be construed to grant the

1 Secretary authority to promulgate regulations on
2 any matter that involves the production of to-
3 bacco leaf or a producer thereof, other than ac-
4 tivities by a manufacturer affecting production.

5 **“SEC. 902. ADULTERATED TOBACCO PRODUCTS.**

6 “A tobacco product shall be deemed to be adulterated
7 if—

8 “(1) it consists in whole or in part of any filthy,
9 putrid, or decomposed substance, or is otherwise
10 contaminated by any added poisonous or added dele-
11 terious substance that may render the product inju-
12 rious to health;

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

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

20 “(4) it is, or purports to be or is represented
21 as, a tobacco product which is subject to a tobacco
22 product standard established under section 907 un-
23 less such tobacco product is in all respects in con-
24 formity with such standard;

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

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

6 “(6) the methods used in, or the facilities or
 7 controls used for, its manufacture, packing or stor-
 8 age are not in conformity with applicable require-
 9 ments under section 906(e)(1) or an applicable con-
 10 dition prescribed by an order under section
 11 906(e)(2); or

12 “(7) it is in violation of section 911.

13 **“SEC. 903. MISBRANDED TOBACCO PRODUCTS.**

14 “(a) IN GENERAL.—A tobacco product shall be
 15 deemed to be misbranded—

16 “(1) if its labeling is false or misleading in any
 17 particular;

18 “(2) if in package form unless it bears a label
 19 containing—

20 “(A) the name and place of business of the
 21 tobacco product manufacturer, packer, or dis-
 22 tributor;

23 “(B) an accurate statement of the quantity
 24 of the contents in terms of weight, measure, or
 25 numerical count;

1 “(C) an accurate statement of the percent-
2 age of the tobacco used in the product that is
3 domestically grown tobacco and the percentage
4 that is foreign grown tobacco; and

5 “(D) the statement required under section
6 921(a),
7 except that under subparagraph (B) reasonable vari-
8 ations shall be permitted, and exemptions as to
9 small packages shall be established, by regulations
10 prescribed by the Secretary;

11 “(3) if any word, statement, or other informa-
12 tion required by or under authority of this chapter
13 to appear on the label or labeling is not prominently
14 placed thereon with such conspicuousness (as com-
15 pared with other words, statements or designs in the
16 labeling) and in such terms as to render it likely to
17 be read and understood by the ordinary individual
18 under customary conditions of purchase and use;

19 “(4) if it has an established name, unless its
20 label bears, to the exclusion of any other nonpropri-
21 etary name, its established name prominently print-
22 ed in type as required by the Secretary by regula-
23 tion;

24 “(5) if the Secretary has issued regulations re-
25 quiring that its labeling bear adequate directions for

1 use, or adequate warnings against use by children,
2 that are necessary for the protection of users unless
3 its labeling conforms in all respects to such regula-
4 tions;

5 “(6) if it was manufactured, prepared, propa-
6 gated, compounded, or processed in any State in an
7 establishment not duly registered under section
8 905(b), 905(c), 905(d), or 905(h), if it was not in-
9 cluded in a list required by section 905(i), if a notice
10 or other information respecting it was not provided
11 as required by such section or section 905(j), or if
12 it does not bear such symbols from the uniform sys-
13 tem for identification of tobacco products prescribed
14 under section 905(e) as the Secretary by regulation
15 requires;

16 “(7) if, in the case of any tobacco product dis-
17 tributed or offered for sale in any State—

18 “(A) its advertising is false or misleading
19 in any particular; or

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

22 “(8) unless, in the case of any tobacco product
23 distributed or offered for sale in any State, the man-
24 ufacturer, packer, or distributor thereof includes in
25 all advertisements and other descriptive printed mat-

1 ter issued or caused to be issued by the manufac-
2 turer, packer, or distributor with respect to that to-
3 bacco product—

4 “(A) a true statement of the tobacco prod-
5 uct’s established name as described in para-
6 graph (4), printed prominently; and

7 “(B) a brief statement of—

8 “(i) the uses of the tobacco product
9 and relevant warnings, precautions, side
10 effects, and contraindications; and

11 “(ii) in the case of specific tobacco
12 products made subject to a finding by the
13 Secretary after notice and opportunity for
14 comment that such action is appropriate to
15 protect the public health, a full description
16 of the components of such tobacco product
17 or the formula showing quantitatively each
18 ingredient of such tobacco product to the
19 extent required in regulations which shall
20 be issued by the Secretary after an oppor-
21 tunity for a hearing;

22 “(9) if it is a tobacco product subject to a to-
23 bacco product standard established under section
24 907, unless it bears such labeling as may be pre-
25 scribed in such tobacco product standard; or

1 “(10) if there was a failure or refusal—

2 “(A) to comply with any requirement pre-
3 scribed under section 904 or 908; or

4 “(B) to furnish any material or informa-
5 tion required under section 909.

6 “(b) PRIOR APPROVAL OF LABEL STATEMENTS.—

7 The Secretary may, by regulation, require prior approval
8 of statements made on the label of a tobacco product. No
9 regulation issued under this subsection may require prior
10 approval by the Secretary of the content of any advertise-
11 ment, except for modified risk tobacco products as pro-
12 vided in section 911. No advertisement of a tobacco prod-
13 uct published after the date of enactment of the Family
14 Smoking Prevention and Tobacco Control Act shall, with
15 respect to the language of label statements as prescribed
16 under section 4 of the Cigarette Labeling and Advertising
17 Act and section 3 of the Comprehensive Smokeless To-
18 bacco Health Education Act of 1986 or the regulations
19 issued under such sections, be subject to the provisions
20 of sections 12 through 15 of the Federal Trade Commis-
21 sion Act (15 U.S.C. 52 through 55).

22 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**
23 **SECRETARY.**

24 “(a) REQUIREMENT.—Not later than 6 months after
25 the date of enactment of the Family Smoking Prevention

1 and Tobacco Control Act, each tobacco product manufac-
2 turer or importer, or agents thereof, shall submit to the
3 Secretary the following information:

4 “(1) A listing of all ingredients, including to-
5 bacco, substances, compounds, and additives that
6 are, as of such date, added by the manufacturer to
7 the tobacco, paper, filter, or other part of each to-
8 bacco product by brand and by quantity in each
9 brand and subbrand.

10 “(2) A description of the content, delivery, and
11 form of nicotine in each tobacco product measured
12 in milligrams of nicotine in accordance with regula-
13 tions promulgated by the Secretary in accordance
14 with section 4(a)(4) of the Federal Cigarette Label-
15 ing and Advertising Act.

16 “(3) A listing of all constituents, including
17 smoke constituents as applicable, identified by the
18 Secretary as harmful or potentially harmful to
19 health in each tobacco product, and as applicable in
20 the smoke of each tobacco product, by brand and by
21 quantity in each brand and subbrand. Effective be-
22 ginning 2 years after the date of enactment of this
23 chapter, the manufacturer, importer, or agent shall
24 comply with regulations promulgated under section

1 915 in reporting information under this paragraph,
2 where applicable.

3 “(4) All documents developed after the date of
4 enactment of the Family Smoking Prevention and
5 Tobacco Control Act that relate to health, toxic-
6 ological, behavioral, or physiologic effects of current
7 or future tobacco products, their constituents (in-
8 cluding smoke constituents), ingredients, compo-
9 nents, and additives.

10 “(b) DATA SUBMISSION.—At the request of the Sec-
11 retary, each tobacco product manufacturer or importer of
12 tobacco products, or agents thereof, shall submit the fol-
13 lowing:

14 “(1) Any or all documents (including under-
15 lying scientific information) relating to research ac-
16 tivities, and research findings, conducted, supported,
17 or possessed by the manufacturer (or agents thereof)
18 on the health, toxicological, behavioral, or physio-
19 logic effects of tobacco products and their constitu-
20 ents (including smoke constituents), ingredients,
21 components, and additives.

22 “(2) Any or all documents (including under-
23 lying scientific information) relating to research ac-
24 tivities, and research findings, conducted, supported,
25 or possessed by the manufacturer (or agents thereof)

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

5 “(3) Any or all documents (including under-
6 lying scientific or financial information) relating to
7 marketing research involving the use of tobacco
8 products or marketing practices and the effective-
9 ness of such practices used by tobacco manufactur-
10 ers and distributors.

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

14 “(c) TIME FOR SUBMISSION.—

15 “(1) IN GENERAL.—At least 90 days prior to
16 the delivery for introduction into interstate com-
17 merce of a tobacco product not on the market on the
18 date of enactment of the Family Smoking Preven-
19 tion and Tobacco Control Act, the manufacturer of
20 such product shall provide the information required
21 under subsection (a).

22 “(2) DISCLOSURE OF ADDITIVE.—If at any
23 time a tobacco product manufacturer adds to its to-
24 bacco products a new tobacco additive or increases
25 the quantity of an existing tobacco additive, the

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

4 “(3) DISCLOSURE OF OTHER ACTIONS.—If at
5 any time a tobacco product manufacturer eliminates
6 or decreases an existing additive, or adds or in-
7 creases an additive that has by regulation been des-
8 ignated by the Secretary as an additive that is not
9 a human or animal carcinogen, or otherwise harmful
10 to health under intended conditions of use, the man-
11 ufacturer shall within 60 days of such action so ad-
12 vise the Secretary in writing.

13 “(d) DATA LIST.—

14 “(1) IN GENERAL.—Not later than 3 years
15 after the date of enactment of the Family Smoking
16 Prevention and Tobacco Control Act, and annually
17 thereafter, the Secretary shall publish in a format
18 that is understandable and not misleading to a lay
19 person, and place on public display (in a manner de-
20 termined by the Secretary) the list established under
21 subsection (e).

22 “(2) CONSUMER RESEARCH.—The Secretary
23 shall conduct periodic consumer research to ensure
24 that the list published under paragraph (1) is not
25 misleading to lay persons. Not later than 5 years

1 after the date of enactment of the Family Smoking
 2 Prevention and Tobacco Control Act, the Secretary
 3 shall submit to the appropriate committees of Con-
 4 gress a report on the results of such research, to-
 5 gether with recommendations on whether such publi-
 6 cation should be continued or modified.

7 “(e) DATA COLLECTION.—Not later than 12 months
 8 after the date of enactment of the Family Smoking Pre-
 9 vention and Tobacco Control Act, the Secretary shall es-
 10 tablish a list of harmful and potentially harmful constitu-
 11 ents, including smoke constituents, to health in each to-
 12 bacco product by brand and by quantity in each brand
 13 and subbrand. The Secretary shall publish a public notice
 14 requesting the submission by interested persons of sci-
 15 entific and other information concerning the harmful and
 16 potentially harmful constituents in tobacco products and
 17 tobacco smoke.

18 **“SEC. 905. ANNUAL REGISTRATION.**

19 “(a) DEFINITIONS.—In this section:

20 “(1) MANUFACTURE, PREPARATION,
 21 COMPOUNDING, OR PROCESSING.—The term ‘manu-
 22 facture, preparation, compounding, or processing’
 23 shall include repackaging or otherwise changing the
 24 container, wrapper, or labeling of any tobacco prod-
 25 uct package in furtherance of the distribution of the

1 tobacco product from the original place of manufac-
 2 ture to the person who makes final delivery or sale
 3 to the ultimate consumer or user.

4 “(2) NAME.—The term ‘name’ shall include in
 5 the case of a partnership the name of each partner
 6 and, in the case of a corporation, the name of each
 7 corporate officer and director, and the State of in-
 8 corporation.

9 “(b) REGISTRATION BY OWNERS AND OPERATORS.—
 10 On or before December 31 of each year every person who
 11 owns or operates any establishment in any State engaged
 12 in the manufacture, preparation, compounding, or proc-
 13 essing of a tobacco product or tobacco products shall reg-
 14 ister with the Secretary the name, places of business, and
 15 all such establishments of that person.

16 “(c) REGISTRATION OF NEW OWNERS AND OPERA-
 17 TORS.—Every person upon first engaging in the manufac-
 18 ture, preparation, compounding, or processing of a tobacco
 19 product or tobacco products in any establishment owned
 20 or operated in any State by that person shall immediately
 21 register with the Secretary that person’s name, place of
 22 business, and such establishment.

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

1 tional establishment which that person owns or operates
2 in any State and in which that person begins the manufac-
3 ture, preparation, compounding, or processing of a tobacco
4 product or tobacco products.

5 “(e) UNIFORM PRODUCT IDENTIFICATION SYS-
6 TEM.—The Secretary may by regulation prescribe a uni-
7 form system for the identification of tobacco products and
8 may require that persons who are required to list such
9 tobacco products under subsection (i) shall list such to-
10 bacco products in accordance with such system.

11 “(f) PUBLIC ACCESS TO REGISTRATION INFORMA-
12 TION.—The Secretary shall make available for inspection,
13 to any person so requesting, any registration filed under
14 this section.

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

1 “(h) FOREIGN ESTABLISHMENTS SHALL REG-
2 ISTER.—Any establishment within any foreign country en-
3 gaged in the manufacture, preparation, compounding, or
4 processing of a tobacco product or tobacco products, shall
5 register under this section under regulations promulgated
6 by the Secretary. Such regulations shall require such es-
7 tablishment to provide the information required by sub-
8 section (i) of this section and shall include provisions for
9 registration of any such establishment upon condition that
10 adequate and effective means are available, by arrange-
11 ment with the government of such foreign country or oth-
12 erwise, to enable the Secretary to determine from time to
13 time whether tobacco products manufactured, prepared,
14 compounded, or processed in such establishment, if im-
15 ported or offered for import into the United States, shall
16 be refused admission on any of the grounds set forth in
17 section 801(a).

18 “(i) REGISTRATION INFORMATION.—

19 “(1) PRODUCT LIST.—Every person who reg-
20 isters with the Secretary under subsection (b), (c),
21 (d), or (h) shall, at the time of registration under
22 any such subsection, file with the Secretary a list of
23 all tobacco products which are being manufactured,
24 prepared, compounded, or processed by that person
25 for commercial distribution and which has not been

1 included in any list of tobacco products filed by that
2 person with the Secretary under this paragraph or
3 paragraph (2) before such time of registration. Such
4 list shall be prepared in such form and manner as
5 the Secretary may prescribe and shall be accom-
6 panied by—

7 “(A) in the case of a tobacco product con-
8 tained in the applicable list with respect to
9 which a tobacco product standard has been es-
10 tablished under section 907 or which is subject
11 to section 910, a reference to the authority for
12 the marketing of such tobacco product and a
13 copy of all labeling for such tobacco product;

14 “(B) in the case of any other tobacco prod-
15 uct contained in an applicable list, a copy of all
16 consumer information and other labeling for
17 such tobacco product, a representative sampling
18 of advertisements for such tobacco product,
19 and, upon request made by the Secretary for
20 good cause, a copy of all advertisements for a
21 particular tobacco product; and

22 “(C) if the registrant filing a list has de-
23 termined that a tobacco product contained in
24 such list is not subject to a tobacco product
25 standard established under section 907, a brief

1 statement of the basis upon which the registrant
2 made such determination if the Secretary re-
3 quests such a statement with respect to that par-
4 ticular tobacco product.

5 “(2) BIENNIAL REPORT OF ANY CHANGE IN
6 PRODUCT LIST.—Each person who registers with the
7 Secretary under this section shall report to the Sec-
8 retary once during the month of June of each year
9 and once during the month of December of each
10 year the following:

11 “(A) A list of each tobacco product intro-
12 duced by the registrant for commercial distribu-
13 tion which has not been included in any list
14 previously filed by that person with the Sec-
15 retary under this subparagraph or paragraph
16 (1). A list under this subparagraph shall list a
17 tobacco product by its established name and
18 shall be accompanied by the other information
19 required by paragraph (1).

20 “(B) If since the date the registrant last
21 made a report under this paragraph that person
22 has discontinued the manufacture, preparation,
23 compounding, or processing for commercial dis-
24 tribution of a tobacco product included in a list
25 filed under subparagraph (A) or paragraph (1),

1 notice of such discontinuance, the date of such
 2 discontinuance, and the identity of its estab-
 3 lished name.

4 “(C) If since the date the registrant re-
 5 ported under subparagraph (B) a notice of dis-
 6 continuance that person has resumed the manu-
 7 facture, preparation, compounding, or proc-
 8 essing for commercial distribution of the to-
 9 bacco product with respect to which such notice
 10 of discontinuance was reported, notice of such
 11 resumption, the date of such resumption, the
 12 identity of such tobacco product by established
 13 name, and other information required by para-
 14 graph (1), unless the registrant has previously
 15 reported such resumption to the Secretary
 16 under this subparagraph.

17 “(D) Any material change in any informa-
 18 tion previously submitted under this paragraph
 19 or paragraph (1).

20 “(j) REPORT PRECEDING INTRODUCTION OF CER-
 21 TAIN SUBSTANTIALLY-EQUIVALENT PRODUCTS INTO
 22 INTERSTATE COMMERCE.—

23 “(1) IN GENERAL.—Each person who is re-
 24 quired to register under this section and who pro-
 25 poses to begin the introduction or delivery for intro-

1 duction into interstate commerce for commercial dis-
2 tribution of a tobacco product intended for human
3 use that was not commercially marketed (other than
4 for test marketing) in the United States as of June
5 1, 2003, shall, at least 90 days prior to making such
6 introduction or delivery, report to the Secretary (in
7 such form and manner as the Secretary shall pre-
8 scribe)—

9 “(A) the basis for such person’s determina-
10 tion that the tobacco product is substantially
11 equivalent, within the meaning of section 910,
12 to a tobacco product commercially marketed
13 (other than for test marketing) in the United
14 States as of June 1, 2003, that is in compliance
15 with the requirements of this Act; and

16 “(B) action taken by such person to com-
17 ply with the requirements under section 907
18 that are applicable to the tobacco product.

19 “(2) APPLICATION TO CERTAIN POST JUNE 1,
20 2003 PRODUCTS.—A report under this subsection for
21 a tobacco product that was first introduced or deliv-
22 ered for introduction into interstate commerce for
23 commercial distribution in the United States after
24 June 1, 2003, and prior to the date that is 15
25 months after the date of enactment of the Family

1 Smoking Prevention and Tobacco Control Act shall
2 be submitted to the Secretary not later than 15
3 months after such date of enactment.

4 “(3) EXEMPTIONS.—

5 “(A) IN GENERAL.—The Secretary may by
6 regulation, exempt from the requirements of
7 this subsection tobacco products that are modi-
8 fied by adding or deleting a tobacco additive, or
9 increasing or decreasing the quantity of an ex-
10 isting tobacco additive, if the Secretary deter-
11 mines that—

12 “(i) such modification would be a
13 minor modification of a tobacco product
14 authorized for sale under this Act;

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

20 “(iii) an exemption is otherwise appro-
21 priate.

22 “(B) REGULATIONS.—Not later than 9
23 months after the date of enactment of the Fam-
24 ily Smoking Prevention and Tobacco Control

1 Act, the Secretary shall issue regulations to im-
2 plement this paragraph.

3 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**
4 **OF TOBACCO PRODUCTS.**

5 “(a) IN GENERAL.—Any requirement established by
6 or under section 902, 903, 905, or 909 applicable to a
7 tobacco product shall apply to such tobacco product until
8 the applicability of the requirement to the tobacco product
9 has been changed by action taken under section 907, sec-
10 tion 910, section 911, or subsection (d) of this section,
11 and any requirement established by or under section 902,
12 903, 905, or 909 which is inconsistent with a requirement
13 imposed on such tobacco product under section 907, sec-
14 tion 910, section 911, or subsection (d) of this section
15 shall not apply to such tobacco product.

16 “(b) INFORMATION ON PUBLIC ACCESS AND COM-
17 MENT.—Each notice of proposed rulemaking under section
18 907, 908, 909, 910, or 911 or under this section, any
19 other notice which is published in the Federal Register
20 with respect to any other action taken under any such sec-
21 tion and which states the reasons for such action, and
22 each publication of findings required to be made in con-
23 nection with rulemaking under any such section shall set
24 forth—

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

4 “(2) the period within which interested persons
5 may present their comments on the notice or find-
6 ings (including the need therefore) orally or in writ-
7 ing, which period shall be at least 60 days but may
8 not exceed 90 days unless the time is extended by
9 the Secretary by a notice published in the Federal
10 Register stating good cause therefore.

11 “(c) LIMITED CONFIDENTIALITY OF INFORMA-
12 TION.—Any information reported to or otherwise obtained
13 by the Secretary or the Secretary’s representative under
14 section 903, 904, 907, 908, 909, 910, 911, or 704, or
15 under subsection (e) or (f) of this section, which is exempt
16 from disclosure under subsection (a) of section 552 of title
17 5, United States Code, by reason of subsection (b)(4) of
18 that section shall be considered confidential and shall not
19 be disclosed, except that the information may be disclosed
20 to other officers or employees concerned with carrying out
21 this chapter, or when relevant in any proceeding under
22 this chapter.

23 “(d) RESTRICTIONS.—

24 “(1) IN GENERAL.—The Secretary may by reg-
25 ulation require restrictions on the sale and distribu-

1 tion of a tobacco product, including restrictions on
 2 the access to, and the advertising and promotion of,
 3 the tobacco product, if the Secretary determines that
 4 such regulation would be appropriate for the protec-
 5 tion of the public health. The Secretary may by reg-
 6 ulation impose restrictions on the advertising and
 7 promotion of a tobacco product consistent with and
 8 to full extent permitted by the first amendment to
 9 the Constitution. The finding as to whether such
 10 regulation would be appropriate for the protection of
 11 the public health shall be determined with respect to
 12 the risks and benefits to the population as a whole,
 13 including users and non-users of the tobacco prod-
 14 uct, and taking into account—

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

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

21 No such regulation may require that the sale or dis-
 22 tribution of a tobacco product be limited to the writ-
 23 ten or oral authorization of a practitioner licensed
 24 by law to prescribe medical products.

1 “(2) LABEL STATEMENTS.—The label of a to-
 2 bacco product shall bear such appropriate state-
 3 ments of the restrictions required by a regulation
 4 under subsection (a) as the Secretary may in such
 5 regulation prescribe.

6 “(3) LIMITATIONS.—

7 “(A) IN GENERAL.—No restrictions under
 8 paragraph (1) may—

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

12 “(ii) establish a minimum age of sale
 13 of tobacco products to any person older
 14 than 18 years of age.

15 “(B) MATCHBOOKS.—For purposes of any
 16 regulations issued by the Secretary, matchbooks
 17 of conventional size containing not more than
 18 20 paper matches, and which are customarily
 19 given away for free with the purchase of to-
 20 bacco products shall be considered as adult
 21 written publications which shall be permitted to
 22 contain advertising. Notwithstanding the pre-
 23 ceding sentence, if the Secretary finds that such
 24 treatment of matchbooks is not appropriate for
 25 the protection of the public health, the Sec-

1 retary may determine by regulation that match-
2 books shall not be considered adult written pub-
3 lications.

4 “(e) GOOD MANUFACTURING PRACTICE REQUIRE-
5 MENTS.—

6 “(1) METHODS, FACILITIES, AND CONTROLS TO
7 CONFORM.—

8 “(A) IN GENERAL.—The Secretary may, in
9 accordance with subparagraph (B), prescribe
10 regulations (which may differ based on the type
11 of tobacco product involved) requiring that the
12 methods used in, and the facilities and controls
13 used for, the manufacture, pre-production de-
14 sign validation (including a process to assess
15 the performance of a tobacco product), packing
16 and storage of a tobacco product, conform to
17 current good manufacturing practice, as pre-
18 scribed in such regulations, to assure that the
19 public health is protected and that the tobacco
20 product is in compliance with this chapter.
21 Good manufacturing practices may include the
22 testing of raw tobacco for pesticide chemical
23 residues regardless of whether a tolerance for
24 such chemical residues has been established.

1 “(B) REQUIREMENTS.—The Secretary
2 shall—

3 “(i) before promulgating any regula-
4 tion under subparagraph (A), afford the
5 Tobacco Products Scientific Advisory Com-
6 mittee an opportunity to submit rec-
7 ommendations with respect to the regula-
8 tion proposed to be promulgated;

9 “(ii) before promulgating any regula-
10 tion under subparagraph (A), afford oppor-
11 tunity for an oral hearing;

12 “(iii) provide the advisory committee a
13 reasonable time to make its recommenda-
14 tion with respect to proposed regulations
15 under subparagraph (A); and

16 “(iv) in establishing the effective date
17 of a regulation promulgated under this
18 subsection, take into account the dif-
19 ferences in the manner in which the dif-
20 ferent types of tobacco products have his-
21 torically been produced, the financial re-
22 sources of the different tobacco product
23 manufacturers, and the state of their exist-
24 ing manufacturing facilities, and shall pro-
25 vide for a reasonable period of time for

1 such manufacturers to conform to good
2 manufacturing practices.

3 “(2) EXEMPTIONS; VARIANCES.—

4 “(A) PETITION.—Any person subject to
5 any requirement prescribed under paragraph
6 (1) may petition the Secretary for a permanent
7 or temporary exemption or variance from such
8 requirement. Such a petition shall be submitted
9 to the Secretary in such form and manner as
10 the Secretary shall prescribe and shall—

11 “(i) in the case of a petition for an ex-
12 emption from a requirement, set forth the
13 basis for the petitioner’s determination
14 that compliance with the requirement is
15 not required to assure that the tobacco
16 product will be in compliance with this
17 chapter;

18 “(ii) in the case of a petition for a
19 variance from a requirement, set forth the
20 methods proposed to be used in, and the
21 facilities and controls proposed to be used
22 for, the manufacture, packing, and storage
23 of the tobacco product in lieu of the meth-
24 ods, facilities, and controls prescribed by
25 the requirement; and

1 “(iii) contain such other information
2 as the Secretary shall prescribe.

3 “(B) REFERRAL TO THE TOBACCO PROD-
4 UCTS SCIENTIFIC ADVISORY COMMITTEE.—The
5 Secretary may refer to the Tobacco Products
6 Scientific Advisory Committee any petition sub-
7 mitted under subparagraph (A). The Tobacco
8 Products Scientific Advisory Committee shall
9 report its recommendations to the Secretary
10 with respect to a petition referred to it within
11 60 days after the date of the petition’s referral.
12 Within 60 days after—

13 “(i) the date the petition was sub-
14 mitted to the Secretary under subpara-
15 graph (A); or

16 “(ii) the day after the petition was re-
17 ferred to the Tobacco Products Scientific
18 Advisory Committee,

19 whichever occurs later, the Secretary shall by
20 order either deny the petition or approve it.

21 “(C) APPROVAL.—The Secretary may ap-
22 prove—

23 “(i) a petition for an exemption for a
24 tobacco product from a requirement if the
25 Secretary determines that compliance with

1 such requirement is not required to assure
2 that the tobacco product will be in compli-
3 ance with this chapter; and

4 “(ii) a petition for a variance for a to-
5 bacco product from a requirement if the
6 Secretary determines that the methods to
7 be used in, and the facilities and controls
8 to be used for, the manufacture, packing,
9 and storage of the tobacco product in lieu
10 of the methods, controls, and facilities pre-
11 scribed by the requirement are sufficient to
12 assure that the tobacco product will be in
13 compliance with this chapter.

14 “(D) CONDITIONS.—An order of the Sec-
15 retary approving a petition for a variance shall
16 prescribe such conditions respecting the meth-
17 ods used in, and the facilities and controls used
18 for, the manufacture, packing, and storage of
19 the tobacco product to be granted the variance
20 under the petition as may be necessary to as-
21 sure that the tobacco product will be in compli-
22 ance with this chapter.

23 “(E) HEARING.—After the issuance of an
24 order under subparagraph (B) respecting a pe-

1 tition, the petitioner shall have an opportunity
2 for an informal hearing on such order.

3 “(3) COMPLIANCE.—Compliance with require-
4 ments under this subsection shall not be required be-
5 fore the period ending 3 years after the date of en-
6 actment of the Family Smoking Prevention and To-
7 bacco Control Act.

8 “(f) RESEARCH AND DEVELOPMENT.—The Secretary
9 may enter into contracts for research, testing, and dem-
10 onstrations respecting tobacco products and may obtain
11 tobacco products for research, testing, and demonstration
12 purposes without regard to section 3324(a) and (b) of title
13 31, United States Code, and section 5 of title 41, United
14 States Code.

15 **“SEC. 907. TOBACCO PRODUCT STANDARDS.**

16 “(a) IN GENERAL.—

17 “(1) SPECIAL RULE FOR CIGARETTES.—A ciga-
18 rette or any of its component parts (including the
19 tobacco, filter, or paper) shall not contain, as a con-
20 stituent (including a smoke constituent) or additive,
21 an artificial or natural flavor (other than tobacco or
22 menthol) or an herb or spice, including strawberry,
23 grape, orange, clove, cinnamon, pineapple, vanilla,
24 coconut, licorice, cocoa, chocolate, cherry, or coffee,
25 that is a characterizing flavor of the tobacco product

1 or tobacco smoke. Nothing in this subparagraph
 2 shall be construed to limit the Secretary's authority
 3 to take action under this section or other sections of
 4 this Act applicable to menthol or any artificial or
 5 natural flavor, herb, or spice not specified in this
 6 paragraph.

7 “(2) REVISION OF TOBACCO PRODUCT STAND-
 8 ARDS.—The Secretary may revise the tobacco prod-
 9 uct standards in paragraph (1) in accordance with
 10 subsection (b).

11 “(3) TOBACCO PRODUCT STANDARDS.—The
 12 Secretary may adopt tobacco product standards in
 13 addition to those in paragraph (1) if the Secretary
 14 finds that a tobacco product standard is appropriate
 15 for the protection of the public health. This finding
 16 shall be determined with respect to the risks and
 17 benefits to the population as a whole, including
 18 users and non-users of the tobacco product, and tak-
 19 ing into account—

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

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

1 “(4) CONTENT OF TOBACCO PRODUCT STAND-
2 ARDS.—A tobacco product standard established
3 under this section for a tobacco product—

4 “(A) shall include provisions that are ap-
5 propriate for the protection of the public health,
6 including provisions, where appropriate—

7 “(i) for the reduction of nicotine
8 yields of the product;

9 “(ii) for the reduction or elimination
10 of other constituents, including smoke con-
11 stituents, or harmful components of the
12 product; or

13 “(iii) relating to any other require-
14 ment under (B);

15 “(B) shall, where appropriate for the pro-
16 tection of the public health, include—

17 “(i) provisions respecting the con-
18 struction, components, ingredients, addi-
19 tives, constituents, including smoke con-
20 stituents, and properties of the tobacco
21 product;

22 “(ii) provisions for the testing (on a
23 sample basis or, if necessary, on an indi-
24 vidual basis) of the tobacco product;

1 “(iii) provisions for the measurement
2 of the tobacco product characteristics of
3 the tobacco product;

4 “(iv) provisions requiring that the re-
5 sults of each or of certain of the tests of
6 the tobacco product required to be made
7 under clause (ii) show that the tobacco
8 product is in conformity with the portions
9 of the standard for which the test or tests
10 were required; and

11 “(v) a provision requiring that the
12 sale and distribution of the tobacco prod-
13 uct be restricted but only to the extent
14 that the sale and distribution of a tobacco
15 product may be restricted under a regula-
16 tion under section 906(d); and

17 “(C) shall, where appropriate, require the
18 use and prescribe the form and content of label-
19 ing for the proper use of the tobacco product.

20 “(5) PERIODIC RE-EVALUATION OF TOBACCO
21 PRODUCT STANDARDS.—The Secretary shall provide
22 for periodic evaluation of tobacco product standards
23 established under this section to determine whether
24 such standards should be changed to reflect new
25 medical, scientific, or other technological data. The

1 Secretary may provide for testing under paragraph
2 (4)(B) by any person.

3 “(6) INVOLVEMENT OF OTHER AGENCIES; IN-
4 FORMED PERSONS.—In carrying out duties under
5 this section, the Secretary shall endeavor to—

6 “(A) use personnel, facilities, and other
7 technical support available in other Federal
8 agencies;

9 “(B) consult with other Federal agencies
10 concerned with standard-setting and other na-
11 tionally or internationally recognized standard-
12 setting entities; and

13 “(C) invite appropriate participation,
14 through joint or other conferences, workshops,
15 or other means, by informed persons represent-
16 ative of scientific, professional, industry, agri-
17 cultural, or consumer organizations who in the
18 Secretary’s judgment can make a significant
19 contribution.

20 “(b) ESTABLISHMENT OF STANDARDS.—

21 “(1) NOTICE.—

22 “(A) IN GENERAL.—The Secretary shall
23 publish in the Federal Register a notice of pro-
24 posed rulemaking for the establishment, amend-

1 ment, or revocation of any tobacco product
2 standard.

3 “(B) REQUIREMENTS OF NOTICE.—A no-
4 tice of proposed rulemaking for the establish-
5 ment or amendment of a tobacco product stand-
6 ard for a tobacco product shall—

7 “(i) set forth a finding with sup-
8 porting justification that the tobacco prod-
9 uct standard is appropriate for the protec-
10 tion of the public health;

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

15 “(iii) invite interested persons to sub-
16 mit an existing tobacco product standard
17 for the tobacco product, including a draft
18 or proposed tobacco product standard, for
19 consideration by the Secretary.

20 “(C) STANDARD.—Upon a determination
21 by the Secretary that an additive, constituent
22 (including smoke constituent), or other compo-
23 nent of the product that is the subject of the
24 proposed tobacco product standard is harmful,
25 it shall be the burden of any party challenging

1 the proposed standard to prove that the pro-
2 posed standard will not reduce or eliminate the
3 risk of illness or injury.

4 “(D) FINDING.—A notice of proposed rule-
5 making for the revocation of a tobacco product
6 standard shall set forth a finding with sup-
7 porting justification that the tobacco product
8 standard is no longer appropriate for the pro-
9 tection of the public health.

10 “(E) CONSIDERATION BY SECRETARY.—
11 The Secretary shall consider all information
12 submitted in connection with a proposed stand-
13 ard, including information concerning the coun-
14 tervailing effects of the tobacco product stand-
15 ard on the health of adolescent tobacco users,
16 adult tobacco users, or non-tobacco users, such
17 as the creation of a significant demand for con-
18 traband or other tobacco products that do not
19 meet the requirements of this chapter and the
20 significance of such demand, and shall issue the
21 standard if the Secretary determines that the
22 standard would be appropriate for the protec-
23 tion of the public health.

1 “(F) COMMENT.—The Secretary shall pro-
2 vide for a comment period of not less than 60
3 days.

4 “(2) PROMULGATION.—

5 “(A) IN GENERAL.—After the expiration of
6 the period for comment on a notice of proposed
7 rulemaking published under paragraph (1) re-
8 specting a tobacco product standard and after
9 consideration of such comments and any report
10 from the Tobacco Products Scientific Advisory
11 Committee, the Secretary shall—

12 “(i) promulgate a regulation estab-
13 lishing a tobacco product standard and
14 publish in the Federal Register findings on
15 the matters referred to in paragraph (1);
16 or

17 “(ii) publish a notice terminating the
18 proceeding for the development of the
19 standard together with the reasons for
20 such termination.

21 “(B) EFFECTIVE DATE.—A regulation es-
22 tablishing a tobacco product standard shall set
23 forth the date or dates upon which the standard
24 shall take effect, but no such regulation may
25 take effect before 1 year after the date of its

1 publication unless the Secretary determines
2 that an earlier effective date is necessary for
3 the protection of the public health. Such date or
4 dates shall be established so as to minimize,
5 consistent with the public health, economic loss
6 to, and disruption or dislocation of, domestic
7 and international trade.

8 “(3) POWER RESERVED TO CONGRESS.—Be-
9 cause of the importance of a decision of the Sec-
10 retary to issue a regulation establishing a tobacco
11 product standard—

12 “(A) banning all cigarettes, all smokeless
13 tobacco products, all little cigars, all cigars
14 other than little cigars, all pipe tobacco, or all
15 roll your own tobacco products; or

16 “(B) requiring the reduction of nicotine
17 yields of a tobacco product to zero,

18 Congress expressly reserves to itself such power.

19 “(4) AMENDMENT; REVOCATION.—

20 “(A) AUTHORITY.—The Secretary, upon
21 the Secretary’s own initiative or upon petition
22 of an interested person may by a regulation,
23 promulgated in accordance with the require-
24 ments of paragraphs (1) and (2)(B), amend or
25 revoke a tobacco product standard.

1 “(B) EFFECTIVE DATE.—The Secretary
2 may declare a proposed amendment of a to-
3 bacco product standard to be effective on and
4 after its publication in the Federal Register and
5 until the effective date of any final action taken
6 on such amendment if the Secretary determines
7 that making it so effective is in the public inter-
8 est.

9 “(5) REFERENCE TO ADVISORY COMMITTEE.—
10 The Secretary may—

11 “(A) on the Secretary’s own initiative,
12 refer a proposed regulation for the establish-
13 ment, amendment, or revocation of a tobacco
14 product standard; or

15 “(B) upon the request of an interested per-
16 son which demonstrates good cause for referral
17 and which is made before the expiration of the
18 period for submission of comments on such pro-
19 posed regulation,

20 refer such proposed regulation to the Tobacco Products
21 Scientific Advisory Committee, for a report and rec-
22 ommendation with respect to any matter involved in the
23 proposed regulation which requires the exercise of sci-
24 entific judgment. If a proposed regulation is referred
25 under this paragraph to the Tobacco Products Scientific

1 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.

13 **“SEC. 908. NOTIFICATION AND OTHER REMEDIES.**

14 “(a) NOTIFICATION.—If the Secretary determines
15 that—

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

20 “(2) notification under this subsection is necessary to eliminate the unreasonable risk of such
21 harm and no more practicable means is available
22 under the provisions of this chapter (other than this
23 section) to eliminate such risk,
24

1 the Secretary may issue such order as may be necessary
2 to assure that adequate notification is provided in an ap-
3 propriate form, by the persons and means best suited
4 under the circumstances involved, to all persons who
5 should properly receive such notification in order to elimi-
6 nate such risk. The Secretary may order notification by
7 any appropriate means, including public service announce-
8 ments. Before issuing an order under this subsection, the
9 Secretary shall consult with the persons who are to give
10 notice under the order.

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

18 “(c) RECALL AUTHORITY.—

19 “(1) IN GENERAL.—If the Secretary finds that
20 there is a reasonable probability that a tobacco prod-
21 uct contains a manufacturing or other defect not or-
22 dinarily contained in tobacco products on the market
23 that would cause serious, adverse health con-
24 sequences or death, the Secretary shall issue an
25 order requiring the appropriate person (including the

1 manufacturers, importers, distributors, or retailers of
2 the tobacco product) to immediately cease distribu-
3 tion of such tobacco product. The order shall provide
4 the person subject to the order with an opportunity
5 for an informal hearing, to be held not later than 10
6 days after the date of the issuance of the order, on
7 the actions required by the order and on whether the
8 order should be amended to require a recall of such
9 tobacco product. If, after providing an opportunity
10 for such a hearing, the Secretary determines that in-
11 adequate grounds exist to support the actions re-
12 quired by the order, the Secretary shall vacate the
13 order.

14 “(2) AMENDMENT OF ORDER TO REQUIRE RE-
15 CALL.—

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

1 the Secretary describing the progress of the re-
2 call.

3 “(B) NOTICE.—An amended order under
4 subparagraph (A)—

5 “(i) shall not include recall of a to-
6 bacco product from individuals; and

7 “(ii) shall provide for notice to per-
8 sons subject to the risks associated with
9 the use of such tobacco product.

10 In providing the notice required by clause (ii),
11 the Secretary may use the assistance of retail-
12 ers and other persons who distributed such to-
13 bacco product. If a significant number of such
14 persons cannot be identified, the Secretary shall
15 notify such persons under section 705(b).

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

19 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**
20 **UCTS.**

21 “(a) IN GENERAL.—Every person who is a tobacco
22 product manufacturer or importer of a tobacco product
23 shall establish and maintain such records, make such re-
24 ports, and provide such information, as the Secretary may
25 by regulation reasonably require to assure that such to-

1 bacco product is not adulterated or misbranded and to
2 otherwise protect public health. Regulations prescribed
3 under the preceding sentence—

4 “(1) may require a tobacco product manufac-
5 turer or importer to report to the Secretary when-
6 ever the manufacturer or importer receives or other-
7 wise becomes aware of information that reasonably
8 suggests that one of its marketed tobacco products
9 may have caused or contributed to a serious unex-
10 pected adverse experience associated with the use of
11 the product or any significant increase in the fre-
12 quency of a serious, expected adverse product experi-
13 ence;

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

17 “(3) shall not impose requirements unduly bur-
18 densome to a tobacco product manufacturer or im-
19 porter, taking into account the cost of complying
20 with such requirements and the need for the protec-
21 tion of the public health and the implementation of
22 this chapter;

23 “(4) when prescribing the procedure for making
24 requests for reports or information, shall require
25 that each request made under such regulations for

1 submission of a report or information to the Sec-
2 retary state the reason or purpose for such request
3 and identify to the fullest extent practicable such re-
4 port or information;

5 “(5) when requiring submission of a report or
6 information to the Secretary, shall state the reason
7 or purpose for the submission of such report or in-
8 formation and identify to the fullest extent prac-
9 ticable such report or information; and

10 “(6) may not require that the identity of any
11 patient or user be disclosed in records, reports, or
12 information required under this subsection unless re-
13 quired for the medical welfare of an individual, to
14 determine risks to public health of a tobacco prod-
15 uct, or to verify a record, report, or information sub-
16 mitted under this chapter.

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

24 “(b) REPORTS OF REMOVALS AND CORRECTIONS.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), the Secretary shall by regulation require
3 a tobacco product manufacturer or importer of a to-
4 bacco product to report promptly to the Secretary
5 any corrective action taken or removal from the
6 market of a tobacco product undertaken by such
7 manufacturer or importer if the removal or correc-
8 tion was undertaken—

9 “(A) to reduce a risk to health posed by
10 the tobacco product; or

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

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

19 “(2) EXCEPTION.—No report of the corrective
20 action or removal of a tobacco product may be re-
21 quired under paragraph (1) if a report of the correc-
22 tive action or removal is required and has been sub-
23 mitted under subsection (a).

1 **“SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TO-**
2 **BACCO PRODUCTS.**

3 “(a) IN GENERAL.—

4 “(1) NEW TOBACCO PRODUCT DEFINED.—For
5 purposes of this section the term ‘new tobacco prod-
6 uct’ means—

7 “(A) any tobacco product (including those
8 products in test markets) that was not commer-
9 cially marketed in the United States as of June
10 1, 2003; or

11 “(B) any modification (including a change
12 in design, any component, any part, or any con-
13 stituent, including a smoke constituent, or in
14 the content, delivery or form of nicotine, or any
15 other additive or ingredient) of a tobacco prod-
16 uct where the modified product was commer-
17 cially marketed in the United States after June
18 1, 2003.

19 “(2) PREMARKET APPROVAL REQUIRED.—

20 “(A) NEW PRODUCTS.—Approval under
21 this section of an application for premarket ap-
22 proval for any new tobacco product is required
23 unless—

24 “(i) the manufacturer has submitted a
25 report under section 905(j); and

1 “(ii) the Secretary has issued an order
2 that the tobacco product—

3 “(I) is substantially equivalent to
4 a tobacco product commercially mar-
5 keted (other than for test marketing)
6 in the United States as of June 1,
7 2003; and

8 “(II)(aa) is in compliance with
9 the requirements of this Act; or

10 “(bb) is exempt from the require-
11 ments of section 905(j) pursuant to a
12 regulation issued under section
13 905(j)(3).

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

17 “(i) that was first introduced or deliv-
18 ered for introduction into interstate com-
19 merce for commercial distribution in the
20 United States after June 1, 2003, and
21 prior to the date that is 15 months after
22 the date of enactment of the Family Smok-
23 ing Prevention and Tobacco Control Act;
24 and

1 “(ii) for which a report was submitted
 2 under section 905(j) within such 15-month
 3 period, until the Secretary issues an order
 4 that the tobacco product is not substan-
 5 tially equivalent.

6 “(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

7 “(A) IN GENERAL.—In this section and
 8 section 905(j), the terms ‘substantially equiva-
 9 lent’ or ‘substantial equivalence’ mean, with re-
 10 spect to the tobacco product being compared to
 11 the predicate tobacco product, that the Sec-
 12 retary by order has found that the tobacco
 13 product—

14 “(i) has the same characteristics as
 15 the predicate tobacco product; or

16 “(ii) has different characteristics and
 17 the information submitted contains infor-
 18 mation, including clinical data if deemed
 19 necessary by the Secretary, that dem-
 20 onstrates that it is not appropriate to reg-
 21 ulate the product under this section be-
 22 cause the product does not raise different
 23 questions of public health.

24 “(B) CHARACTERISTICS.—In subpara-
 25 graph (A), the term ‘characteristics’ means the

1 materials, ingredients, design, composition,
2 heating source, or other features of a tobacco
3 product.

4 “(C) LIMITATION.—A tobacco product may
5 not be found to be substantially equivalent to a
6 predicate tobacco product that has been re-
7 moved from the market at the initiative of the
8 Secretary or that has been determined by a ju-
9 dicial order to be misbranded or adulterated.

10 “(4) HEALTH INFORMATION.—

11 “(A) SUMMARY.—As part of a submission
12 under section 905(j) respecting a tobacco prod-
13 uct, the person required to file a premarket no-
14 tification under such section shall provide an
15 adequate summary of any health information
16 related to the tobacco product or state that
17 such information will be made available upon
18 request by any person.

19 “(B) REQUIRED INFORMATION.—Any sum-
20 mary under subparagraph (A) respecting a to-
21 bacco product shall contain detailed information
22 regarding data concerning adverse health effects
23 and shall be made available to the public by the
24 Secretary within 30 days of the issuance of a

1 determination that such tobacco product is sub-
2 stantially equivalent to another tobacco product.

3 “(b) APPLICATION.—

4 “(1) CONTENTS.—An application for premarket
5 approval shall contain—

6 “(A) full reports of all information, pub-
7 lished or known to, or which should reasonably
8 be known to, the applicant, concerning inves-
9 tigations which have been made to show the
10 health risks of such tobacco product and wheth-
11 er such tobacco product presents less risk than
12 other tobacco products;

13 “(B) a full statement of the components,
14 ingredients, additives, and properties, and of
15 the principle or principles of operation, of such
16 tobacco product;

17 “(C) a full description of the methods used
18 in, and the facilities and controls used for, the
19 manufacture, processing, and, when relevant,
20 packing and installation of, such tobacco prod-
21 uct;

22 “(D) an identifying reference to any to-
23 bacco product standard under section 907
24 which would be applicable to any aspect of such
25 tobacco product, and either adequate informa-

1 tion to show that such aspect of such tobacco
 2 product fully meets such tobacco product stand-
 3 ard or adequate information to justify any devi-
 4 ation from such standard;

5 “(E) such samples of such tobacco product
 6 and of components thereof as the Secretary
 7 may reasonably require;

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

10 “(G) such other information relevant to
 11 the subject matter of the application as the Sec-
 12 retary may require.

13 “(2) REFERENCE TO TOBACCO PRODUCTS SCI-
 14 ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an
 15 application meeting the requirements set forth in
 16 paragraph (1), the Secretary—

17 “(A) may, on the Secretary’s own initia-
 18 tive; or

19 “(B) may, upon the request of an appli-
 20 cant,

21 refer such application to the Tobacco Products Sci-
 22 entific Advisory Committee for reference and for
 23 submission (within such period as the Secretary may
 24 establish) of a report and recommendation respect-
 25 ing 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

1 standard in effect under section 907, compli-
2 ance with which is a condition to approval of
3 the application, and there is a lack of adequate
4 information to justify the deviation from such
5 standard.

6 “(3) DENIAL INFORMATION.—Any denial of an
7 application shall, insofar as the Secretary determines
8 to be practicable, be accompanied by a statement in-
9 forming the applicant of the measures required to
10 place such application in approvable form (which
11 measures may include further research by the appli-
12 cant in accordance with 1 or more protocols pre-
13 scribed by the Secretary).

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

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

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

4 “(5) BASIS FOR ACTION.—

5 “(A) INVESTIGATIONS.—For purposes of
6 paragraph (2)(A), whether permitting a tobacco
7 product to be marketed would be appropriate
8 for the protection of the public health shall,
9 when appropriate, be determined on the basis of
10 well-controlled investigations, which may in-
11 clude 1 or more clinical investigations by ex-
12 perts qualified by training and experience to
13 evaluate the tobacco product.

14 “(B) OTHER EVIDENCE.—If the Secretary
15 determines that there exists valid scientific evi-
16 dence (other than evidence derived from inves-
17 tigations described in subparagraph (A)) which
18 is sufficient to evaluate the tobacco product the
19 Secretary may authorize that the determination
20 for purposes of paragraph (2)(A) be made on the
21 basis of such evidence.

22 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

23 “(1) IN GENERAL.—The Secretary shall, upon
24 obtaining, where appropriate, advice on scientific
25 matters from an advisory committee, and after due

1 notice and opportunity for informal hearing to the
2 holder of an approved application for a tobacco
3 product, issue an order withdrawing approval of the
4 application if the Secretary finds—

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

8 “(B) that the application contained or was
9 accompanied by an untrue statement of a mate-
10 rial fact;

11 “(C) that the applicant—

12 “(i) has failed to establish a system
13 for maintaining records, or has repeatedly
14 or deliberately failed to maintain records
15 or to make reports, required by an applica-
16 ble regulation under section 909;

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

20 “(iii) has not complied with the re-
21 quirements of section 905;

22 “(D) on the basis of new information be-
23 fore the Secretary with respect to such tobacco
24 product, evaluated together with the evidence
25 before the Secretary when the application was

1 approved, that the methods used in, or the fa-
2 cilities and controls used for, the manufacture,
3 processing, packing, or installation of such to-
4 bacco product do not conform with the require-
5 ments of section 906(e) and were not brought
6 into conformity with such requirements within a
7 reasonable time after receipt of written notice
8 from the Secretary of nonconformity;

9 “(E) on the basis of new information be-
10 fore the Secretary, evaluated together with the
11 evidence before the Secretary when the applica-
12 tion was approved, that the labeling of such to-
13 bacco product, based on a fair evaluation of all
14 material facts, is false or misleading in any par-
15 ticular and was not corrected within a reason-
16 able time after receipt of written notice from
17 the Secretary of such fact; or

18 “(F) on the basis of new information be-
19 fore the Secretary, evaluated together with the
20 evidence before the Secretary when the applica-
21 tion was approved, that such tobacco product is
22 not shown to conform in all respects to a to-
23 bacco product standard which is in effect under
24 section 907, compliance with which was a con-
25 dition to approval of the application, and that

1 there is a lack of adequate information to jus-
2 tify the deviation from such standard.

3 “(2) APPEAL.—The holder of an application
4 subject to an order issued under paragraph (1) with-
5 drawing approval of the application may, by petition
6 filed on or before the 30th day after the date upon
7 which such holder receives notice of such with-
8 drawal, obtain review thereof in accordance with
9 subsection (e).

10 “(3) TEMPORARY SUSPENSION.—If, after pro-
11 viding an opportunity for an informal hearing, the
12 Secretary determines there is reasonable probability
13 that the continuation of distribution of a tobacco
14 product under an approved application would cause
15 serious, adverse health consequences or death, that
16 is greater than ordinarily caused by tobacco prod-
17 ucts on the market, the Secretary shall by order
18 temporarily suspend the approval of the application
19 approved under this section. If the Secretary issues
20 such an order, the Secretary shall proceed expedi-
21 tiously under paragraph (1) to withdraw such appli-
22 cation.

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

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

3 “(2) by mailing the order by registered mail or
4 certified mail addressed to the applicant at the ap-
5 plicant’s last known address in the records of the
6 Secretary.

7 “(f) RECORDS.—

8 “(1) ADDITIONAL INFORMATION.—In the case
9 of any tobacco product for which an approval of an
10 application filed under subsection (b) is in effect, the
11 applicant shall establish and maintain such records,
12 and make such reports to the Secretary, as the Sec-
13 retary may by regulation, or by order with respect
14 to such application, prescribe on the basis of a find-
15 ing that such records and reports are necessary in
16 order to enable the Secretary to determine, or facili-
17 tate a determination of, whether there is or may be
18 grounds for withdrawing or temporarily suspending
19 such approval.

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

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

3 “(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMP-
4 TION FOR INVESTIGATIONAL USE.—The Secretary may
5 exempt tobacco products intended for investigational use
6 from the provisions of this chapter under such conditions
7 as the Secretary may by regulation prescribe.

8 **“SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.**

9 “(a) IN GENERAL.—No person may introduce or de-
10 liver for introduction into interstate commerce any modi-
11 fied risk tobacco product unless approval of an application
12 filed pursuant to subsection (d) is effective with respect
13 to such product.

14 “(b) DEFINITIONS.—In this section:

15 “(1) MODIFIED RISK TOBACCO PRODUCT.—The
16 term ‘modified risk tobacco product’ means any to-
17 bacco product that is sold or distributed for use to
18 reduce harm or the risk of tobacco-related disease
19 associated with commercially marketed tobacco prod-
20 ucts.

21 “(2) SOLD OR DISTRIBUTED.—

22 “(A) IN GENERAL.—With respect to a to-
23 bacco product, the term ‘sold or distributed for
24 use to reduce harm or the risk of tobacco-re-
25 lated disease associated with commercially mar-

1 keted tobacco products’ means a tobacco prod-
2 uct—

3 “(i) the label, labeling, or advertising
4 of which represents explicitly or implicitly
5 that—

6 “(I) the tobacco product presents
7 a lower risk of tobacco-related disease
8 or is less harmful than one or more
9 other commercially marketed tobacco
10 products;

11 “(II) the tobacco product or its
12 smoke contains a reduced level of a
13 substance or presents a reduced expo-
14 sure to a substance; or

15 “(III) the tobacco product or its
16 smoke does not contain or is free of a
17 substance;

18 “(ii) the label, labeling, or advertising
19 of which uses the descriptors ‘light’, ‘mild’,
20 or ‘low’ or similar descriptors; or

21 “(iii) the tobacco product manufac-
22 turer of which has taken any action di-
23 rected to consumers through the media or
24 otherwise, other than by means of the to-
25 bacco product’s label, labeling or adver-

1 tising, after the date of enactment of the
2 Family Smoking Prevention and Tobacco
3 Control Act, respecting the product that
4 would be reasonably expected to result in
5 consumers believing that the tobacco prod-
6 uct or its smoke may present a lower risk
7 of disease or is less harmful than one or
8 more commercially marketed tobacco prod-
9 ucts, or presents a reduced exposure to, or
10 does not contain or is free of, a substance
11 or substances.

12 “(B) LIMITATION.—No tobacco product
13 shall be considered to be ‘sold or distributed for
14 use to reduce harm or the risk of tobacco-re-
15 lated disease associated with commercially mar-
16 keted tobacco products’, except as described in
17 subparagraph (A).

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

23 “(d) FILING.—Any person may file with the Sec-
24 retary an application for a modified risk tobacco product.
25 Such application shall include—

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

3 “(2) the conditions for using the product;

4 “(3) the formulation of the product;

5 “(4) sample product labels and labeling;

6 “(5) all documents (including underlying sci-
7 entific information) relating to research findings
8 conducted, supported, or possessed by the tobacco
9 product manufacturer relating to the effect of the
10 product on tobacco related diseases and health-re-
11 lated conditions, including information both favor-
12 able and unfavorable to the ability of the product to
13 reduce risk or exposure and relating to human
14 health;

15 “(6) data and information on how consumers
16 actually use the tobacco product; and

17 “(7) such other information as the Secretary
18 may require.

19 “(e) PUBLIC AVAILABILITY.—The Secretary shall
20 make the application described in subsection (d) publicly
21 available (except matters in the application which are
22 trade secrets or otherwise confidential, commercial infor-
23 mation) and shall request comments by interested persons
24 on the information contained in the application and on the

1 label, labeling, and advertising accompanying such appli-
 2 cation.

3 “(f) ADVISORY COMMITTEE.—

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

7 “(2) RECOMMENDATIONS.—Not later than 60
 8 days after the date an application is referred to an
 9 advisory committee under paragraph (1), the advi-
 10 sory committee shall report its recommendations on
 11 the application to the Secretary.

12 “(g) APPROVAL.—

13 “(1) MODIFIED RISK PRODUCTS.—Except as
 14 provided in paragraph (2), the Secretary shall ap-
 15 prove an application for a modified risk tobacco
 16 product filed under this section only if the Secretary
 17 determines that the applicant has demonstrated that
 18 such product, as it is actually used by consumers,
 19 will—

20 “(A) significantly reduce harm and the
 21 risk of tobacco-related disease to individual to-
 22 bacco users; and

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

1 bacco products and persons who do not cur-
2 rently use tobacco products.

3 “(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

4 “(A) IN GENERAL.—The Secretary may
5 approve an application for a tobacco product
6 that has not been approved as a modified risk
7 tobacco product pursuant to paragraph (1) if
8 the Secretary makes the findings required
9 under this paragraph and determines that the
10 applicant has demonstrated that—

11 “(i) the approval of the application
12 would be appropriate to promote the public
13 health;

14 “(ii) any aspect of the label, labeling,
15 and advertising for such product that
16 would cause the tobacco product to be a
17 modified risk tobacco product under sub-
18 section (b)(2) is limited to an explicit or
19 implicit representation that such tobacco
20 product or its smoke contains or is free of
21 a substance or contains a reduced level of
22 a substance, or presents a reduced expo-
23 sure to a substance in tobacco smoke;

24 “(iii) scientific evidence is not avail-
25 able and, using the best available scientific

1 methods, cannot be made available without
2 conducting long-term epidemiological stud-
3 ies for an application to meet the stand-
4 ards set forth in paragraph (1); and

5 “(iv) the scientific evidence that is
6 available without conducting long-term epi-
7 demiological studies demonstrates that a
8 measurable and substantial reduction in
9 morbidity or mortality among individual
10 tobacco users is anticipated in subsequent
11 studies.

12 “(B) ADDITIONAL FINDINGS REQUIRED.—

13 In order to approve an application under sub-
14 paragraph (A) the Secretary must also find
15 that the applicant has demonstrated that—

16 “(i) the magnitude of the overall re-
17 ductions in exposure to the substance or
18 substances which are the subject of the ap-
19 plication is substantial, such substance or
20 substances are harmful, and the product as
21 actually used exposes consumers to the
22 specified reduced level of the substance or
23 substances;

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

1 levels of other harmful substances com-
2 pared to the similar types of tobacco prod-
3 ucts then on the market unless such in-
4 creases are minimal and the anticipated
5 overall impact of use of the product re-
6 mains a substantial and measurable reduc-
7 tion in overall morbidity and mortality
8 among individual tobacco users;

9 “(iii) testing of actual consumer per-
10 ception shows that, as the applicant pro-
11 poses to label and market the product, con-
12 sumers will not be misled into believing
13 that the product—

14 “(I) is or has been demonstrated
15 to be less harmful; or

16 “(II) presents or has been dem-
17 onstrated to present less of a risk of
18 disease than 1 or more other commer-
19 cially marketed tobacco products; and

20 “(iv) approval of the application is ex-
21 pected to benefit the health of the popu-
22 lation as a whole taking into account both
23 users of tobacco products and persons who
24 do not currently use tobacco products.

25 “(C) CONDITIONS OF APPROVAL.—

1 “(i) IN GENERAL.—Applications ap-
2 proved under this paragraph shall be lim-
3 ited to a term of not more than 5 years,
4 but may be renewed upon a finding by the
5 Secretary that the requirements of this
6 paragraph continue to be satisfied based
7 on the filing of a new application.

8 “(ii) AGREEMENTS BY APPLICANT.—
9 Applications approved under this para-
10 graph shall be conditioned on the appli-
11 cant’s agreement to conduct post-market
12 surveillance and studies and to submit to
13 the Secretary the results of such surveil-
14 lance and studies to determine the impact
15 of the application approval on consumer
16 perception, behavior, and health and to en-
17 able the Secretary to review the accuracy
18 of the determinations upon which the ap-
19 proval was based in accordance with a pro-
20 tocol approved by the Secretary.

21 “(iii) ANNUAL SUBMISSION.—The re-
22 sults of such post-market surveillance and
23 studies described in clause (ii) shall be
24 submitted annually.

1 “(3) BASIS.—The determinations under para-
2 graphs (1) and (2) shall be based on—

3 “(A) the scientific evidence submitted by
4 the applicant; and

5 “(B) scientific evidence and other informa-
6 tion that is available to the Secretary.

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

11 “(A) the relative health risks to individuals
12 of the tobacco product that is the subject of the
13 application;

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

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

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

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

4 “(E) comments, data, and information
5 submitted by interested persons.

6 “(h) ADDITIONAL CONDITIONS FOR APPROVAL.—

7 “(1) MODIFIED RISK PRODUCTS.—The Sec-
8 retary shall require for the approval of an applica-
9 tion under this section that any advertising or label-
10 ing concerning modified risk products enable the
11 public to comprehend the information concerning
12 modified risk and to understand the relative signifi-
13 cance of such information in the context of total
14 health and in relation to all of the diseases and
15 health-related conditions associated with the use of
16 tobacco products.

17 “(2) COMPARATIVE CLAIMS.—

18 “(A) IN GENERAL.—The Secretary may re-
19 quire for the approval of an application under
20 this subsection that a claim comparing a to-
21 bacco product to 1 or more other commercially
22 marketed tobacco products shall compare the
23 tobacco product to a commercially marketed to-
24 bacco product that is representative of that type
25 of tobacco product on the market (for example

1 the average value of the top 3 brands of an es-
2 tablished regular tobacco product).

3 “(B) QUANTITATIVE COMPARISONS.—The
4 Secretary may also require, for purposes of sub-
5 paragraph (A), that the percent (or fraction) of
6 change and identity of the reference tobacco
7 product and a quantitative comparison of the
8 amount of the substance claimed to be reduced
9 shall be stated in immediate proximity to the
10 most prominent claim.

11 “(3) LABEL DISCLOSURE.—

12 “(A) IN GENERAL.—The Secretary may re-
13 quire the disclosure on the label of other sub-
14 stances in the tobacco product, or substances
15 that may be produced by the consumption of
16 that tobacco product, that may affect a disease
17 or health-related condition or may increase the
18 risk of other diseases or health-related condi-
19 tions associated with the use of tobacco prod-
20 ucts.

21 “(B) CONDITIONS OF USE.—If the condi-
22 tions of use of the tobacco product may affect
23 the risk of the product to human health, the
24 Secretary may require the labeling of conditions
25 of use.

1 “(4) TIME.—The Secretary shall limit an ap-
2 proval under subsection (g)(1) for a specified period
3 of time.

4 “(5) ADVERTISING.—The Secretary may re-
5 quire that an applicant, whose application has been
6 approved under this subsection, comply with require-
7 ments relating to advertising and promotion of the
8 tobacco product.

9 “(i) POSTMARKET SURVEILLANCE AND STUDIES.—

10 “(1) IN GENERAL.—The Secretary shall require
11 that an applicant under subsection (g)(1) conduct
12 post market surveillance and studies for a tobacco
13 product for which an application has been approved
14 to determine the impact of the application approval
15 on consumer perception, behavior, and health, to en-
16 able the Secretary to review the accuracy of the de-
17 terminations upon which the approval was based,
18 and to provide information that the Secretary deter-
19 mines is otherwise necessary regarding the use or
20 health risks involving the tobacco product. The re-
21 sults of post-market surveillance and studies shall be
22 submitted to the Secretary on an annual basis.

23 “(2) SURVEILLANCE PROTOCOL.—Each appli-
24 cant required to conduct a surveillance of a tobacco
25 product under paragraph (1) shall, within 30 days

1 after receiving notice that the applicant is required
2 to conduct such surveillance, submit, for the ap-
3 proval of the Secretary, a protocol for the required
4 surveillance. The Secretary, within 60 days of the
5 receipt of such protocol, shall determine if the prin-
6 cipal investigator proposed to be used in the surveil-
7 lance has sufficient qualifications and experience to
8 conduct such surveillance and if such protocol will
9 result in collection of the data or other information
10 designated by the Secretary as necessary to protect
11 the public health.

12 “(j) WITHDRAWAL OF APPROVAL.—The Secretary,
13 after an opportunity for an informal hearing, shall with-
14 draw the approval of an application under this section if
15 the Secretary determines that—

16 “(1) the applicant, based on new information,
17 can no longer make the demonstrations required
18 under subsection (g), or the Secretary can no longer
19 make the determinations required under subsection
20 (g);

21 “(2) the application failed to include material
22 information or included any untrue statement of ma-
23 terial fact;

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

4 “(A) a tobacco product standard is estab-
5 lished pursuant to section 907;

6 “(B) an action is taken that affects the
7 risks presented by other commercially marketed
8 tobacco products that were compared to the
9 product that is the subject of the application; or

10 “(C) any postmarket surveillance or stud-
11 ies reveal that the approval of the application is
12 no longer consistent with the protection of the
13 public health;

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

17 “(5) the applicant failed to meet a condition
18 imposed under subsection (h).

19 “(k) CHAPTER IV OR V.—A product approved in ac-
20 cordance with this section shall not be subject to chapter
21 IV or V.

22 “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

23 “(1) SCIENTIFIC EVIDENCE.—Not later than 2
24 years after the date of enactment of the Family
25 Smoking Prevention and Tobacco Control Act, the

1 Secretary shall issue regulations or guidance (or any
2 combination thereof) on the scientific evidence re-
3 quired for assessment and ongoing review of modi-
4 fied risk tobacco products. Such regulations or guid-
5 ance shall—

6 “(A) establish minimum standards for sci-
7 entific studies needed prior to approval to show
8 that a substantial reduction in morbidity or
9 mortality among individual tobacco users is
10 likely;

11 “(B) include validated biomarkers, inter-
12 mediate clinical endpoints, and other feasible
13 outcome measures, as appropriate;

14 “(C) establish minimum standards for post
15 market studies, that shall include regular and
16 long-term assessments of health outcomes and
17 mortality, intermediate clinical endpoints, con-
18 sumer perception of harm reduction, and the
19 impact on quitting behavior and new use of to-
20 bacco products, as appropriate;

21 “(D) establish minimum standards for re-
22 quired postmarket surveillance, including ongo-
23 ing assessments of consumer perception; and

24 “(E) require that data from the required
25 studies and surveillance be made available to

1 the Secretary prior to the decision on renewal
2 of a modified risk tobacco product.

3 “(2) CONSULTATION.—The regulations or guid-
4 ance issued under paragraph (1) shall be developed
5 in consultation with the Institute of Medicine, and
6 with the input of other appropriate scientific and
7 medical experts, on the design and conduct of such
8 studies and surveillance.

9 “(3) REVISION.—The regulations or guidance
10 under paragraph (1) shall be revised on a regular
11 basis as new scientific information becomes avail-
12 able.

13 “(4) NEW TOBACCO PRODUCTS.—Not later
14 than 2 years after the date of enactment of the
15 Family Smoking Prevention and Tobacco Control
16 Act, the Secretary shall issue a regulation or guid-
17 ance that permits the filing of a single application
18 for any tobacco product that is a new tobacco prod-
19 uct under section 910 and for which the applicant
20 seeks approval as a modified risk tobacco product
21 under this section.

22 “(m) DISTRIBUTORS.—No distributor may take any
23 action, after the date of enactment of the Family Smoking
24 Prevention and Tobacco Control Act, with respect to a to-
25 bacco product that would reasonably be expected to result

1 in consumers believing that the tobacco product or its
 2 smoke may present a lower risk of disease or is less harm-
 3 ful than one or more commercially marketed tobacco prod-
 4 ucts, or presents a reduced exposure to, or does not con-
 5 tain or is free of, a substance or substances.

6 **“SEC. 912. JUDICIAL REVIEW.**

7 “(a) RIGHT TO REVIEW.—

8 “(1) IN GENERAL.—Not later than 30 days
 9 after—

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

13 “(B) a denial of an application for ap-
 14 proval under section 910(c),
 15 any person adversely affected by such regulation or
 16 denial may file a petition for judicial review of such
 17 regulation or denial with the United States Court of
 18 Appeals for the District of Columbia or for the cir-
 19 cuit in which such person resides or has their prin-
 20 cipal place of business.

21 “(2) REQUIREMENTS.—

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

1 “(B) RECORD OF PROCEEDINGS.—On re-
2 ceipt of a petition under subparagraph (A), the
3 Secretary shall file in the court in which such
4 petition was filed—

5 “(i) the record of the proceedings on
6 which the regulation or order was based;
7 and

8 “(ii) a statement of the reasons for
9 the issuance of such a regulation or order.

10 “(C) DEFINITION OF RECORD.—In this
11 section, the term ‘record’ means—

12 “(i) all notices and other matter pub-
13 lished in the Federal Register with respect
14 to the regulation or order reviewed;

15 “(ii) all information submitted to the
16 Secretary with respect to such regulation
17 or order;

18 “(iii) proceedings of any panel or ad-
19 visory committee with respect to such reg-
20 ulation or order;

21 “(iv) any hearing held with respect to
22 such regulation or order; and

23 “(v) any other information identified
24 by the Secretary, in the administrative pro-
25 ceeding held with respect to such regula-

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

3 “(b) STANDARD OF REVIEW.—Upon the filing of the
4 petition under subsection (a) for judicial review of a regu-
5 lation or order, the court shall have jurisdiction to review
6 the regulation or order in accordance with chapter 7 of
7 title 5, United States Code, and to grant appropriate re-
8 lief, including interim relief, as provided for in such chap-
9 ter. A regulation or denial described in subsection (a) shall
10 be reviewed in accordance with section 706(2)(A) of title
11 5, United States Code.

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

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

21 “(e) REGULATIONS AND ORDERS MUST RECITE
22 BASIS IN RECORD.—To facilitate judicial review, a regula-
23 tion or order issued under section 906, 907, 908, 909,
24 910, or 916 shall contain a statement of the reasons for

1 the issuance of such regulation or order in the record of
2 the proceedings held in connection with its issuance.

3 **“SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.**

4 “The Secretary shall issue regulations to require that
5 retail establishments for which the predominant business
6 is the sale of tobacco products comply with any advertising
7 restrictions applicable to retail establishments accessible
8 to individuals under the age of 18.

9 **“SEC. 914. JURISDICTION OF AND COORDINATION WITH**
10 **THE FEDERAL TRADE COMMISSION.**

11 “(a) JURISDICTION.—

12 “(1) IN GENERAL.—Except where expressly
13 provided in this chapter, nothing in this chapter
14 shall be construed as limiting or diminishing the au-
15 thority of the Federal Trade Commission to enforce
16 the laws under its jurisdiction with respect to the
17 advertising, sale, or distribution of tobacco products.

18 “(2) ENFORCEMENT.—Any advertising that vio-
19 lates this chapter or a provision of the regulations
20 referred to in section 232 of the Family Smoking
21 Prevention and Tobacco Control Act, is an unfair or
22 deceptive act or practice under section 5(a) of the
23 Federal Trade Commission Act (15 U.S.C. 45(a))
24 and shall be considered a violation of a rule promul-
25 gated under section 18 of that Act (15 U.S.C. 57a).

1 “(b) COORDINATION.—With respect to the require-
 2 ments of section 4 of the Federal Cigarette Labeling and
 3 Advertising Act (15 U.S.C. 1333) and section 3 of the
 4 Comprehensive Smokeless Tobacco Health Education Act
 5 of 1986 (15 U.S.C. 4402)—

6 “(1) the Chairman of the Federal Trade Com-
 7 mission shall coordinate with the Secretary con-
 8 cerning the enforcement of such Act as such enforce-
 9 ment relates to unfair or deceptive acts or practices
 10 in the advertising of cigarettes or smokeless tobacco;
 11 and

12 “(2) the Secretary shall consult with the Chair-
 13 man of such Commission in revising the label state-
 14 ments and requirements under such sections.

15 **“SEC. 915. CONGRESSIONAL REVIEW PROVISIONS.**

16 “In accordance with section 801 of title 5, United
 17 States Code, Congress shall review, and may disapprove,
 18 any rule under this chapter that is subject to section 801.
 19 This section and section 801 do not apply to the regula-
 20 tions referred to in section 232 of the Family Smoking
 21 Prevention and Tobacco Control Act.

22 **“SEC. 916. REGULATION REQUIREMENT.**

23 “(a) TESTING, REPORTING, AND DISCLOSURE.—Not
 24 later than 24 months after the date of enactment of the
 25 Family Smoking Prevention and Tobacco Control Act, the

1 Secretary, acting through the Commissioner of the Food
2 and Drug Administration, shall promulgate regulations
3 under this Act that meet the requirements of subsection
4 (b).

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

20 “(c) AUTHORITY.—The Food and Drug Administra-
21 tion shall have the authority under this chapter to conduct
22 or to require the testing, reporting, or disclosure of to-
23 bacco product constituents, including smoke constituents.

1 **“SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHOR-**
2 **ITY.**

3 “(a) IN GENERAL.—

4 “(1) PRESERVATION.—Nothing in this chapter,
5 or rules promulgated under this chapter, shall be
6 construed to limit the authority of a Federal agency
7 (including the Armed Forces), a State or political
8 subdivision of a State, or the government of an In-
9 dian tribe to enact, adopt, promulgate, and enforce
10 any law, rule, regulation, or other measure with re-
11 spect to tobacco products that is in addition to, or
12 more stringent than, requirements established under
13 this chapter, including a law, rule, regulation, or
14 other measure relating to or prohibiting the sale,
15 distribution, possession, exposure to, access to, ad-
16 vertising and promotion of, or use of tobacco prod-
17 ucts by individuals of any age, information reporting
18 to the State, or measures relating to fire safety
19 standards for tobacco products. No provision of this
20 chapter shall limit or otherwise affect any State,
21 Tribal, or local taxation of tobacco products.

22 “(2) PREEMPTION OF CERTAIN STATE AND
23 LOCAL REQUIREMENTS.—

24 “(A) IN GENERAL.—Except as provided in
25 paragraph (1) and subparagraph (B), no State
26 or political subdivision of a State may establish

1 or continue in effect with respect to a tobacco
2 product any requirement which is different
3 from, or in addition to, any requirement under
4 the provisions of this chapter relating to to-
5 bacco product standards, premarket approval,
6 adulteration, misbranding, labeling, registra-
7 tion, good manufacturing standards, or reduced
8 risk products.

9 “(B) EXCEPTION.—Subparagraph (A)
10 does not apply to requirements relating to the
11 sale, distribution, possession, information re-
12 porting to the State, exposure to, access to, the
13 advertising and promotion of, or use of, tobacco
14 products by individuals of any age, or relating
15 to fire safety standards for tobacco products.
16 Information disclosed to a State under subpara-
17 graph (A) that is exempt from disclosure under
18 section 554(b)(4) of title 5, United States Code,
19 shall be treated as trade secret and confidential
20 information by the State.

21 “(b) RULE OF CONSTRUCTION REGARDING PRODUCT
22 LIABILITY.—No provision of this chapter relating to a to-
23 bacco product shall be construed to modify or otherwise
24 affect any action or the liability of any person under the
25 product liability law of any State.

1 **“SEC. 918. TOBACCO PRODUCTS SCIENTIFIC ADVISORY**
2 **COMMITTEE.**

3 “(a) ESTABLISHMENT.—Not later than 1 year after
4 the date of enactment of the Family Smoking Prevention
5 and Tobacco Control Act, the Secretary shall establish an
6 11-member advisory committee, to be known as the ‘To-
7 bacco Products Scientific Advisory Committee’.

8 “(b) MEMBERSHIP.—

9 “(1) IN GENERAL.—

10 “(A) MEMBERS.—The Secretary shall ap-
11 point as members of the Tobacco Products Sci-
12 entific Advisory Committee individuals who are
13 technically qualified by training and experience
14 in the medicine, medical ethics, science, or tech-
15 nology involving the manufacture, evaluation, or
16 use of tobacco products, who are of appro-
17 priately diversified professional backgrounds.
18 The committee shall be composed of—

19 “(i) 7 individuals who are physicians,
20 dentists, scientists, or health care profes-
21 sionals practicing in the area of oncology,
22 pulmonology, cardiology, toxicology, phar-
23 macology, addiction, or any other relevant
24 specialty;

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

4 “(iii) 1 individual as a representative
5 of the general public;

6 “(iv) 1 individual as a representative
7 of the interests in the tobacco manufac-
8 turing industry; and

9 “(v) 1 individual as a representative
10 of the interests of the tobacco growers.

11 “(B) NONVOTING MEMBERS.—The mem-
12 bers of the committee appointed under clauses
13 (iv) and (v) of subparagraph (A) shall serve as
14 consultants to those described in clauses (i)
15 through (iii) of subparagraph (A) and shall be
16 nonvoting representatives.

17 “(2) LIMITATION.—The Secretary may not ap-
18 point to the Advisory Committee any individual who
19 is in the regular full-time employ of the Food and
20 Drug Administration or any agency responsible for
21 the enforcement of this Act. The Secretary may ap-
22 point Federal officials as ex officio members.

23 “(3) CHAIRPERSON.—The Secretary shall des-
24 ignate 1 of the members of the Advisory Committee
25 to serve as chairperson.

1 “(c) DUTIES.—The Tobacco Products Scientific Ad-
 2 visory Committee shall provide advice, information, and
 3 recommendations to the Secretary—

4 “(1) as provided in this chapter;

5 “(2) on the effects of the alteration of the nico-
 6 tine yields from tobacco products;

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

10 “(4) on its review of other safety, dependence,
 11 or health issues relating to tobacco products as re-
 12 quested by the Secretary.

13 “(d) COMPENSATION; SUPPORT; FACA.—

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

1 ber may be allowed travel expenses, including per
 2 diem in lieu of subsistence, as authorized by section
 3 5703 of title 5, United States Code, for persons in
 4 the Government service employed intermittently.

5 “(2) ADMINISTRATIVE SUPPORT.—The Sec-
 6 retary shall furnish the Advisory Committee clerical
 7 and other assistance.

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

11 “(e) PROCEEDINGS OF ADVISORY PANELS AND COM-
 12 MITTEES.—The Advisory Committee shall make and
 13 maintain a transcript of any proceeding of the panel or
 14 committee. Each such panel and committee shall delete
 15 from any transcript made under this subsection informa-
 16 tion which is exempt from disclosure under section 552(b)
 17 of title 5, United States Code.

18 **“SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**
 19 **PENDENCE.**

20 “The Secretary shall consider—

21 “(1) at the request of the applicant, designating
 22 nicotine replacement products as fast track research
 23 and approval products within the meaning of section
 24 506;

1 “(2) direct the Commissioner to consider ap-
2 proving the extended use of nicotine replacement
3 products (such as nicotine patches, nicotine gum,
4 and nicotine lozenges) for the treatment of tobacco
5 dependence;

6 “(3) review and consider the evidence for addi-
7 tional indications for nicotine replacement products,
8 such as for craving relief or relapse prevention; and

9 “(4) consider—

10 “(A) relieving companies of premarket bur-
11 dens under section 505 if the requirement is re-
12 dundant considering other nicotine replacement
13 therapies already on the market; and

14 “(B) time and extent applications for nico-
15 tine replacement therapies that have been ap-
16 proved by a regulatory body in a foreign coun-
17 try and have marketing experience in such
18 country.

19 **“SEC. 920. USER FEE.**

20 “(a) ESTABLISHMENT OF QUARTERLY USER FEE.—

21 The Secretary shall assess a quarterly user fee with re-
22 spect to every quarter of each fiscal year commencing fis-
23 cal year 2004, calculated in accordance with this section,
24 upon each manufacturer and importer of tobacco products
25 subject to this chapter.

1 “(b) FUNDING OF FDA REGULATION OF TOBACCO
2 PRODUCTS.—The Secretary shall make user fees collected
3 pursuant to this section available to pay, in each fiscal
4 year, for the costs of the activities of the Food and Drug
5 Administration related to the regulation of tobacco prod-
6 ucts under this chapter.

7 “(c) ASSESSMENT OF USER FEE.—

8 “(1) AMOUNT OF ASSESSMENT.—Except as
9 provided in paragraph (4), the total user fees as-
10 sessed each year pursuant to this section shall be
11 sufficient, and shall not exceed what is necessary, to
12 pay for the costs of the activities described in sub-
13 section (b) for each fiscal year.

14 “(2) ALLOCATION OF ASSESSMENT BY CLASS
15 OF TOBACCO PRODUCTS.—

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

23 “(B) APPLICABLE PERCENTAGE.—For
24 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-

1 ject to a user fee under this section, the portion of
 2 the user fee assigned to such class under subsection
 3 (d)(2) shall be allocated by the Secretary on a pro
 4 rata basis among the classes of tobacco products
 5 that are subject to a user fee under this section.
 6 Such pro rata allocation for each class of tobacco
 7 products that are subject to a user fee under this
 8 section shall be the quotient of—

9 “(A) the sum of the percentages assigned
 10 to all classes of tobacco products subject to this
 11 section; divided by

12 “(B) the percentage assigned to such class
 13 under paragraph (2).

14 “(4) ANNUAL LIMIT ON ASSESSMENT.—The
 15 total assessment under this section—

16 “(A) for fiscal year 2004 shall be
 17 \$85,000,000;

18 “(B) for fiscal year 2005 shall be
 19 \$175,000,000;

20 “(C) for fiscal year 2006 shall be
 21 \$300,000,000; and

22 “(D) for each subsequent fiscal year, shall
 23 not exceed the limit on the assessment imposed
 24 during the previous fiscal year, as adjusted by

1 the Secretary (after notice, published in the
2 Federal Register) to reflect the greater of—

3 “(i) the total percentage change that
4 occurred in the Consumer Price Index for
5 all urban consumers (all items; United
6 States city average) for the 12-month pe-
7 riod ending on June 30 of the preceding
8 fiscal year for which fees are being estab-
9 lished; or

10 “(ii) the total percentage change for
11 the previous fiscal year in basic pay under
12 the General Schedule in accordance with
13 section 5332 of title 5, United States
14 Code, as adjusted by any locality-based
15 comparability payment pursuant to section
16 5304 of such title for Federal employees
17 stationed in the District of Columbia.

18 “(5) TIMING OF USER FEE ASSESSMENT.—The
19 Secretary shall notify each manufacturer and im-
20 porter of tobacco products subject to this section of
21 the amount of the quarterly assessment imposed on
22 such manufacturer or importer under subsection (f)
23 during each quarter of each fiscal year. Such notifi-
24 cations shall occur not earlier than 3 months prior
25 to the end of the quarter for which such assessment

1 is made, and payments of all assessments shall be
 2 made not later than 60 days after each such notifi-
 3 cation.

4 “(d) DETERMINATION OF USER FEE BY COMPANY
 5 MARKET SHARE.—

6 “(1) IN GENERAL.—The user fee to be paid by
 7 each manufacturer or importer of a given class of to-
 8 bacco products shall be determined in each quarter
 9 by multiplying—

10 “(A) such manufacturer’s or importer’s
 11 market share of such class of tobacco products;
 12 by

13 “(B) the portion of the user fee amount
 14 for the current quarter to be assessed on manu-
 15 facturers and importers of such class of tobacco
 16 products as determined under subsection (e).

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

21 “(e) DETERMINATION OF VOLUME OF DOMESTIC
 22 SALES.—

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

1 and importers as a group, shall be made by the Sec-
 2 retary using information provided by manufacturers
 3 and importers pursuant to subsection (f), as well as
 4 any other relevant information provided to or ob-
 5 tained by the Secretary.

6 “(2) MEASUREMENT.—For purposes of the cal-
 7 culations under this subsection and the information
 8 provided under subsection (f) by the Secretary, gross
 9 domestic volume shall be measured by—

10 “(A) in the case of cigarettes, the number
 11 of cigarettes sold;

12 “(B) in the case of little cigars, the num-
 13 ber of little cigars sold;

14 “(C) in the case of large cigars, the num-
 15 ber of cigars weighing more than 3 pounds per
 16 thousand sold; and

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

20 “(f) MEASUREMENT OF GROSS DOMESTIC VOL-
 21 UME.—

22 “(1) IN GENERAL.—Each manufacturer and
 23 importer of tobacco products shall submit to the
 24 Secretary a certified copy of each of the returns or
 25 forms described by this paragraph that are required

1 to be filed with a Government agency on the same
2 date that those returns or forms are filed, or required
3 to be filed, with such agency. The returns and forms
4 described by this paragraph are those returns and
5 forms related to the release of tobacco products into
6 domestic commerce, as defined by section 5702(k) of
7 the Internal Revenue Code of 1986, and the repay-
8 ment of the taxes imposed under chapter 52 of such
9 Code (ATF Form 500.24 and United States Customs
10 Form 7501 under currently applicable regulations).

11 “(2) PENALTIES.—Any person that knowingly
12 fails to provide information required under this sub-
13 section or that provides false information under this
14 subsection shall be subject to the penalties described
15 in section 1003 of title 18, United States Code. In
16 addition, such person may be subject to a civil pen-
17 alty in an amount not to exceed 2 percent of the
18 value of the kind of tobacco products manufactured
19 or imported by such person during the applicable
20 quarter, as determined by the Secretary.

21 “(h) EFFECTIVE DATE.—The user fees prescribed by
22 this section shall be assessed in fiscal year 2004, based
23 on domestic sales of tobacco products during fiscal year
24 2003 and shall be assessed in each fiscal year thereafter.”.

1 **SEC. 232. INTERIM FINAL RULE.**

2 (a) CIGARETTES AND SMOKELESS TOBACCO.—

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

10 (2) CONTENTS OF RULE.—Except as provided
11 in this subsection, the interim final rule published
12 under paragraph (1), shall be identical in its provi-
13 sions to part 897 of the regulations promulgated by
14 the Secretary of Health and Human Services in the
15 August 28, 1996, issue of the Federal Register (61
16 Fed. Reg., 44615–44618). Such rule shall—

17 (A) provide for the designation of jurisdic-
18 tional authority that is in accordance with this
19 subsection;

20 (B) strike Subpart C—Labeling and sec-
21 tion 897.32(e); and

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

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

1 in accordance with the Administrative Procedures
2 Act.

3 (4) RULE OF CONSTRUCTION.—Except as pro-
4 vided in paragraph (3), nothing in this section shall
5 be construed to limit the authority of the Secretary
6 to amend, in accordance with the Administrative
7 Procedures Act, the regulation promulgated pursu-
8 ant to this section.

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

17 (1) The preamble to the proposed rule in the
18 document entitled “Regulations Restricting the Sale
19 and Distribution of Cigarettes and Smokeless To-
20 bacco Products to Protect Children and Adoles-
21 cents” (60 Fed. Reg. 41314–41372 (August 11,
22 1995)).

23 (2) The document entitled “Nicotine in Ciga-
24 rettes and Smokeless Tobacco Products is a Drug
25 and These Products Are Nicotine Delivery Devices

1 Under the Federal Food, Drug, and Cosmetic Act”
 2 (60 Fed. Reg. 41453–41787 (August 11, 1995)).

3 (3) The preamble to the final rule in the docu-
 4 ment entitled “Regulations Restricting the Sale and
 5 Distribution of Cigarettes and Smokeless Tobacco to
 6 Protect Children and Adolescents” (61 Fed. Reg.
 7 44396–44615 (August 28, 1996)).

8 (4) The document entitled “Nicotine in Ciga-
 9 rettes and Smokeless Tobacco is a Drug and These
 10 Products are Nicotine Delivery Devices Under the
 11 Federal Food, Drug, and Cosmetic Act; Jurisdic-
 12 tional Determination” (61 Fed. Reg. 44619–45318
 13 (August 28, 1996)).

14 **SEC. 233. CONFORMING AND OTHER AMENDMENTS TO GEN-**
 15 **ERAL PROVISIONS.**

16 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND
 17 COSMETIC ACT.—Except as otherwise expressly provided,
 18 whenever in this section an amendment is expressed in
 19 terms of an amendment to, or repeal of, a section or other
 20 provision, the reference is to a section or other provision
 21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 22 301 et seq.).

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

1 (1) in subsection (a), by inserting “tobacco
2 product,” after “device,”;

3 (2) in subsection (b), by inserting “tobacco
4 product,” after “device,”;

5 (3) in subsection (c), by inserting “tobacco
6 product,” after “device,”;

7 (4) in subsection (e), by striking “515(f), or
8 519” and inserting “515(f), 519, or 909”;

9 (5) in subsection (g), by inserting “tobacco
10 product,” after “device,”;

11 (6) in subsection (h), by inserting “tobacco
12 product,” after “device,”;

13 (7) in subsection (j), by striking “708, or 721”
14 and inserting “708, 721, 904, 905, 906, 907, 908,
15 909, or section 921(b)”;

16 (8) in subsection (k), by inserting “tobacco
17 product,” after “device,”;

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

20 “(p) The failure to register in accordance with section
21 510 or 905, the failure to provide any information re-
22 quired by section 510(j), 510(k), 905(i), or 905(j), or the
23 failure to provide a notice required by section 510(j)(2)
24 or 905(i)(2).”;

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

3 “(q)(1) The failure or refusal—

4 “(A) to comply with any requirement prescribed
5 under section 518, 520(g), 903(b)(8), or 908, or
6 condition prescribed under section
7 903(b)(6)(B)(ii)(II);

8 “(B) to furnish any notification or other mate-
9 rial or information required by or under section 519,
10 520(g), 904, 909, or section 921; or

11 “(C) to comply with a requirement under sec-
12 tion 522 or 913.”;

13 (11) in subsection (q)(2), by striking “device,”
14 and inserting “device or tobacco product,”;

15 (12) in subsection (r), by inserting “or tobacco
16 product” after “device” each time that it appears;
17 and

18 (13) by adding at the end the following:

19 “(aa) The sale of tobacco products in violation
20 of a no-tobacco-sale order issued under section
21 303(f).

22 “(bb) The introduction or delivery for introduc-
23 tion into interstate commerce of a tobacco product
24 in violation of section 911.

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

8 “(2) Making, selling, disposing of, or keeping in
9 possession, control, or custody, or concealing any
10 punch, die, plate, stone, or other item that is de-
11 signed to print, imprint, or reproduce the trade-
12 mark, trade name, or other identifying mark, im-
13 print, or device of another or any likeness of any of
14 the foregoing upon any tobacco product or container
15 or labeling thereof so as to render such tobacco
16 product a counterfeit tobacco product.

17 “(3) The doing of any act that causes a tobacco
18 product to be a counterfeit tobacco product, or the
19 sale or dispensing, or the holding for sale or dis-
20 pensing, of a counterfeit tobacco product.

21 “(dd) The charitable distribution of tobacco
22 products.

23 “(ee) The failure of a manufacturer or dis-
24 tributor to notify the Attorney General of their
25 knowledge of tobacco products used in illicit trade.”.

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

3 (1) by striking the subsection heading and in-
 4 serting the following:

5 “(f) CIVIL PENALTIES; NO-TOBACCO-SALE OR-
 6 DERS.—”;

7 (2) in paragraph (1)(A), by inserting “or to-
 8 bacco products” after “devices”;

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

12 “(3) If the Secretary finds that a person has
 13 committed repeated violations of restrictions promul-
 14 gated under section 906(d) at a particular retail out-
 15 let then the Secretary may impose a no-tobacco-sale
 16 order on that person prohibiting the sale of tobacco
 17 products in that outlet. A no-tobacco-sale order may
 18 be imposed with a civil penalty under paragraph
 19 (1).”;

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

21 (A) in subparagraph (A)—

22 (i) by striking “assessed” the first
 23 time it appears and inserting “assessed, or
 24 a no-tobacco-sale order may be imposed,”;
 25 and

1 (ii) by striking “penalty” and insert-
2 ing “penalty, or upon whom a no-tobacco-
3 order is to be imposed,”;

4 (B) in subparagraph (B)—

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

8 (ii) by adding at the end the fol-
9 lowing: “A no-tobacco-sale order perma-
10 nently prohibiting an individual retail out-
11 let from selling tobacco products shall in-
12 clude provisions that allow the outlet, after
13 a specified period of time, to request that
14 the Secretary compromise, modify, or ter-
15 minate the order.”; and

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

17 “(D) The Secretary may compromise, mod-
18 ify, or terminate, with or without conditions,
19 any no-tobacco-sale order.”;

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

21 (A) by striking “(3)(A)” as redesignated,
22 and inserting “(4)(A)”;

23 (B) by inserting “or the imposition of a
24 no-tobacco-sale order” after “penalty” the first
25 2 places it appears; and

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

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

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

9 (1) in subsection (a)(2)—

10 (A) by striking “and” before “(D)”;

11 (B) by striking “device.” and inserting the
 12 following: “, (E) Any adulterated or misbranded
 13 tobacco product.”;

14 (2) in subsection (d)(1), by inserting “tobacco
 15 product,” after “device,”;

16 (3) in subsection (g)(1), by inserting “or to-
 17 bacco product” after “device” each place it appears;
 18 and

19 (4) in subsection (g)(2)(A), by inserting “or to-
 20 bacco product” after “device” each place it appears.

21 (e) SECTION 702.—Section 702(a) (21 U.S.C.
 22 372(a)) is amended—

23 (1) by inserting “(1)” after “(a)”;

24 (2) by adding at the end thereof the following:

1 “(2) For a tobacco product, to the extent feasible,
2 the Secretary shall contract with the States in accordance
3 with paragraph (1) to carry out inspections of retailers
4 in connection with the enforcement of this Act.”.

5 (f) SECTION 703.—Section 703 (21 U.S.C. 373) is
6 amended—

7 (1) by inserting “tobacco product,” after “de-
8 vice,” each place it appears; and

9 (2) by inserting “tobacco products,” after “de-
10 vices,” each place it appears.

11 (g) SECTION 704.—Section 704 (21 U.S.C. 374) is
12 amended—

13 (1) in subsection (a)(1)(A), by inserting “to-
14 bacco products,” after “devices,” each place it ap-
15 pears;

16 (2) in subsection (a)(1)(B), by inserting “or to-
17 bacco product” after “restricted devices” each place
18 it appears; and

19 (3) in subsection (b), by inserting “tobacco
20 product,” after “device,”.

21 (h) SECTION 705.—Section 705(b) (21 U.S.C.
22 375(b)) is amended by inserting “tobacco products,” after
23 “devices,”.

24 (i) SECTION 709.—Section 709 (21 U.S.C. 379) is
25 amended by inserting “or tobacco product” after “device”.

1 (j) SECTION 801.—Section 801 (21 U.S.C. 381) is
2 amended—

3 (1) in subsection (a)—

4 (A) by inserting “tobacco products,” after
5 “devices,” the first time it appears;

6 (B) by inserting “or section 905(j)” after
7 “section 510”; and

8 (C) by striking “drugs or devices” each
9 time it appears and inserting “drugs, devices,
10 or tobacco products”;

11 (2) in subsection (e)(1), by inserting “tobacco
12 product,” after “device,”; and

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

14 “(p)(1) Not later than 2 years after the date of enact-
15 ment of the Family Smoking Prevention and Tobacco
16 Control Act, and annually thereafter, the Secretary shall
17 submit to the Committee on Health, Education, Labor,
18 and Pensions of the Senate and the Committee on Energy
19 and Commerce of the House of Representatives, a report
20 regarding—

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

1 “(B) the public health implications of such ex-
 2 ports, including any evidence of a negative public
 3 health impact; and

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

8 “(2) The Secretary is authorized to establish appro-
 9 priate information disclosure requirements to carry out
 10 this subsection.”.

11 (k) SECTION 1003.—Section 1003(d)(2)(C) (as re-
 12 designated by section 101(a)) is amended—

13 (1) by striking “and” after “cosmetics,”; and

14 (2) inserting a comma and “and tobacco prod-
 15 ucts” after “devices”.

16 (l) EFFECTIVE DATE FOR NO-TOBACCO-SALE
 17 ORDER AMENDMENTS.—The amendments made by sub-
 18 section (c), other than the amendment made by paragraph
 19 (2) of such subsection, shall take effect upon the issuance
 20 of guidance by the Secretary of Health and Human Serv-
 21 ices—

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

1 tions of particular requirements over a specified pe-
2 riod of time at a particular retail outlet that con-
3 stitute a repeated violation;

4 (2) providing for timely and effective notice to
5 the retailer of each alleged violation at a particular
6 retail outlet and an expedited procedure for the ad-
7 ministrative appeal of an alleged violation;

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

12 (4) establishing a period of time during which,
13 if there are no violations by a particular retail out-
14 let, that outlet will not be considered to have been
15 the site of repeated violations when the next viola-
16 tion occurs; and

17 (5) providing that good faith reliance on the
18 presentation of a false government issued photo-
19 graphic identification that contains the bearer's date
20 of birth does not constitute a violation of any min-
21 imum age requirement for the sale of tobacco prod-
22 ucts if the retailer has taken effective steps to pre-
23 vent such violations, including—

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

1 (B) informing its employees of all applica-
2 ble laws;

3 (C) establishing disciplinary sanctions for
4 employee noncompliance; and

5 (D) requiring its employees to verify age
6 by way of photographic identification or elec-
7 tronic scanning device.

8 **CHAPTER 2—TOBACCO PRODUCT WARN-**
9 **INGS; CONSTITUENT AND SMOKE CON-**
10 **STITUENT DISCLOSURE**

11 **SEC. 241. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

12 Section 4 of the Federal Cigarette Labeling and Ad-
13 vertising Act (15 U.S.C. 1333) is amended to read as fol-
14 lows:

15 **“SEC. 4. LABELING.**

16 **“(a) LABEL REQUIREMENTS.—**

17 **“(1) IN GENERAL.—**It shall be unlawful for any
18 person to manufacture, package, sell, offer to sell,
19 distribute, or import for sale or distribution within
20 the United States any cigarettes the package of
21 which fails to bear, in accordance with the require-
22 ments of this section, one of the following labels:

23 ‘WARNING: Cigarettes are addictive’.

24 ‘WARNING: Tobacco smoke can harm your chil-
25 dren’.

1 ‘WARNING: Cigarettes cause fatal lung disease’.

2 ‘WARNING: Cigarettes cause cancer’.

3 ‘WARNING: Cigarettes cause strokes and heart dis-
4 ease’.

5 ‘WARNING: Smoking during pregnancy can harm
6 your baby’.

7 ‘WARNING: Smoking can kill you’.

8 ‘WARNING: Tobacco smoke causes fatal lung dis-
9 ease in non-smokers’.

10 ‘WARNING: Quitting smoking now greatly reduces
11 serious risks to your health’.

12 “(2) PLACEMENT; TYPOGRAPHY; ETC.—

13 “(A) IN GENERAL.—Each label statement
14 required by paragraph (1) shall be located in
15 the upper portion of the front and rear panels
16 of the package, directly on the package under-
17 neath the cellophane or other clear wrapping.
18 Except as provided in subparagraph (B), each
19 label statement shall comprise at least the top
20 30 percent of the front and rear panels of the
21 package. The word ‘WARNING’ shall appear in
22 capital letters and all text shall be in con-
23 spicuous and legible 17-point type, unless the
24 text of the label statement would occupy more
25 than 70 percent of such area, in which case the

1 text may be in a smaller conspicuous and leg-
2 ible type size, provided that at least 60 percent
3 of such area is occupied by required text. The
4 text shall be black on a white background, or
5 white on a black background, in a manner that
6 contrasts, by typography, layout, or color, with
7 all other printed material on the package, in an
8 alternating fashion under the plan submitted
9 under subsection (b)(4).

10 “(B) FLIP-TOP BOXES.—For any cigarette
11 brand package manufactured or distributed be-
12 fore January 1, 2000, which employs a flip-top
13 style (if such packaging was used for that
14 brand in commerce prior to June 21, 1997), the
15 label statement required by paragraph (1) shall
16 be located on the flip-top area of the package,
17 even if such area is less than 25 percent of the
18 area of the front panel. Except as provided in
19 this paragraph, the provisions of this subsection
20 shall apply to such packages.

21 “(3) DOES NOT APPLY TO FOREIGN DISTRIBU-
22 TION.—The provisions of this subsection do not
23 apply to a tobacco product manufacturer or dis-
24 tributor of cigarettes which does not manufacture,

1 package, or import cigarettes for sale or distribution
2 within the United States.

3 “(4) APPLICABILITY TO RETAILERS.—A retailer
4 of cigarettes shall not be in violation of this sub-
5 section for packaging that is supplied to the retailer
6 by a tobacco product manufacturer, importer, or dis-
7 tributor and is not altered by the retailer in a way
8 that is material to the requirements of this sub-
9 section except that this paragraph shall not relieve
10 a retailer of liability if the retailer sells or distributes
11 tobacco products that are not labeled in accordance
12 with this subsection.

13 “(b) ADVERTISING REQUIREMENTS.—

14 “(1) IN GENERAL.—It shall be unlawful for any
15 tobacco product manufacturer, importer, distributor,
16 or retailer of cigarettes to advertise or cause to be
17 advertised within the United States any cigarette
18 unless its advertising bears, in accordance with the
19 requirements of this section, one of the labels speci-
20 fied in subsection (a) of this section.

21 “(2) TYPOGRAPHY, ETC.—Each label statement
22 required by subsection (a) of this section in cigarette
23 advertising shall comply with the standards set forth
24 in this paragraph. For press and poster advertise-
25 ments, each such statement and (where applicable)

1 any required statement relating to tar, nicotine, or
2 other constituent (including a smoke constituent)
3 yield shall comprise at least 20 percent of the area
4 of the advertisement and shall appear in a con-
5 spicuous and prominent format and location at the
6 top of each advertisement within the trim area. The
7 Secretary may revise the required type sizes in such
8 area in such manner as the Secretary determines ap-
9 propriate. The word 'WARNING' shall appear in
10 capital letters, and each label statement shall appear
11 in conspicuous and legible type. The text of the label
12 statement shall be black if the background is white
13 and white if the background is black, under the plan
14 submitted under paragraph (4) of this subsection.
15 The label statements shall be enclosed by a rectan-
16 gular border that is the same color as the letters of
17 the statements and that is the width of the first
18 downstroke of the capital 'W' of the word 'WARN-
19 ING' in the label statements. The text of such label
20 statements shall be in a typeface pro rata to the fol-
21 lowing requirements: 45-point type for a whole-page
22 broadsheet newspaper advertisement; 39-point type
23 for a half-page broadsheet newspaper advertisement;
24 39-point type for a whole-page tabloid newspaper ad-
25 vertisement; 27-point type for a half-page tabloid

1 newspaper advertisement; 31.5-point type for a dou-
2 ble page spread magazine or whole-page magazine
3 advertisement; 22.5-point type for a 28 centimeter
4 by 3 column advertisement; and 15-point type for a
5 20 centimeter by 2 column advertisement. The label
6 statements shall be in English, except that in the
7 case of—

8 “(A) an advertisement that appears in a
9 newspaper, magazine, periodical, or other publi-
10 cation that is not in English, the statements
11 shall appear in the predominant language of the
12 publication; and

13 “(B) in the case of any other advertise-
14 ment that is not in English, the statements
15 shall appear in the same language as that prin-
16 cipally used in the advertisement.

17 “(3) MATCHBOOKS.—Notwithstanding para-
18 graph (2), for matchbooks (defined as containing not
19 more than 20 matches) customarily given away with
20 the purchase of tobacco products, each label state-
21 ment required by subsection (a) may be printed on
22 the inside cover of the matchbook.

23 “(4) ADJUSTMENT BY SECRETARY.—The Sec-
24 retary may, through a rulemaking under section 553
25 of title 5, United States Code, adjust the format and

1 type sizes for the label statements required by this section
2 or the text, format, and type sizes of any required tar,
3 nicotine yield, or other constituent (including smoke con-
4 stituent) disclosures, or to establish the text, format, and
5 type sizes for any other disclosures required under the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
7 et seq.). The text of any such label statements or discolo-
8 sures shall be required to appear only within the 20 per-
9 cent area of cigarette advertisements provided by para-
10 graph (2) of this subsection. The Secretary shall promul-
11 gate regulations which provide for adjustments in the for-
12 mat and type sizes of any text required to appear in such
13 area to ensure that the total text required to appear by
14 law will fit within such area.

15 “(5) MARKETING REQUIREMENTS.—

16 “(A) The label statements specified in sub-
17 section (a)(1) shall be randomly displayed in
18 each 12-month period, in as equal a number of
19 times as is possible on each brand of the prod-
20 uct and be randomly distributed in all areas of
21 the United States in which the product is mar-
22 keted in accordance with a plan submitted by
23 the tobacco product manufacturer, importer,
24 distributor, or retailer and approved by the Sec-
25 retary.

1 “(B) The label statements specified in sub-
2 section (a)(1) shall be rotated quarterly in al-
3 ternating sequence in advertisements for each
4 brand of cigarettes in accordance with a plan
5 submitted by the tobacco product manufacturer,
6 importer, distributor, or retailer to, and ap-
7 proved by, the Secretary.

8 “(C) The Secretary shall review each plan
9 submitted under subparagraph (B) and approve
10 it if the plan—

11 “(i) will provide for the equal distribu-
12 tion and display on packaging and the ro-
13 tation required in advertising under this
14 subsection; and

15 “(ii) assures that all of the labels re-
16 quired under this section will be displayed
17 by the tobacco product manufacturer, im-
18 porter, distributor, or retailer at the same
19 time.

20 “(6) APPLICABILITY TO RETAILERS.—This sub-
21 section applies to a retailer only if that retailer is re-
22 sponsible for or directs the label statements required
23 under this section except that this paragraph shall
24 not relieve a retailer of liability if the retailer dis-
25 plays, in a location open to the public, an advertise-

1 ment that is not labeled in accordance with the re-
2 quirements of this subsection.”.

3 **SEC. 242. AUTHORITY TO REVISE CIGARETTE WARNING**
4 **LABEL STATEMENTS.**

5 Section 4 of the Federal Cigarette Labeling and Ad-
6 vertising Act (15 U.S.C. 1333), as amended by section
7 241, is further amended by adding at the end the fol-
8 lowing:

9 “(c) CHANGE IN REQUIRED STATEMENTS.—The Sec-
10 retary may, by a rulemaking conducted under section 553
11 of title 5, United States Code, adjust the format, type size,
12 and text of any of the label requirements, require color
13 graphics to accompany the text, increase the required label
14 area from 30 percent up to 50 percent of the front and
15 rear panels of the package, or establish the format, type
16 size, and text of any other disclosures required under the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
18 et seq.), if the Secretary finds that such a change would
19 promote greater public understanding of the risks associ-
20 ated with the use of tobacco products.”.

21 **SEC. 243. STATE REGULATION OF CIGARETTE ADVER-**
22 **TISING AND PROMOTION.**

23 Section 5 of the Federal Cigarette Labeling and Ad-
24 vertising Act (15 U.S.C. 1334) is amended by adding at
25 the end the following:

1 “(c) EXCEPTION.—Notwithstanding subsection (b), a
 2 State or locality may enact statutes and promulgate regu-
 3 lations, based on smoking and health, that take effect
 4 after the effective date of the Family Smoking Prevention
 5 and Tobacco Control Act, imposing specific bans or re-
 6 strictions on the time, place, and manner, but not content,
 7 of the advertising or promotion of any cigarettes.”.

8 **SEC. 244. SMOKELESS TOBACCO LABELS AND ADVERTISING**
 9 **WARNINGS.**

10 Section 3 of the Comprehensive Smokeless Tobacco
 11 Health Education Act of 1986 (15 U.S.C. 4402) is amend-
 12 ed to read as follows:

13 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

14 “(a) GENERAL RULE.—

15 “(1) It shall be unlawful for any person to man-
 16 ufacture, package, sell, offer to sell, distribute, or
 17 import for sale or distribution within the United
 18 States any smokeless tobacco product unless the
 19 product package bears, in accordance with the re-
 20 quirements of this Act, one of the following labels:

21 ‘WARNING: This product can cause mouth cancer’.

22 ‘WARNING: This product can cause gum disease
 23 and tooth loss’.

24 ‘WARNING: This product is not a safe alternative
 25 to cigarettes’.

1 ‘WARNING: Smokeless tobacco is addictive’.

2 “(2) Each label statement required by para-
3 graph (1) shall be—

4 “(A) located on the 2 principal display
5 panels of the package, and each label statement
6 shall comprise at least 30 percent of each such
7 display panel; and

8 “(B) in 17-point conspicuous and legible
9 type and in black text on a white background,
10 or white text on a black background, in a man-
11 ner that contrasts by typography, layout, or
12 color, with all other printed material on the
13 package, in an alternating fashion under the
14 plan submitted under subsection (b)(3), except
15 that if the text of a label statement would oc-
16 cupy more than 70 percent of the area specified
17 by subparagraph (A), such text may appear in
18 a smaller type size, so long as at least 60 per-
19 cent of such warning area is occupied by the
20 label statement.

21 “(3) The label statements required by para-
22 graph (1) shall be introduced by each tobacco prod-
23 uct manufacturer, packager, importer, distributor, or
24 retailer of smokeless tobacco products concurrently
25 into the distribution chain of such products.

1 “(4) The provisions of this subsection do not
2 apply to a tobacco product manufacturer or dis-
3 tributor of any smokeless tobacco product that does
4 not manufacture, package, or import smokeless to-
5 bacco products for sale or distribution within the
6 United States.

7 “(5) A retailer of smokeless tobacco products
8 shall not be in violation of this subsection for pack-
9 aging that is supplied to the retailer by a tobacco
10 products manufacturer, importer, or distributor and
11 that is not altered by the retailer unless the retailer
12 offers for sale, sells, or distributes a smokeless to-
13 bacco product that is not labeled in accordance with
14 this subsection.

15 “(b) REQUIRED LABELS.—

16 “(1) It shall be unlawful for any tobacco prod-
17 uct manufacturer, packager, importer, distributor, or
18 retailer of smokeless tobacco products to advertise or
19 cause to be advertised within the United States any
20 smokeless tobacco product unless its advertising
21 bears, in accordance with the requirements of this
22 section, one of the labels specified in subsection (a).

23 “(2) Each label statement required by sub-
24 section (a) in smokeless tobacco advertising shall
25 comply with the standards set forth in this para-

1 graph. For press and poster advertisements, each
2 such statement and (where applicable) any required
3 statement relating to tar, nicotine, or other con-
4 stituent yield shall—

5 “(A) comprise at least 20 percent of the
6 area of the advertisement, and the warning area
7 shall be delineated by a dividing line of con-
8 trasting color from the advertisement; and

9 “(B) the word ‘WARNING’ shall appear in
10 capital letters and each label statement shall
11 appear in conspicuous and legible type. The text
12 of the label statement shall be black on a white
13 background, or white on a black background, in
14 an alternating fashion under the plan submitted
15 under paragraph (3).

16 “(3)(A) The label statements specified in sub-
17 section (a)(1) shall be randomly displayed in each
18 12-month period, in as equal a number of times as
19 is possible on each brand of the product and be ran-
20 domly distributed in all areas of the United States
21 in which the product is marketed in accordance with
22 a plan submitted by the tobacco product manufac-
23 turer, importer, distributor, or retailer and approved
24 by the Secretary.

1 “(B) The label statements specified in sub-
2 section (a)(1) shall be rotated quarterly in alter-
3 nating sequence in advertisements for each brand of
4 smokeless tobacco product in accordance with a plan
5 submitted by the tobacco product manufacturer, im-
6 porter, distributor, or retailer to, and approved by,
7 the Secretary.

8 “(C) The Secretary shall review each plan sub-
9 mitted under subparagraph (B) and approve it if the
10 plan—

11 “(i) will provide for the equal distribution
12 and display on packaging and the rotation re-
13 quired in advertising under this subsection; and

14 “(ii) assures that all of the labels required
15 under this section will be displayed by the to-
16 bacco product manufacturer, importer, dis-
17 tributor, or retailer at the same time.

18 “(D) This paragraph applies to a retailer only
19 if that retailer is responsible for or directs the label
20 statements under this section, unless the retailer dis-
21 plays in a location open to the public, an advertise-
22 ment that is not labeled in accordance with the re-
23 quirements of this subsection.

24 “(c) TELEVISION AND RADIO ADVERTISING.—It is
25 unlawful to advertise smokeless tobacco on any medium

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

3 **SEC. 245. AUTHORITY TO REVISE SMOKELESS TOBACCO**
4 **PRODUCT WARNING LABEL STATEMENTS.**

5 Section 3 of the Comprehensive Smokeless Tobacco
6 Health Education Act of 1986 (15 U.S.C. 4402), as
7 amended by section 243, is further amended by adding
8 at the end the following:

9 “(d) **AUTHORITY TO REVISE WARNING LABEL**
10 **STATEMENTS.**—The Secretary may, by a rulemaking con-
11 ducted under section 553 of title 5, United States Code,
12 adjust the format, type size, and text of any of the label
13 requirements, require color graphics to accompany the
14 text, increase the required label area from 30 percent up
15 to 50 percent of the front and rear panels of the package,
16 or establish the format, type size, and text of any other
17 disclosures required under the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary
19 finds that such a change would promote greater public un-
20 derstanding of the risks associated with the use of smoke-
21 less tobacco products.”.

22 **SEC. 246. TAR, NICOTINE, AND OTHER SMOKE CON-**
23 **STITUENT DISCLOSURE TO THE PUBLIC.**

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

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

3 “(4)(A) The Secretary shall, by a rulemaking
4 conducted under section 553 of title 5, United
5 States Code, determine (in the Secretary’s sole dis-
6 cretion) whether cigarette and other tobacco product
7 manufacturers shall be required to include in the
8 area of each cigarette advertisement specified by
9 subsection (b) of this section, or on the package
10 label, or both, the tar and nicotine yields of the ad-
11 vertised or packaged brand. Any such disclosure
12 shall be in accordance with the methodology estab-
13 lished under such regulations, shall conform to the
14 type size requirements of subsection (b) of this sec-
15 tion, and shall appear within the area specified in
16 subsection (b) of this section.

17 “(B) Any differences between the requirements
18 established by the Secretary under subparagraph (A)
19 and tar and nicotine yield reporting requirements es-
20 tablished by the Federal Trade Commission shall be
21 resolved by a memorandum of understanding be-
22 tween the Secretary and the Federal Trade Commis-
23 sion.

24 “(C) In addition to the disclosures required by
25 subparagraph (A) of this paragraph, the Secretary

1 may, under a rulemaking conducted under section
2 553 of title 5, United States Code, prescribe disclo-
3 sure requirements regarding the level of any ciga-
4 rette or other tobacco product constituent including
5 any smoke constituent. Any such disclosure may be
6 required if the Secretary determines that disclosure
7 would be of benefit to the public health, or otherwise
8 would increase consumer awareness of the health
9 consequences of the use of tobacco products, except
10 that no such prescribed disclosure shall be required
11 on the face of any cigarette package or advertise-
12 ment. Nothing in this section shall prohibit the Sec-
13 retary from requiring such prescribed disclosure
14 through a cigarette or other tobacco product pack-
15 age or advertisement insert, or by any other means
16 under the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 301 et seq.).

18 “(D) This paragraph applies to a retailer only
19 if that retailer is responsible for or directs the label
20 statements required under this section, except that
21 this paragraph shall not relieve a retailer of liability
22 if the retailer sells or distributes tobacco products
23 that are not labeled in accordance with the require-
24 ments of this subsection.”.

1 **CHAPTER 3—PREVENTION OF ILLICIT**
2 **TRADE IN TOBACCO PRODUCTS**

3 **SEC. 251. LABELING, RECORDKEEPING, RECORDS INSPEC-**
4 **TION.**

5 Chapter IX of the Federal Food, Drug, and Cosmetic
6 Act, as added by section 231, is further amended by add-
7 ing at the end the following:

8 **“SEC. 921. LABELING, RECORDKEEPING, RECORDS INSPEC-**
9 **TION.**

10 “(a) ORIGIN LABELING.—The label, packaging, and
11 shipping containers of tobacco products for introduction
12 or delivery for introduction into interstate commerce shall
13 bear the statement ‘sale only allowed in the United
14 States.’

15 “(b) REGULATIONS CONCERNING RECORDKEEPING
16 FOR TRACKING AND TRACING.—

17 “(1) IN GENERAL.—Not later than 9 months
18 after the date of enactment of the Family Smoking
19 Prevention and Tobacco Control Act, the Secretary
20 shall promulgate regulations regarding the establish-
21 ment and maintenance of records by any person who
22 manufactures, processes, transports, distributes, re-
23 ceives, packages, holds, exports, or imports tobacco
24 products.

1 “(2) INSPECTION.—In promulgating the regula-
2 tions described in paragraph (1), the Secretary shall
3 consider which records are needed for inspection to
4 monitor the movement of tobacco products from the
5 point of manufacture through distribution to retail
6 outlets to assist in investigating potential illicit
7 trade, smuggling or counterfeiting of tobacco prod-
8 ucts.

9 “(3) CODES.—The Secretary may require codes
10 on the labels of tobacco products or other designs or
11 devices for the purpose of tracking or tracing the to-
12 bacco product through the distribution system.

13 “(4) SIZE OF BUSINESS.—The Secretary shall
14 take into account the size of a business in promul-
15 gating regulations under this section.

16 “(5) RECORDKEEPING BY RETAILERS.—The
17 Secretary shall not require any retailer to maintain
18 records relating to individual purchasers of tobacco
19 products for personal consumption.

20 “(c) RECORDS INSPECTION.—If the Secretary has a
21 reasonable belief that a tobacco product is part of an illicit
22 trade or smuggling or is a counterfeit product, each person
23 who manufactures, processes, transports, distributes, re-
24 ceives, holds, packages, exports, or imports tobacco prod-
25 ucts shall, at the request of an officer or employee duly

1 designated by the Secretary, permit such officer or em-
 2 ployee, at reasonable times and within reasonable limits
 3 and in a reasonable manner, upon the presentation of ap-
 4 propriate credentials and a written notice to such person,
 5 to have access to and copy all records (including financial
 6 records) relating to such article that are needed to assist
 7 the Secretary in investigating potential illicit trade, smug-
 8 gling or counterfeiting of tobacco products.

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

15 “(A) imported, exported, distributed or of-
 16 ferred for sale in interstate commerce by a per-
 17 son without paying duties or taxes required by
 18 law; or

19 “(B) imported, exported, distributed or di-
 20 verted for possible illicit marketing,

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

23 “(e) KNOWLEDGE DEFINED.—For purposes of this
 24 subsection, the term ‘knowledge’ as applied to a manufac-
 25 turer or distributor means—

1 “(1) the actual knowledge that the manufac-
2 turer or distributor had; or

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

7 **SEC. 252. STUDY AND REPORT.**

8 (a) STUDY.—The Comptroller General of the United
9 States shall conduct a study of cross-border trade in to-
10 bacco products to—

11 (1) collect data on cross-border trade in tobacco
12 products, including illicit trade and trade of counter-
13 feit tobacco products and make recommendations on
14 the monitoring of such trade; and

15 (2) collect data on cross-border advertising (any
16 advertising intended to be broadcast, transmitted, or
17 distributed from the United States to another coun-
18 try) of tobacco products and make recommendations
19 on how to prevent or eliminate, and what tech-
20 nologies could help facilitate the elimination of,
21 cross-border advertising.

22 (b) REPORT.—Not later than 18 months after the
23 date of enactment of this Act, the Comptroller General
24 of the United States shall submit to the Committee on
25 Health, Education, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the House
 2 of Representatives a report on the study described in sub-
 3 section (a).

4 **TITLE III—RESPONSIBLE MAR-**
 5 **KETING AND CONSUMER**
 6 **AWARENESS**

7 **Subtitle A—General Provisions**

8 **SEC. 301. NUTRITION LABELING OF RESTAURANT FOODS.**

9 Section 403(q)(5) of the Federal Food, Drug, and
 10 Cosmetic Act (21 U.S.C. 343(q)(5)(A)(i)) is amended—

11 (1) in clause (A)—

12 (A) in subclause (i), by inserting “except
 13 as provided in clauses (H) and (I),” before
 14 “which” the first place it appears; and

15 (B) in subclause (ii), by inserting “except
 16 as provided in clauses (H) and (I),” before
 17 “which” the first place it appears; and

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

19 “(H) RESTAURANTS AND RETAIL FOOD ESTABLISH-
 20 MENTS.—

21 “(i) IN GENERAL.—Except for food described in
 22 subclause (iii), in the case of food that—

23 “(I) is served in a restaurant or similar re-
 24 tail food establishment; or

1 “(II) is processed and prepared primarily
2 in a retail establishment;
3 that is part of a chain with 20 or more locations
4 doing business under the same trade name (regard-
5 less of the type of ownership of the locations), the
6 restaurant of the establishment shall disclose the in-
7 formation described in subclause (ii).

8 “(ii) INFORMATION REQUIRED TO BE DIS-
9 CLOSED.—Except as provided in clause (iii), the es-
10 tablishment shall disclose—

11 “(I)(aa) in a statement adjacent to the
12 name of the food on any menu listing the food
13 for sale, or by any other means approved by the
14 Secretary, the number of calories, grams of
15 saturated fat plus trans fat, and milligrams of
16 sodium contained in a serving of the food, as
17 offered for sale, in a clear and conspicuous
18 manner; and

19 “(bb) information, specified by the Sec-
20 retary by regulation, designed to enable the
21 public to understand, in the context of a total
22 daily diet, the significance of the nutrition in-
23 formation that is provided; and

24 “(II) in a statement adjacent to the name
25 of the food on any menu board or other sign

1 listing the food for sale, or by any other means
 2 approved by the Secretary, the number of cal-
 3 ories contained in a serving of the food, as of-
 4 fered for sale, in a clear and conspicuous man-
 5 ner.

6 “(iii) NONAPPLICABILITY TO CERTAIN FOOD.—

7 This clause does not apply to—

8 “(I) items that are not listed on a menu or
 9 menu board (such as condiments, other items
 10 placed on the table or counter for general use,
 11 and items from salad bars or other self-service
 12 facilities); or

13 “(II) daily specials, temporary menu items,
 14 or other irregular menu items, as specified by
 15 the Secretary by regulation.

16 “(iv) SELF-SERVICE FACILITIES.—

17 “(I) IN GENERAL.—In the case of food
 18 sold at a salad bar, buffet line, cafeteria line, or
 19 similar self-service facility, a restaurant or
 20 other establishment shall place a sign that lists
 21 calories per standard serving adjacent to the
 22 name of each food offered.

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

1 prospective purchaser to examine the article so
 2 as to be able to read a statement affixed to the
 3 article as required under subclause (I) before
 4 purchasing the article, a restaurant or other es-
 5 tablishment (or, in the case of a vending ma-
 6 chine that is owned and operated by a vending
 7 machine operator, the vending machine oper-
 8 ator) shall provide a conspicuous sign, in close
 9 proximity to the article, identifying the food
 10 and including a statement disclosing the num-
 11 ber of calories contained in the article.

12 “(v) VOLUNTARY PROVISION OF NUTRITION IN-
 13 FORMATION; STATE REGULATION OF NUTRITION IN-
 14 FORMATION FOR RESTAURANT FOOD.—

15 “(I) RETAIL FOOD ESTABLISHMENTS.—
 16 Nothing in this clause precludes a restaurant or
 17 similar retail food establishment from providing
 18 additional nutrition information, voluntarily, if
 19 the information complies with the nutrition la-
 20 beling requirements contained in this subpara-
 21 graph.

22 “(II) STATE OR LOCAL REQUIREMENTS.—
 23 Nothing in this clause precludes a State or po-
 24 litical subdivision of a State from requiring that
 25 a restaurant or similar food establishment pro-

1 vide nutrition information in addition to that
2 required under this clause.

3 “(vi) REGULATIONS.—

4 “(I) PROPOSED REGULATION.—Not later
5 than 1 year after the date of enactment of this
6 clause, the Secretary shall promulgate proposed
7 regulations to carry out this clause.

8 “(II) CONTENTS.—The regulations shall
9 allow for the variations in serving sizes and in
10 food preparation that can reasonably be ex-
11 pected to result from inadvertent human error,
12 training of food service workers, and other fac-
13 tors.

14 “(III) FINAL REGULATIONS.—Not later
15 than 2 years after the date of enactment of this
16 clause, the Secretary shall promulgate final reg-
17 ulations to implement this clause.

18 “(IV) FAILURE TO PROMULGATE FINAL
19 REGULATIONS BY REQUIRED DATE.—If the Sec-
20 retary does not promulgate final regulations
21 under item (III) by the date that is 2 years
22 after the date of enactment of this clause—

23 “(aa) the proposed regulations issued
24 in accordance with item (I) shall become

1 effective as the final regulations on the day
2 after that date; and

3 “(bb) the Secretary shall publish in
4 the Federal Register notice of the final
5 regulations.

6 “(I) VENDING MACHINES.—

7 “(i) IN GENERAL.—In the case of an article of
8 food sold from a vending machine that—

9 “(I) does not permit a prospective pur-
10 chaser to examine the article so as to be able
11 to read a statement affixed to the article before
12 purchasing the article; and

13 “(II) is operated by a person that is en-
14 gaged in the business of owning and operating
15 20 or more vending machines;

16 the vending machine operator shall provide a con-
17 spicuous sign, in close proximity to the article, iden-
18 tifying the food and including a statement disclosing
19 the number of calories contained in the article.

20 “(ii) VOLUNTARY PROVISION OF NUTRITION IN-
21 FORMATION; STATE REGULATION OF NUTRITION IN-
22 FORMATION FOR VENDING MACHINES.—

23 “(I) VENDING MACHINE OPERATORS.—

24 Nothing in this clause precludes a vending ma-
25 chine 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 Sec-

retary 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

1 effective as the final regulations on the day
2 after that date; and

3 “(bb) the Secretary shall publish in
4 the Federal Register notice of the final
5 regulations.”.

6 **SEC. 302. RULEMAKING AUTHORITY FOR ADVERTISING TO**
7 **CHILDREN.**

8 (a) PURPOSE.—The purpose of this section is to allow
9 the Federal Trade Commission to issue regulations that
10 restrict the marketing or advertising of foods and bev-
11 erages to children under the age of 18 years if the Federal
12 Trade Commission determines that there is evidence that
13 consumption of certain foods and beverages is detrimental
14 to the health of children or it determines advertising to
15 children to be unfair or deceptive.

16 (b) AUTHORITY.—Section 18 of the Federal Trade
17 Commission Act (15 U.S.C. 57a) is amended by striking
18 subsection (h).

19 **SEC. 303. FOOD ADVERTISING IN SCHOOLS.**

20 Section 10 of the Child Nutrition Act of 1966 (42
21 U.S.C. 1779) is amended by adding at the end the fol-
22 lowing:

23 “(d) FOOD ADVERTISING.—The Secretary may pro-
24 hibit the advertising of food in participating schools if the
25 Secretary determines that consumption of the advertised

1 food has a detrimental effect on the diets or health of chil-
 2 dren.”.

3 **SEC. 304. DISALLOWANCE OF DEDUCTIONS FOR ADVER-**
 4 **TISING AND MARKETING EXPENSES RELAT-**
 5 **ING TO TOBACCO PRODUCT USE.**

6 (a) IN GENERAL.—Part IX of subchapter B of chap-
 7 ter 1 of subtitle A of the Internal Revenue Code of 1986
 8 (relating to items not deductible) is amended by adding
 9 at the end the following new section:

10 **“SEC. 280I. DISALLOWANCE OF DEDUCTION FOR TOBACCO**
 11 **ADVERTISING AND MARKETING EXPENSES.**

12 No deduction shall be allowed under this chapter for
 13 expenses relating to advertising or marketing cigars, ciga-
 14 rettes, smokeless tobacco, pipe tobacco, or any similar to-
 15 bacco product. For purposes of this section, any term used
 16 in this section which is also used in section 5702 shall
 17 have the same meaning given such term by section 5702.”.

18 (b) CONFORMING AMENDMENT.—The table of sec-
 19 tions for such part IX is amended by adding after the
 20 item relating to section 280H the following new item:

“Sec. 280I. Disallowance of deduction for tobacco advertising
 and marketing expenses.”.

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

1 **SEC. 305. FEDERAL-STATE TOBACCO COUNTER-ADVER-**
 2 **TISING PROGRAMS.**

3 Part P of title III of the Public Health Service Act
 4 (42 U.S.C. 280g et seq.), as amended in section 212, is
 5 further amended by adding at the end the following:

6 **“SEC. 399S. FEDERAL-STATE TOBACCO COUNTER-ADVER-**
 7 **TISING PROGRAMS.**

8 “(a) IN GENERAL.—The Secretary, acting through
 9 the Director of the Centers for Disease Control and Pre-
 10 vention, shall award grants to and enter into contracts
 11 with eligible entities for the implementation of national
 12 and local media (such as counter-advertising) and non-
 13 media campaigns designed to reduce the use of tobacco
 14 products.

15 “(b) ELIGIBILITY.—To be eligible to receive a grant
 16 under subsection (a), an entity shall be—

17 “(1) a public entity, including a State public
 18 health department; or

19 “(2) a private, nonprofit entity that—

20 “(A) is not affiliated with a manufacturer
 21 or importer of a tobacco product;

22 “(B) has demonstrated a record of con-
 23 ducting a national antitobacco public education
 24 campaign to effectively reduce the use of to-
 25 bacco products;

1 “(C) has expertise in conducting a multi-
2 media communications campaign; and

3 “(D) has expertise in developing strategies
4 that affect behavior changes in children and
5 other targeted populations.

6 “(c) APPLICATION.—An eligible entity shall submit
7 an application to the Secretary for a grant under this sec-
8 tion at such time, in such manner, and accompanied by
9 such information as the Secretary may require.

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

12 “(1) design and implement multimedia public
13 education and social marketing campaigns that—

14 “(A) discourage the use of tobacco prod-
15 ucts;

16 “(B) encourage the use of products de-
17 signed to enable tobacco use cessation; and

18 “(C) educate the public about the hazards
19 of environmental tobacco smoke exposure; or

20 “(2) conduct research related to the effective-
21 ness of the campaigns described in paragraph (1).

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

24 “(1) 50 percent of such amounts to eligible
25 public entities; and

1 “(2) 50 percent of such amounts to eligible pri-
2 vate, nonprofit entities.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated \$200,000,000 to carry
5 out this section.”.

6 **Subtitle B—Penalties for Failure to** 7 **Reduce Teen Smoking**

8 **SEC. 311. CHILD CIGARETTE USE SURVEYS.**

9 (a) ANNUAL PERFORMANCE SURVEY.—

10 (1) IN GENERAL.—Not later than August 31,
11 2005, and annually thereafter, the Secretary of
12 Health and Human Services (referred to in this sec-
13 tion as the “Secretary”) shall publish the results of
14 an annual cigarette survey, to be carried out after
15 the date of enactment of this Act and completed
16 prior to August 21, 2005, and prior to August 21
17 of each year thereafter, to determine—

18 (A) the percentage of all young individuals
19 who used a type of cigarette within the 30-day
20 period prior to the conduct of the survey in-
21 volved; and

22 (B) the percentage of young individuals
23 who identify each brand of each type of ciga-
24 rette as the usual brand smoked within such
25 30-day period.

1 (2) YOUNG INDIVIDUALS.—For the purposes of
2 this subtitle, the term “young individuals” means in-
3 dividuals who are under 18 years of age.

4 (b) SIZE AND METHODOLOGY.—

5 (1) IN GENERAL.—The survey referred to in
6 subsection (a) shall be comparable in size and meth-
7 odology to the Monitoring the Future survey that
8 was completed in 1999 to measure the use of ciga-
9 rettes (by brand) by youths under 18 years of age
10 within the 30 day period prior to the conduct of the
11 study.

12 (2) CONCLUSIVE ACCURATENESS.—A survey
13 using the methodology described in paragraph (1)
14 shall be deemed conclusively proper, correct, and ac-
15 curate for purposes of this section.

16 (3) DEFINITION.—In this subtitle, the term
17 “Monitoring the Future survey” means the com-
18 bined survey of 8th, 10th, and 12th grade students
19 that was conducted at the Institute for Social Re-
20 search at the University of Michigan.

21 (c) REDUCTION.—The Secretary, based on a com-
22 parison of the results of the first annual cigarette survey
23 referred to in subsection (a) and the Monitoring the Fu-
24 ture survey referred to in subsection (b)(1), shall deter-

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

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

8 (e) NONAPPLICABILITY.—Chapter 35 of title 44,
9 United States Code, shall not apply to information re-
10 quired for the purposes of carrying out this section.

11 (f) DEFINITION.—In this subtitle the term “ciga-
12 rette” has the meaning given such term in section 3(1)
13 of the Federal Cigarette Labeling and Advertising Act (15
14 U.S.C. 1332(1)).

15 **SEC. 312. CIGARETTE USE REDUCTION GOAL AND NON-**
16 **COMPLIANCE.**

17 (a) GOAL.—It shall be the cigarette use reduction
18 goal that each manufacturer reduce youth cigarette use
19 by at least 15 percent during the period between the Moni-
20 toring the Future survey referred to in section 311(b)(1)
21 and the completion of the first annual cigarette survey
22 (and such subsequent surveys as compared to the previous
23 year’s survey) referred to in section 311(a).

24 (b) NONCOMPLIANCE.—

1 (1) INDUSTRY-WIDE PENALTY.—If the Sec-
2 retary determines that the cigarette use reduction
3 goal under subsection (a) has not been achieved, the
4 Secretary shall, not later than September 10, 2005,
5 and September 10 of each year thereafter, impose
6 an industry-wide penalty on the manufacturers of
7 cigarettes in an amount that is in the aggregate
8 equal to—

9 (A) if youth cigarette use has been reduced
10 by 5 percent or less, \$6,000,000,000;

11 (B) if youth cigarette use has been reduced
12 by at least 6 percent but less than 10 percent,
13 \$4,000,000,000; and

14 (C) if youth cigarette use has been reduced
15 by at least 11 percent but less than 15 percent,
16 \$2,000,000,000.

17 (2) PAYMENT.—The industry-wide penalty im-
18 posed under this subsection shall be paid by each
19 manufacturer based on the percentage of cigarettes
20 of each such manufacturer that, are used by youth
21 (as determined under the Monitoring the Future
22 survey and compared to the cigarettes manufactured
23 by all manufacturers) as such percentage relates to
24 the total amount to be paid by all manufacturers.

1 (3) FINAL DETERMINATION.—The determina-
2 tion of the Secretary as to the amount and allocation
3 of a surcharge under this subtitle shall be final and
4 the manufacturer shall pay such surcharge within 10
5 days of the date on which the manufacturer is as-
6 sessed. Such payment shall be retained by the Sec-
7 retary pending final judicial review of what, if any,
8 change in the surcharge is appropriate.

9 (4) COMPLIANCE BY CERTAIN MANUFACTUR-
10 ERS.—A manufacturer that individually complies
11 with the goal under subsection (a) shall not be liable
12 for the payment of any portion of the penalty under
13 this subsection.

14 (5) LIMITATION.—With respect to cigarettes, a
15 manufacturer with a market share of 1 percent or
16 less of youth cigarette use shall not be liable for the
17 payment of a surcharge under this section.

18 (c) PENALTIES NONDEDUCTIBLE.—The payment of
19 penalties under this subtitle shall not be considered to be
20 an ordinary and necessary expense in carrying on a trade
21 or business for purposes of the Internal Revenue Code of
22 1986 and shall not be deductible.

23 (d) JUDICIAL REVIEW.—

24 (1) AFTER PAYMENT.—A manufacturer of ciga-
25 rettes may seek judicial review of any action under

1 this subtitle only after the assessment involved has
2 been paid by the manufacturer to the Department of
3 the Treasury and only in the United States District
4 Court for the District of Columbia.

5 (2) REVIEW BY ATTORNEY GENERAL.—Prior to
6 the filing of an action by a manufacturer seeking ju-
7 dicial review of an action under this subtitle, the
8 manufacturer shall notify the Attorney General of
9 such intent to file and the Attorney General shall
10 have 30 days in which to respond to the action.

11 (3) REVIEW.—The amount of any surcharge
12 paid under this subtitle shall be subject to judicial
13 review by the United States Court of Appeals for the
14 District of Columbia Circuit, based on the arbitrary
15 and capricious standard of section 706 of title 5,
16 United States Code. Notwithstanding any other pro-
17 vision of law, no court shall have the authority to
18 stay any surcharge payment due to the Secretary
19 under this subtitle pending judicial review until the
20 Secretary has made or failed to make a compliance
21 determination, as described under this subtitle, that
22 has adversely affected the person seeking the review.

23 **SEC. 313. ENFORCEMENT.**

24 (a) INITIAL PENALTY.—There is hereby imposed an
25 initial penalty on the failure of any manufacturer to make

1 any payment required under this subtitle within 10 days
2 after the date on which such payment is due.

3 (b) AMOUNT OF PENALTY.—The amount of the pen-
4 alty imposed by subsection (a) on any failure with respect
5 to a manufacturer shall be an amount equal to 2 percent
6 of the penalty owed under section 312 for each day during
7 the noncompliance period.

8 (c) NONCOMPLIANCE PERIOD.—For purposes of this
9 section, the term “noncompliance period” means, with re-
10 spect to any failure to make the surcharge payment re-
11 quired under this subtitle, the period—

12 (1) beginning on the due date for such pay-
13 ment; and

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

16 (d) LIMITATIONS.—No penalty shall be imposed by
17 subsection (a) on—

18 (1) any failure to make a surcharge payment
19 under this subtitle during any period for which it is
20 established to the satisfaction of the Secretary that
21 none of the persons responsible for such failure
22 knew or, exercising reasonable diligence, would have
23 known, that such failure existed; or

1 (2) any manufacturer that produces less than 1
2 percent of cigarettes used by youth in that year (as
3 determined by the annual survey).

4 **TITLE IV—REIMBURSEMENT**
5 **AND COVERAGE OF PREVEN-**
6 **TIVE SERVICES**

7 **SEC. 401. COVERAGE OF SUBSTANCE USE (OTHER THAN TO-**
8 **BACCO), DIET, EXERCISE, INJURY PREVEN-**
9 **TION, AND DENTAL HEALTH COUNSELING.**

10 (a) COVERAGE.—

11 (1) IN GENERAL.—Section 1861(s)(2) of the
12 Social Security Act (42 U.S.C. 1395x(s)(2)), as
13 amended by section 642(a) of the Medicare Prescrip-
14 tion Drug, Improvement, and Modernization Act of
15 2003 (Public Law 108–173; 117 Stat. 2322), is
16 amended—

17 (A) in subparagraph (Y), by striking
18 “and” after the semicolon at the end;

19 (B) in subparagraph (Z), by adding “and”
20 after the semicolon at the end; and

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

23 “(AA) substance use (other than tobacco), diet,
24 exercise, injury prevention, and dental health coun-
25 seling (as defined in subsection (bbb)(1));”.

1 (2) CONFORMING AMENDMENTS.—(A) Section
 2 1862(a)(12) of the Social Security Act (42 U.S.C.
 3 1395y(a)(12)) is amended by inserting “(except as
 4 otherwise allowed under subsection
 5 1861(s)(2)(AA))” after “directly supporting teeth”.

6 (B) Clauses (i) and (ii) of section
 7 1861(s)(2)(K) of the Social Security Act (42 U.S.C.
 8 1395x(s)(2)(K)), as amended by section 611(d)(2) of
 9 the Medicare Prescription Drug, Improvement, and
 10 Modernization Act of 2003 (Public Law 108–173;
 11 117 Stat. 2304), are each amended by striking
 12 “subsection (ww)(1)” and inserting “subsections
 13 (ww)(1) and (bbb)”.

14 (b) SERVICES DESCRIBED.—Section 1861 of the So-
 15 cial Security Act (42 U.S.C. 1395x), as amended by sec-
 16 tion 706(b) of the Medicare Prescription Drug, Improve-
 17 ment, and Modernization Act of 2003 (Public Law 108–
 18 173; 117 Stat. 2339), is amended by adding at the end
 19 the following new subsection:

20 “Substance Use (Other Than Tobacco), Diet, Exercise,
 21 Injury Prevention, and Dental Health Counseling
 22 “(bbb) The term ‘substance use (other than tobacco),
 23 diet, exercise, injury prevention, and dental health coun-
 24 seling’ means therapy and counseling relating to substance

1 use (other than tobacco), diet, exercise, injury prevention,
 2 and dental health counseling that is furnished—

3 “(1) by or under the supervision of a physician;

4 or

5 “(2) by any other health care professional
 6 who—

7 “(A) is legally authorized to furnish such
 8 services under State law (or the State regu-
 9 latory mechanism provided by State law) of the
 10 State in which the services are furnished; and

11 “(B) is authorized to receive payment for
 12 other services under this title or is designated
 13 by the Secretary for this purpose.”.

14 (c) PAYMENT AND ELIMINATION OF COST-SHAR-
 15 ING.—

16 (1) PAYMENT AND ELIMINATION OF COINSUR-
 17 ANCE.—Section 1833(a)(1) of the Social Security
 18 Act (42 U.S.C. 1395l(a)(1)), as amended by section
 19 302(b)(2) of the Medicare Prescription Drug, Im-
 20 provement, and Modernization Act of 2003 (Public
 21 Law 108–173; 117 Stat. 2229), is amended—

22 (A) in subparagraph (N), by inserting “or
 23 substance use (other than tobacco), diet, exer-
 24 cise, injury prevention, and dental health coun-

1 seling (as defined in section 1861(bbb))” after
 2 “(as defined in section 1848(j)(3))”;

3 (B) by striking “and” before “(V)”;

4 (C) by inserting before the semicolon at
 5 the end the following: “and (W) with respect to
 6 substance use (other than tobacco), diet, exer-
 7 cise, injury prevention, and dental health coun-
 8 seling (as defined in section 1861(bbb) the
 9 amount paid shall be the lesser of the actual
 10 charge for the services or the amount deter-
 11 mined under the payment basis determined
 12 under section 1848”.

13 (2) PAYMENT UNDER PHYSICIAN FEE SCHED-
 14 ULE.—Section 1848(j)(3) of the Social Security Act
 15 (42 U.S.C. 1395w-4(j)(3)), as amended by section
 16 611(c) of the Medicare Prescription Drug, Improve-
 17 ment, and Modernization Act of 2003 (Public Law
 18 108-173; 117 Stat. 2304), is amended by inserting
 19 “(2)(AA),” after “(2)(W),”.

20 (3) ELIMINATION OF COINSURANCE IN OUT-
 21 PATIENT HOSPITAL SETTINGS.—

22 (A) EXCLUSION FROM OPD FEE SCHED-
 23 ULE.—Section 1833(t)(1)(B)(iv) of the Social
 24 Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)), as
 25 amended by section 614(a) of the Medicare

1 Prescription Drug, Improvement, and Mod-
 2 ernization Act of 2003 (Public Law 108–173;
 3 117 Stat. 2306), is amended by striking “and
 4 diagnostic mammography” and inserting “, di-
 5 agnostic mammography, or substance use
 6 (other than tobacco), diet, exercise, injury pre-
 7 vention, and dental health counseling (as de-
 8 fined in section 1861(bbb))”.

9 (B) CONFORMING AMENDMENTS.—Section
 10 1833(a)(2) of the Social Security Act (42
 11 U.S.C. 1395l(a)(2)) is amended—

12 (i) in subparagraph (F), by striking
 13 “and” after the semicolon at the end;

14 (ii) in subparagraph (G)(ii), by strik-
 15 ing the comma at the end and inserting
 16 “; and”; and

17 (iii) by inserting after subparagraph
 18 (G)(ii) the following new subparagraph:

19 “(H) with respect to substance use (other
 20 than tobacco), diet, exercise, injury prevention,
 21 and dental health counseling (as defined in sec-
 22 tion 1861(bbb)) furnished by an outpatient de-
 23 partment of a hospital, the amount determined
 24 under paragraph (1)(W),”.

1 (4) ELIMINATION OF DEDUCTIBLE.—The first
2 sentence of section 1833(b) of the Social Security
3 Act (42 U.S.C. 1395l(b)) is amended—

4 (A) by striking “and” before “(6)”; and

5 (B) by inserting before the period at the
6 end the following: “, and (7) such deductible
7 shall not apply with respect to substance use
8 (other than tobacco), diet, exercise, injury pre-
9 vention, and dental health counseling (as de-
10 fined in section 1861(bbb))”.

11 (d) APPLICATION OF LIMITS ON BILLING.—Section
12 1842(b)(18)(C) of the Social Security Act (42 U.S.C.
13 1395u(b)(18)(C)) is amended by adding at the end the
14 following new clause:

15 “(vii) Any health care professional designated
16 under section 1861(bbb)(2)(B) to perform substance
17 use (other than tobacco), diet, exercise, injury pre-
18 vention, and dental health counseling that is not oth-
19 erwise described in this subparagraph.”.

20 (e) EFFECTIVE DATE.—The amendments made by
21 this section shall take effect as if included in the enact-
22 ment of the Medicare Prescription Drug, Improvement,
23 and Modernization Act of 2003 (Public Law 108–173; 117
24 Stat. 2066) and shall apply to services furnished on and
25 after January 1, 2005.

1 **SEC. 402. PREVENTIVE MENTAL HEALTH SCREENINGS.**

2 (a) COVERAGE.—

3 (1) IN GENERAL.—Section 1861(s)(2) of the
4 Social Security Act (42 U.S.C. 1395x(s)(2)), as
5 amended by section 401(a)(1), is amended—

6 (A) in subparagraph (Z), by striking
7 “and” after the semicolon at the end;

8 (B) in subparagraph (AA), by adding
9 “and” after the semicolon at the end; and

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

12 “(BB) screenings for clinical depression, anx-
13 iety, and impaired cognitive functioning (as defined
14 in subsection (ccc)(1));”.

15 (2) CONFORMING AMENDMENTS.—Clauses (i)
16 and (ii) of section 1861(s)(2)(K) of the Social Secu-
17 rity Act (42 U.S.C. 1395x(s)(2)(K)), as amended by
18 section 401(a)(2)(B), are each amended by striking
19 “and (bbb)” and inserting “(bbb), and (ccc)”.

20 (b) SERVICES DESCRIBED.—Section 1861 of the So-
21 cial Security Act (42 U.S.C. 1395x), as amended by sec-
22 tion 401(b), is amended by adding at the end the following
23 new subsection:

1 “Screenings for Clinical Depression, Anxiety, and
2 Impaired Cognitive Functioning

3 “(ccc)(1) The term ‘screening for clinical depression,
4 anxiety, and impaired cognitive functioning’ means a con-
5 sultation for the purpose of detecting clinical depression,
6 anxiety, and impaired cognitive functioning during which
7 a qualified health professional (as defined in paragraph
8 (2))—

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

11 “(B) assesses the individual’s risk of clinical de-
12 pression, anxiety, and impaired cognitive func-
13 tioning; and

14 “(C) if the qualified health professional deter-
15 mines that the individual is at high risk for clinical
16 depression, anxiety, or impaired cognitive func-
17 tioning, refers the individual for a full diagnostic
18 evaluation and such additional treatment as may be
19 required.

20 Nothing in subparagraph (C) shall be construed as prohib-
21 iting a qualified health professional performing the screen-
22 ing for clinical depression, anxiety, and impaired cognitive
23 functioning with respect to an individual from directly pro-
24 viding the diagnostic evaluation and additional treatment
25 described in such clause to such individual if such profes-

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

5 “(2) For purposes of this subsection, the term ‘quali-
 6 fied health professional’ means an individual who—

7 “(A) is—

8 “(i) a physician (as defined in subsection
 9 (r)(1));

10 “(ii) a nurse practitioner (as defined in
 11 subsection (aa)(5)); or

12 “(iii) a mental health care professional (in-
 13 cluding clinical psychologists (as defined by the
 14 Secretary for purposes of section 1861(ii)) and
 15 clinical social workers (as defined in subsection
 16 1861(hh))) that is licensed or certified to per-
 17 form mental health services by the State in
 18 which the screenings are performed; and

19 “(B) has an agreement in effect with the Sec-
 20 retary to accept—

21 “(i) the amount determined under section
 22 1833(a)(1)(W) as full payment for screenings
 23 for clinical depression, anxiety, and impaired
 24 cognitive functioning; and

1 “(ii) an assignment described in section
 2 1842(b)(3)(B)(ii) with respect to payment for
 3 each screening furnished by the professional to
 4 an individual enrolled under part B.

5 “(3) The Secretary shall, in consultation with mental
 6 health professionals and other stakeholders with experi-
 7 ence in screening for clinical depression, anxiety, and im-
 8 paired cognitive functioning, shall establish or identify a
 9 list of approved screenings to be used under this para-
 10 graph. The Secretary, in consultation with such profes-
 11 sionals and stakeholders, shall review and update such list
 12 not less frequently than once every 5 years.”.

13 (c) PAYMENT AND ELIMINATION OF COST-SHAR-
 14 ING.—

15 (1) PAYMENT AND ELIMINATION OF COINSUR-
 16 ANCE.—Section 1833(a)(1) of the Social Security
 17 Act (42 U.S.C. 1395l(a)(1)), as amended by section
 18 401(c)(1), is amended—

19 (A) in subparagraph (N), by striking “or
 20 substance use (other than tobacco), diet, exer-
 21 cise, injury prevention, and dental health coun-
 22 seling (as defined in section 1861(bbb))” and
 23 inserting “substance use (other than tobacco),
 24 diet, exercise, injury prevention, and dental
 25 health counseling (as defined in section

1 1861(bbb)), or screenings for clinical depres-
 2 sion, anxiety, and impaired cognitive func-
 3 tioning (as defined in section 1861(ccc))”; and

4 (B) in subparagraph (W), by inserting
 5 “and screenings for clinical depression, anxiety,
 6 and impaired cognitive functioning (as defined
 7 in section 1861(ccc))” after “(as defined in sec-
 8 tion 1861(bbb))”.

9 (2) PAYMENT UNDER PHYSICIAN FEE SCHED-
 10 ULE.—Section 1848(j)(3) of the Social Security Act
 11 (42 U.S.C. 1395w-4(j)(3)), as amended by section
 12 401(c)(2), is amended by inserting “(2)(BB),” after
 13 “(2)(AA),”.

14 (3) ELIMINATION OF COINSURANCE IN OUT-
 15 PATIENT HOSPITAL SETTINGS.—

16 (A) EXCLUSION FROM OPD FEE SCHED-
 17 ULE.—Section 1833(t)(1)(B)(iv) of the Social
 18 Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)), as
 19 amended by section 401(c)(3)(A), is amended
 20 by striking “or substance use (other than to-
 21 bacco), diet, exercise, injury prevention, and
 22 dental health counseling (as defined in section
 23 1861(bbb))” and inserting “substance use
 24 (other than tobacco), diet, exercise, injury pre-
 25 vention, and dental health counseling (as de-

1 fined in section 1861(bbb)), or screenings for
2 clinical depression, anxiety, and impaired cog-
3 nitive functioning (as defined in section
4 1861(ccc))”.

5 (B) CONFORMING AMENDMENT.—Section
6 1833(a)(2)(H) of the Social Security Act (42
7 U.S.C. 1395l(a)(2)(H)), as added by section
8 401(c)(3)(B)(iii), is amended by inserting “and
9 screenings for clinical depression, anxiety, and
10 impaired cognitive functioning (as defined in
11 section 1861(ccc))” after “(as defined in section
12 1861(bbb))”.

13 (4) ELIMINATION OF DEDUCTIBLE.—Section
14 1833(b)(7) of the Social Security Act (42 U.S.C.
15 1395l(b)(7)), as amended by section 401(c)(4), is
16 amended by inserting “or screenings for clinical de-
17 pression, anxiety, and impaired cognitive functioning
18 (as defined in section 1861(ccc))” before the period
19 at the end.

20 (d) APPLICATION OF LIMITS ON BILLING.—Section
21 1842(b)(18)(C) of the Social Security Act (42 U.S.C.
22 1395u(b)(18)(C)), as amended by section 401(d), is
23 amended by adding at the end the following new clause:
24 “(viii) A mental health care professional de-
25 scribed in section 1861(ccc)(2) that is authorized to

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

5 (e) FREQUENCY.—Section 1862(a)(1) of the Social
6 Security Act (42 U.S.C. 1395y(a)(1)), as amended by sec-
7 tion 613(c) of the Medicare Prescription Drug, Improve-
8 ment, and Modernization Act of 2003 (Public Law 108–
9 173; 117 Stat. 2306), is amended—

10 (1) in subparagraph (L), by striking “and”
11 after the comma at the end;

12 (2) in subparagraph (M), by striking the semi-
13 colon at the end and inserting “, and”; and

14 (3) by adding at the end the following new sub-
15 paragraph:

16 “(N) in the case of screenings for clinical de-
17 pression, anxiety, and impaired cognitive functioning
18 (as defined in section 1861(ccc)(1)), which is per-
19 formed more frequently than is covered under such
20 section;”.

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

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

3 **SEC. 403. ENCOURAGEMENT OF CESSATION OF TOBACCO**
 4 **USE.**

5 (a) MEDICARE COVERAGE OF COUNSELING AND
 6 PHARMACOTHERAPY FOR CESSATION OF TOBACCO
 7 USE.—

8 (1) COVERAGE.—

9 (A) IN GENERAL.—Section 1861(s)(2) of
 10 the Social Security Act (42 U.S.C.
 11 1395x(s)(2)), as amended by section 402(a)(1),
 12 is amended—

13 (i) in subparagraph (AA), by striking
 14 “and” after the semicolon at the end;

15 (ii) in subparagraph (BB), by adding
 16 “and” after the semicolon at the end; and

17 (iii) by adding at the end the fol-
 18 lowing new subparagraph:

19 “(CC) counseling and pharmacotherapy for ces-
 20 sation of tobacco use (as defined in subsection
 21 (ddd)(1));”.

22 (B) CONFORMING AMENDMENTS.—Clauses
 23 (i) and (ii) of section 1861(s)(2)(K) of the So-
 24 cial Security Act (42 U.S.C. 1395x(s)(2)(K)),
 25 as amended by section 402(a)(2), are each

7 “Counseling and Pharmacotherapy for Cessation of
8 Tobacco Use

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

20 “(B) by any other health care professional
21 who—

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

4 “(2) Such term is limited to—

5 “(A) services recommended in ‘Treating To-
 6 bacco Use and Dependence: A Clinical Practice
 7 Guideline’, published by the Public Health Service in
 8 June 2000, or any subsequent modification of such
 9 Guideline; and

10 “(B) such other services that the Secretary rec-
 11 ognizes to be effective.

12 “(3) Each individual who is described in paragraph
 13 (1) and enrolled under part B shall be eligible for the serv-
 14 ices described in this subsection for up to 3 attempts to
 15 cease the use of tobacco.”.

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

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

22 (i) in subparagraph (N) by striking
 23 “or screenings for clinical depression, anx-
 24 iety, and impaired cognitive functioning (as
 25 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 de-
fined in section 1861(ccc))” and inserting
“screenings for clinical depression, anxiety,
and impaired cognitive functioning (as de-
fined in section 1861(ccc)), or counseling
and pharmacotherapy for cessation of to-
bacco use (as defined in section
1861(ddd))”.

(ii) CONFORMING AMENDMENT.—Sec-
tion 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 de-
pression, anxiety, and impaired cognitive
functioning (as defined in section
1861(ccc))” and inserting “screenings for
clinical depression, anxiety, and impaired

1 cognitive functioning (as defined in section
2 1861(ccc)), and counseling and
3 pharmacotherapy for cessation of tobacco
4 use (as defined in section 1861(ddd))”.

5 (D) ELIMINATION OF DEDUCTIBLE.—Sec-
6 tion 1833(b)(7) of the Social Security Act (42
7 U.S.C. 1395l(b)(7)), as added by section
8 402(c)(4), is amended by striking “or
9 screenings for clinical depression, anxiety, and
10 impaired cognitive functioning (as defined in
11 section 1861(ccc))” and inserting “screenings
12 for clinical depression, anxiety, and impaired
13 cognitive functioning (as defined in section
14 1861(ccc)), or counseling and pharmacotherapy
15 for cessation of tobacco use (as defined in sec-
16 tion 1861(ddd))”.

17 (4) APPLICATION OF LIMITS ON BILLING.—Sec-
18 tion 1842(b)(18)(C) of the Social Security Act (42
19 U.S.C. 1395u(b)(18)(C)), as amended by section
20 402(d), is amended by adding at the end the fol-
21 lowing new clause:

22 “(ix) Any individual designated by the Sec-
23 retary 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”.

1 (c) COVERAGE UNDER FEHBP.—The last sentence
 2 of section 8904(a) of title 5, United States Code, is
 3 amended by striking “both for costs associated with care
 4 in a general hospital and for other health services of a
 5 catastrophic nature” and inserting “for costs associated
 6 with care in a general hospital, for other health services
 7 of a catastrophic nature, and for counseling and
 8 pharmacotherapy for cessation of tobacco use (as defined
 9 in section 1861(ddd)(1) of the Social Security Act)”.

10 (d) EFFECTIVE DATE.—The amendments made by
 11 this section shall take effect as if included in the enact-
 12 ment of the Medicare Prescription Drug, Improvement,
 13 and Modernization Act of 2003 (Public Law 108–173; 117
 14 Stat. 2066) and shall apply to services furnished on and
 15 after January 1, 2005.

16 **SEC. 404. PREVENTIVE HEALTH SERVICES FOR WOMEN.**

17 Section 1509 of the Public Health Service Act (42
 18 U.S.C. 300n–4a) is amended to read as follows:

19 **“SEC. 1509. ESTABLISHMENT OF PROGRAM FOR ADDI-**
 20 **TIONAL PREVENTIVE HEALTH SERVICES.**

21 “(a) IN GENERAL.—The Secretary, acting through
 22 the Director of the Centers for Disease Control and Pre-
 23 vention, may, through a competitive review process, award
 24 grants to States that have received grants under section

1 1501 for a fiscal year, to enable such State to carry out
2 programs—

3 “(1) to provide preventive health services, in ad-
4 dition to the services authorized in such section
5 1501, for diseases such as cardiovascular diseases,
6 osteoporosis, and obesity;

7 “(2) to provide screenings, such as screening
8 for blood pressure, cholesterol, and osteoporosis, and
9 other services that the Secretary, acting through the
10 Director of the Centers for Disease Control and Pre-
11 vention, determines to be appropriate and feasible;

12 “(3) for health education, counseling, and inter-
13 ventions for behavioral risk factors, such as physical
14 inactivity and poor nutrition, and diseases referred
15 to in paragraph (1);

16 “(4) to provide appropriate referrals for medical
17 treatment of women receiving services pursuant to
18 paragraph (1) through (3), and ensuring, to the ex-
19 tent practicable, the provision of appropriate follow-
20 up services; and

21 “(5) to evaluate the activities conducted under
22 paragraphs (1) through (4) through appropriate sur-
23 veillance, research, or program monitoring activities.

24 “(b) STATUS AS PARTICIPANT IN PROGRAM REGARD-
25 ING BREAST AND CERVICAL CANCER.—The Secretary

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

6 “(c) APPLICABILITY OF PROVISIONS.—The provi-
7 sions of this title shall apply to a grant under subsection
8 (a) to the same extent and in the same manner as such
9 provisions apply to a grant under section 1501.

10 “(d) FUNDING.—

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

15 “(2) LIMITATION REGARDING FUNDING WITH
16 RESPECT TO BREAST AND CERVICAL CANCER.—No
17 additional resources shall be appropriated for a fis-
18 cal year under paragraph (1) unless the amount ap-
19 propriated under section 1510(a) for such fiscal year
20 is at least \$173,920,000.”.

1 **TITLE V—HELP (HEALTHY LIFE-**
2 **STYLES AND PREVENTION)**
3 **AMERICA TRUST FUND**

4 **SEC. 501. HELP (HEALTHY LIFESTYLES AND PREVENTION)**
5 **AMERICA TRUST FUND.**

6 (a) CREATION OF TRUST FUND.—There is estab-
7 lished in the Treasury of the United States a trust fund
8 to be known as the ‘HeLP (Healthy Lifestyles and Preven-
9 tion) America Trust Fund’ (referred to in this section as
10 the ‘Trust Fund’), consisting of such amounts as may be
11 appropriated or credited to the Trust Fund as provided
12 in this section.

13 (b) TRANSFERS TO TRUST FUND.—There is hereby
14 appropriated to the Trust Fund an amount equivalent
15 to—

16 (1) the increase in revenues received in the
17 Treasury as the result of the amendment made by
18 section 304 of this Act,

19 (2) the increase in revenues received in the
20 Treasury as the result of the amendments made by
21 title VII of this Act, and

22 (3) the receipts paid by tobacco companies
23 under subtitle B of title III of this Act.

24 (c) DISTRIBUTION OF AMOUNTS IN TRUST FUND.—

1 (1) MANDATORY EXPENDITURES.—On a fiscal
2 year basis (beginning with fiscal year 2005) and
3 without further appropriation the Secretary of the
4 Treasury shall distribute from amounts in the Trust
5 Fund such amounts as are necessary to provide for
6 the Federal expenditures attributable to the fol-
7 lowing:

8 (A) Smoking cessation drugs under title
9 XIX of the Social Security Act as identified by
10 the Secretary of Health and Human Services.

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

14 (C) The amendments made to the medi-
15 care program under title XVIII of the Social
16 Security Act by sections 401 and 402 of this
17 Act.

18 Such amounts shall be in addition to any other
19 amounts appropriated for such purposes.

20 (2) DISCRETIONARY EXPENDITURES.—Amounts
21 in the Trust Fund not to exceed \$1,600,000,000
22 shall be available, as provided in appropriation Acts,
23 for each fiscal year (beginning with fiscal year 2005)
24 only for purposes of making expenditures to carry
25 out the following:

1 (A) Fruit and vegetable program under
2 section 18(g) of the Richard B. Russell Na-
3 tional School Lunch Act.

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

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

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

13 (E) Community grants to prevent and re-
14 duce the incidence of chronic disease under sec-
15 tion 399P of the Public Health Service Act.

16 (F) Living well with a disability and work-
17 ing well with a disability programs under sec-
18 tions 399Q and 399R of the Public Health
19 Service Act.

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

23 (H) Mental health surveillance measures
24 under section 506C of the Public Health Serv-
25 ice Act.

1 (I) Federal-State tobacco counter-adver-
2 tising programs under section 399S of the Pub-
3 lic Health Service Act.

4 (J) Preventive health services for women,
5 including well-integrated screening and evalua-
6 tion for women across the Nation, under section
7 1509 of the Public Health Service Act.

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

12 (L) Research regarding obesity under sec-
13 tion 601 of this Act.

14 (M) Expanded Food and Nutrition Edu-
15 cation Program under section 3175 of title 23,
16 United States Code.

17 (N) The following programs under the au-
18 thority of the Secretary of Health and Human
19 Services through the Centers for Disease Con-
20 trol and Prevention:

21 (i) Nutrition and physical activity
22 grants.

23 (ii) Coordinated school health.

24 (iii) Verb Campaign.

25 (iv) Prevention research centers.

1 (v) 5-a-day programs.

2 (vi) Steps to a healthier United
3 States.

4 (d) APPLICATION OF CERTAIN RULES.—For pur-
5 poses of this section, rules similar to the rules of sections
6 9601 and 9602 of the Internal Revenue Code of 1986 shall
7 apply.

8 **TITLE VI—RESEARCH**

9 **SEC. 601. EXPANSION OF RESEARCH REGARDING OBESITY.**

10 The Secretary of Health and Human Services shall,
11 based on the conclusions of the United States Preventive
12 Services Task Force on Obesity, conduct research on obe-
13 sity prevention, treatment, and control with regard to the
14 following:

15 (1) The effectiveness of physical activity and di-
16 etary counseling with children and adolescents in the
17 primary care setting to prevent, treat, and control
18 obesity.

19 (2) The cost-effectiveness of intensive dietary
20 and physical activity counseling to prevent, treat,
21 and control obesity in a variety of populations.

22 (3) The effectiveness of dietary and physical ac-
23 tivity counseling among children and adolescents,
24 low income populations, and minority groups in the

1 primary care setting to prevent, treat, and control
 2 obesity.

3 (4) The effectiveness of the assessment of obe-
 4 sity by a primary care physician and subsequent re-
 5 ferral for obesity counseling to a nonaffiliated obe-
 6 sity expert or specialist.

7 **TITLE VII—PROVISIONS DE-**
 8 **SIGNED TO CURTAIL TAX**
 9 **SHELTERS**

10 **SEC. 700. AMENDMENT OF 1986 CODE.**

11 Except as otherwise expressly provided, whenever in
 12 this title an amendment or repeal is expressed in terms
 13 of an amendment to, or repeal of, a section or other provi-
 14 sion, the reference shall be considered to be made to a
 15 section or other provision of the Internal Revenue Code
 16 of 1986.

17 **SEC. 701. CLARIFICATION OF ECONOMIC SUBSTANCE DOC-**
 18 **TRINE.**

19 (a) IN GENERAL.—Section 7701 is amended by re-
 20 designating subsection (n) as subsection (o) and by insert-
 21 ing after subsection (m) the following new subsection:

22 “(n) CLARIFICATION OF ECONOMIC SUBSTANCE
 23 DOCTRINE; ETC.—

24 “(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

1 such financial accounting benefit is a re-
2 duction of income tax.

3 “(ii) SPECIAL RULE WHERE TAX-
4 PAYER RELIES ON PROFIT POTENTIAL.—A
5 transaction shall not be treated as having
6 economic substance by reason of having a
7 potential for profit unless—

8 “(I) the present value of the rea-
9 sonably expected pre-tax profit from
10 the transaction is substantial in rela-
11 tion to the present value of the ex-
12 pected net tax benefits that would be
13 allowed if the transaction were re-
14 spected, and

15 “(II) the reasonably expected
16 pre-tax profit from the transaction ex-
17 ceeds a risk-free rate of return.

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

23 “(2) SPECIAL RULES FOR TRANSACTIONS WITH
24 TAX-INDIFFERENT PARTIES.—

1 “(A) SPECIAL RULES FOR FINANCING
2 TRANSACTIONS.—The form of a transaction
3 which is in substance the borrowing of money
4 or the acquisition of financial capital directly or
5 indirectly from a tax-indifferent party shall not
6 be respected if the present value of the deduc-
7 tions to be claimed with respect to the trans-
8 action is substantially in excess of the present
9 value of the anticipated economic returns of the
10 person lending the money or providing the fi-
11 nancial capital. A public offering shall be treat-
12 ed as a borrowing, or an acquisition of financial
13 capital, from a tax-indifferent party if it is rea-
14 sonably expected that at least 50 percent of the
15 offering will be placed with tax-indifferent par-
16 ties.

17 “(B) ARTIFICIAL INCOME SHIFTING AND
18 BASIS ADJUSTMENTS.—The form of a trans-
19 action with a tax-indifferent party shall not be
20 respected if—

21 “(i) it results in an allocation of in-
22 come or gain to the tax-indifferent party in
23 excess of such party’s economic income or
24 gain, or

1 “(ii) it results in a basis adjustment
 2 or shifting of basis on account of over-
 3 stating the income or gain of the tax-indif-
 4 ferent party.

5 “(3) DEFINITIONS AND SPECIAL RULES.—For
 6 purposes of this subsection—

7 “(A) ECONOMIC SUBSTANCE DOCTRINE.—
 8 The term ‘economic substance doctrine’ means
 9 the common law doctrine under which tax bene-
 10 fits under subtitle A with respect to a trans-
 11 action are not allowable if the transaction does
 12 not have economic substance or lacks a business
 13 purpose.

14 “(B) TAX-INDIFFERENT PARTY.—The
 15 term ‘tax-indifferent party’ means any person
 16 or entity not subject to tax imposed by subtitle
 17 A. A person shall be treated as a tax-indifferent
 18 party with respect to a transaction if the items
 19 taken into account with respect to the trans-
 20 action have no substantial impact on such per-
 21 son’s liability under subtitle A.

22 “(C) EXCEPTION FOR PERSONAL TRANS-
 23 ACTIONS OF INDIVIDUALS.—In the case of an
 24 individual, this subsection shall apply only to
 25 transactions entered into in connection with a

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

3 “(D) TREATMENT OF LESSORS.—In apply-
4 ing paragraph (1)(B)(ii) to the lessor of tan-
5 gible property subject to a lease, the expected
6 net tax benefits with respect to the leased prop-
7 erty shall not be taken into account.

8 “(4) OTHER COMMON LAW DOCTRINES NOT AF-
9 FECTED.—Except as specifically provided in this
10 subsection, the provisions of this subsection shall not
11 be construed as altering or supplanting any other
12 rule of law, and the requirements of this subsection
13 shall be construed as being in addition to any such
14 other rule of law.

15 “(5) REGULATIONS.—The Secretary shall pre-
16 scribe such regulations as may be necessary or ap-
17 propriate to carry out the purposes of this sub-
18 section. Such regulations may include exemptions
19 from the application of this subsection.”.

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

1 **SEC. 702. PENALTY FOR FAILING TO DISCLOSE REPORT-**
2 **ABLE TRANSACTION.**

3 (a) IN GENERAL.—Part I of subchapter B of chapter
4 68 (relating to assessable penalties) is amended by insert-
5 ing after section 6707 the following new section:

6 **“SEC. 6707A. PENALTY FOR FAILURE TO INCLUDE REPORT-**
7 **ABLE TRANSACTION INFORMATION WITH RE-**
8 **TURN OR STATEMENT.**

9 “(a) IMPOSITION OF PENALTY.—Any person who
10 fails to include on any return or statement any informa-
11 tion with respect to a reportable transaction which is re-
12 quired under section 6011 to be included with such return
13 or statement shall pay a penalty in the amount determined
14 under subsection (b).

15 “(b) AMOUNT OF PENALTY.—

16 “(1) IN GENERAL.—Except as provided in para-
17 graphs (2) and (3), the amount of the penalty under
18 subsection (a) shall be \$50,000.

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

22 “(3) INCREASE IN PENALTY FOR LARGE ENTI-
23 TIES AND HIGH NET WORTH INDIVIDUALS.—

24 “(A) IN GENERAL.—In the case of a fail-
25 ure under subsection (a) by—

26 “(i) a large entity, or

1 “(ii) a high net worth individual,
2 the penalty under paragraph (1) or (2) shall be
3 twice the amount determined without regard to
4 this paragraph.

5 “(B) LARGE ENTITY.—For purposes of
6 subparagraph (A), the term ‘large entity’
7 means, with respect to any taxable year, a per-
8 son (other than a natural person) with gross re-
9 ceipts in excess of \$10,000,000 for the taxable
10 year in which the reportable transaction occurs
11 or the preceding taxable year. Rules similar to
12 the rules of paragraph (2) and subparagraphs
13 (B), (C), and (D) of paragraph (3) of section
14 448(c) shall apply for purposes of this subpara-
15 graph.

16 “(C) HIGH NET WORTH INDIVIDUAL.—For
17 purposes of subparagraph (A), the term ‘high
18 net worth individual’ means, with respect to a
19 reportable transaction, a natural person whose
20 net worth exceeds \$2,000,000 immediately be-
21 fore the transaction.

22 “(c) DEFINITIONS.—For purposes of this section—

23 “(1) REPORTABLE TRANSACTION.—The term
24 ‘reportable transaction’ means any transaction with
25 respect to which information is required to be in-

1 cluded with a return or statement because, as deter-
2 mined under regulations prescribed under section
3 6011, such transaction is of a type which the Sec-
4 retary determines as having a potential for tax
5 avoidance or evasion.

6 “(2) LISTED TRANSACTION.—Except as pro-
7 vided in regulations, the term ‘listed transaction’
8 means a reportable transaction which is the same as,
9 or substantially similar to, a transaction specifically
10 identified by the Secretary as a tax avoidance trans-
11 action for purposes of section 6011.

12 “(d) AUTHORITY TO RESCIND PENALTY.—

13 “(1) IN GENERAL.—The Commissioner of In-
14 ternal Revenue may rescind all or any portion of any
15 penalty imposed by this section with respect to any
16 violation if—

17 “(A) the violation is with respect to a re-
18 portable transaction other than a listed trans-
19 action,

20 “(B) the person on whom the penalty is
21 imposed has a history of complying with the re-
22 quirements of this title,

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

1 “(D) imposing the penalty would be
2 against equity and good conscience, and

3 “(E) rescinding the penalty would promote
4 compliance with the requirements of this title
5 and effective tax administration.

6 “(2) DISCRETION.—The exercise of authority
7 under paragraph (1) shall be at the sole discretion
8 of the Commissioner and may be delegated only to
9 the head of the Office of Tax Shelter Analysis. The
10 Commissioner, in the Commissioner’s sole discretion,
11 may establish a procedure to determine if a penalty
12 should be referred to the Commissioner or the head
13 of such Office for a determination under paragraph
14 (1).

15 “(3) NO APPEAL.—Notwithstanding any other
16 provision of law, any determination under this sub-
17 section may not be reviewed in any administrative or
18 judicial proceeding.

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

1 “(A) the facts and circumstances of the
2 transaction,

3 “(B) the reasons for the rescission, and

4 “(C) the amount of the penalty rescinded.

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

9 “(A) a summary of the total number and
10 aggregate amount of penalties imposed, and re-
11 scinded, under this section, and

12 “(B) a description of each penalty re-
13 scinded under this subsection and the reasons
14 therefor.

15 “(e) PENALTY REPORTED TO SEC.—In the case of
16 a person—

17 “(1) which is required to file periodic reports
18 under section 13 or 15(d) of the Securities Ex-
19 change Act of 1934 or is required to be consolidated
20 with another person for purposes of such reports,
21 and

22 “(2) which—

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

1 “(B) is required to pay a penalty under
 2 section 6662A with respect to any reportable
 3 transaction at a rate prescribed under section
 4 6662A(c), or

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

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

14 “(f) COORDINATION WITH OTHER PENALTIES.—The
 15 penalty imposed by this section is in addition to any pen-
 16 alty imposed under this title.”.

17 (b) DISCLOSURE BY SECRETARY.—

18 (1) IN GENERAL.—Section 6103 is amended by
 19 redesignating subsection (q) as subsection (r) and by
 20 inserting after subsection (p) the following new sub-
 21 section:

22 “(q) DISCLOSURE RELATING TO PAYMENTS OF CER-
 23 TAIN PENALTIES.—Notwithstanding any other provision
 24 of this section, the Secretary shall make public the name

1 of any person required to pay a penalty described in sec-
 2 tion 6707A(e)(2) and the amount of the penalty.”.

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

6 (c) CONFORMING AMENDMENT.—The table of sec-
 7 tions for part I of subchapter B of chapter 68 is amended
 8 by inserting after the item relating to section 6707 the
 9 following:

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

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

14 **SEC. 703. ACCURACY-RELATED PENALTY FOR LISTED**
 15 **TRANSACTIONS AND OTHER REPORTABLE**
 16 **TRANSACTIONS HAVING A SIGNIFICANT TAX**
 17 **AVOIDANCE PURPOSE.**

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

1 **“SEC. 6662A. IMPOSITION OF ACCURACY-RELATED PEN-**
 2 **ALTY ON UNDERSTATEMENTS WITH RESPECT**
 3 **TO REPORTABLE TRANSACTIONS.**

4 “(a) IMPOSITION OF PENALTY.—If a taxpayer has a
 5 reportable transaction understatement for any taxable
 6 year, there shall be added to the tax an amount equal to
 7 20 percent of the amount of such understatement.

8 “(b) REPORTABLE TRANSACTION UNDERSTATE-
 9 MENT.—For purposes of this section—

10 “(1) IN GENERAL.—The term ‘reportable trans-
 11 action understatement’ means the sum of—

12 “(A) the product of—

13 “(i) the amount of the increase (if
 14 any) in taxable income which results from
 15 a difference between the proper tax treat-
 16 ment of an item to which this section ap-
 17 plies and the taxpayer’s treatment of such
 18 item (as shown on the taxpayer’s return of
 19 tax), and

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

23 “(B) the amount of the decrease (if any)
 24 in the aggregate amount of credits determined
 25 under subtitle A which results from a difference
 26 between the taxpayer’s treatment of an item to

1 which this section applies (as shown on the tax-
 2 payer's return of tax) and the proper tax treat-
 3 ment of such item.

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

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

13 “(A) any listed transaction, and

14 “(B) any reportable transaction (other
 15 than a listed transaction) if a significant pur-
 16 pose of such transaction is the avoidance or
 17 evasion of Federal income tax.

18 “(c) HIGHER PENALTY FOR NONDISCLOSED LISTED
 19 AND OTHER AVOIDANCE TRANSACTIONS.—

20 “(1) IN GENERAL.—Subsection (a) shall be ap-
 21 plied by substituting ‘30 percent’ for ‘20 percent’
 22 with respect to the portion of any reportable trans-
 23 action understatement with respect to which the re-
 24 quirement of section 6664(d)(2)(A) is not met.

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

3 “(A) IN GENERAL.—Only upon the ap-
4 proval by the Chief Counsel for the Internal
5 Revenue Service or the Chief Counsel’s delegate
6 at the national office of the Internal Revenue
7 Service may a penalty to which paragraph (1)
8 applies be included in a 1st letter of proposed
9 deficiency which allows the taxpayer an oppor-
10 tunity for administrative review in the Internal
11 Revenue Service Office of Appeals. If such a
12 letter is provided to the taxpayer, only the Com-
13 missioner of Internal Revenue may compromise
14 all or any portion of such penalty.

15 “(B) APPLICABLE RULES.—The rules of
16 paragraphs (2), (3), (4), and (5) of section
17 6707A(d) shall apply for purposes of subpara-
18 graph (A).

19 “(d) DEFINITIONS OF REPORTABLE AND LISTED
20 TRANSACTIONS.—For purposes of this section, the terms
21 ‘reportable transaction’ and ‘listed transaction’ have the
22 respective meanings given to such terms by section
23 6707A(c).

24 “(e) SPECIAL RULES.—

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

4 “(A) the amount of such understatement
 5 (determined without regard to this paragraph)
 6 shall be increased by the aggregate amount of
 7 reportable transaction understatements and
 8 noneconomic substance transaction understate-
 9 ments for purposes of determining whether
 10 such understatement is a substantial under-
 11 statement under section 6662(d)(1), and

12 “(B) the addition to tax under section
 13 6662(a) shall apply only to the excess of the
 14 amount of the substantial understatement (if
 15 any) after the application of subparagraph (A)
 16 over the aggregate amount of reportable trans-
 17 action understatements and noneconomic sub-
 18 stance transaction understatements.

19 “(2) COORDINATION WITH OTHER PEN-
 20 ALTIES.—

21 “(A) APPLICATION OF FRAUD PENALTY.—
 22 References to an underpayment in section 6663
 23 shall be treated as including references to a re-
 24 portable transaction understatement and a non-
 25 economic substance transaction understatement.

1 “(B) NO DOUBLE PENALTY.—This section
2 shall not apply to any portion of an understate-
3 ment on which a penalty is imposed under sec-
4 tion 6662B or 6663.

5 “(3) SPECIAL RULE FOR AMENDED RE-
6 TURNS.—Except as provided in regulations, in no
7 event shall any tax treatment included with an
8 amendment or supplement to a return of tax be
9 taken into account in determining the amount of any
10 reportable transaction understatement or non-
11 economic substance transaction understatement if
12 the amendment or supplement is filed after the ear-
13 lier of the date the taxpayer is first contacted by the
14 Secretary regarding the examination of the return or
15 such other date as is specified by the Secretary.

16 “(4) NONECONOMIC SUBSTANCE TRANSACTION
17 UNDERSTATEMENT.—For purposes of this sub-
18 section, the term ‘noneconomic substance trans-
19 action understatement’ has the meaning given such
20 term by section 6662B(c).

21 “(5) CROSS REFERENCE.—

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

22 (b) DETERMINATION OF OTHER UNDERSTATE-
23 MENTS.—Subparagraph (A) of section 6662(d)(2) is

1 amended by adding at the end the following flush sen-
 2 tence:

3 “The excess under the preceding sentence shall
 4 be determined without regard to items to which
 5 section 6662A applies and without regard to
 6 items with respect to which a penalty is im-
 7 posed by section 6662B.”.

8 (c) REASONABLE CAUSE EXCEPTION.—

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

11 “(d) REASONABLE CAUSE EXCEPTION FOR REPORT-
 12 ABLE TRANSACTION UNDERSTATEMENTS.—

13 “(1) IN GENERAL.—No penalty shall be im-
 14 posed under section 6662A with respect to any por-
 15 tion of a reportable transaction understatement if it
 16 is shown that there was a reasonable cause for such
 17 portion and that the taxpayer acted in good faith
 18 with respect to such portion.

19 “(2) SPECIAL RULES.—Paragraph (1) shall not
 20 apply to any reportable transaction understatement
 21 unless—

22 “(A) the relevant facts affecting the tax
 23 treatment of the item are adequately disclosed
 24 in accordance with the regulations prescribed
 25 under section 6011,

1 “(B) there is or was substantial authority
2 for such treatment, and

3 “(C) the taxpayer reasonably believed that
4 such treatment was more likely than not the
5 proper treatment.

6 A taxpayer failing to adequately disclose in accord-
7 ance with section 6011 shall be treated as meeting
8 the requirements of subparagraph (A) if the penalty
9 for such failure was rescinded under section
10 6707A(d).

11 “(3) RULES RELATING TO REASONABLE BE-
12 LIEF.—For purposes of paragraph (2)(C)—

13 “(A) IN GENERAL.—A taxpayer shall be
14 treated as having a reasonable belief with re-
15 spect to the tax treatment of an item only if
16 such belief—

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

20 “(ii) relates solely to the taxpayer’s
21 chances of success on the merits of such
22 treatment and does not take into account
23 the possibility that a return will not be au-
24 dited, such treatment will not be raised on

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

3 “(B) CERTAIN OPINIONS MAY NOT BE RE-
4 LIED UPON.—

5 “(i) IN GENERAL.—An opinion of a
6 tax advisor may not be relied upon to es-
7 tablish the reasonable belief of a taxpayer
8 if—

9 “(I) the tax advisor is described
10 in clause (ii), or

11 “(II) the opinion is described in
12 clause (iii).

13 “(ii) DISQUALIFIED TAX ADVISORS.—
14 A tax advisor is described in this clause if
15 the tax advisor—

16 “(I) is a material advisor (within
17 the meaning of section 6111(b)(1))
18 who participates in the organization,
19 management, promotion, or sale of
20 the transaction or who is related
21 (within the meaning of section 267(b)
22 or 707(b)(1)) to any person who so
23 participates,

1 “(II) is compensated directly or
2 indirectly by a material advisor with
3 respect to the transaction,

4 “(III) has a fee arrangement
5 with respect to the transaction which
6 is contingent on all or part of the in-
7 tended tax benefits from the trans-
8 action being sustained,

9 “(IV) has an arrangement with
10 respect to the transaction which pro-
11 vides that contractual disputes be-
12 tween the taxpayer and the advisor
13 are to be settled by arbitration or
14 which limits damages by reference to
15 fees paid to the advisor for such
16 transaction, or

17 “(V) as determined under regula-
18 tions prescribed by the Secretary, has
19 a disqualifying financial interest with
20 respect to the transaction.

21 “(iii) DISQUALIFIED OPINIONS.—For
22 purposes of clause (i), an opinion is dis-
23 qualified if the opinion—

1 “(I) is based on unreasonable
2 factual or legal assumptions (includ-
3 ing assumptions as to future events),

4 “(II) unreasonably relies on rep-
5 resentations, statements, findings, or
6 agreements of the taxpayer or any
7 other person,

8 “(III) does not identify and con-
9 sider all relevant facts,

10 “(IV) is not signed by all individ-
11 uals who are principal authors of the
12 opinion, or

13 “(V) fails to meet any other re-
14 quirement as the Secretary may pre-
15 scribe.”.

16 (2) CONFORMING AMENDMENT.—The heading
17 for subsection (c) of section 6664 is amended by in-
18 serting “FOR UNDERPAYMENTS” after “EXCEP-
19 TION”.

20 (d) CONFORMING AMENDMENTS.—

21 (1) Subparagraph (C) of section 461(i)(3) is
22 amended by striking “section 6662(d)(2)(C)(iii)”
23 and inserting “section 1274(b)(3)(C)”.

24 (2) Paragraph (3) of section 1274(b) is amend-
25 ed—

1 (A) by striking “(as defined in section
 2 6662(d)(2)(C)(iii))” in subparagraph (B)(i),
 3 and

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

6 “(C) TAX SHELTER.—For purposes of sub-
 7 paragraph (B), the term ‘tax shelter’ means—

8 “(i) a partnership or other entity,

9 “(ii) any investment plan or arrange-
 10 ment, or

11 “(iii) any other plan or arrangement,
 12 if a significant purpose of such partnership, en-
 13 tity, plan, or arrangement is the avoidance or
 14 evasion of Federal income tax.”.

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

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

19 (5) Subsection (b) of section 7525 is amended
 20 by striking “section 6662(d)(2)(C)(iii)” and insert-
 21 ing “section 1274(b)(3)(C)”.

22 (6)(A) The heading for section 6662 is amend-
 23 ed to read as follows:

1 **“SEC. 6662. IMPOSITION OF ACCURACY-RELATED PENALTY**
 2 **ON UNDERPAYMENTS.”.**

3 (B) The table of sections for part II of sub-
 4 chapter A of chapter 68 is amended by striking the
 5 item relating to section 6662 and inserting the fol-
 6 lowing new items:

“Sec. 6662. Imposition of accuracy-related penalty on underpay-
 ments.

“Sec. 6662A. Imposition of accuracy-related penalty on under-
 statements with respect to reportable trans-
 actions.”.

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

10 **SEC. 704. PENALTY FOR UNDERSTATEMENTS ATTRIB-**
 11 **UTABLE TO TRANSACTIONS LACKING ECO-**
 12 **NOMIC SUBSTANCE, ETC.**

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

16 **“SEC. 6662B. PENALTY FOR UNDERSTATEMENTS ATTRIB-**
 17 **UTABLE TO TRANSACTIONS LACKING ECO-**
 18 **NOMIC SUBSTANCE, ETC.**

19 “(a) IMPOSITION OF PENALTY.—If a taxpayer has an
 20 noneconomic substance transaction understatement for
 21 any taxable year, there shall be added to the tax an
 22 amount equal to 40 percent of the amount of such under-
 23 statement.

1 “(b) REDUCTION OF PENALTY FOR DISCLOSED
 2 TRANSACTIONS.—Subsection (a) shall be applied by sub-
 3 stituting ‘20 percent’ for ‘40 percent’ with respect to the
 4 portion of any noneconomic substance transaction under-
 5 statement with respect to which the relevant facts affect-
 6 ing the tax treatment of the item are adequately disclosed
 7 in the return or a statement attached to the return.

8 “(c) NONECONOMIC SUBSTANCE TRANSACTION UN-
 9 DERSTATEMENT.—For purposes of this section—

10 “(1) IN GENERAL.—The term ‘noneconomic
 11 substance transaction understatement’ means any
 12 amount which would be an understatement under
 13 section 6662A(b)(1) if section 6662A were applied
 14 by taking into account items attributable to non-
 15 economic substance transactions rather than items
 16 to which section 6662A would apply without regard
 17 to this paragraph.

18 “(2) NONECONOMIC SUBSTANCE TRANS-
 19 ACTION.—The term ‘noneconomic substance trans-
 20 action’ means any transaction if—

21 “(A) there is a lack of economic substance
 22 (within the meaning of section 7701(n)(1)) for
 23 the transaction giving rise to the claimed ben-
 24 efit or the transaction was not respected under
 25 section 7701(n)(2), or

1 “(B) the transaction fails to meet the re-
2 quirements of any similar rule of law.

3 “(d) RULES APPLICABLE TO COMPROMISE OF PEN-
4 ALTY.—

5 “(1) IN GENERAL.—If the 1st letter of pro-
6 posed deficiency which allows the taxpayer an oppor-
7 tunity for administrative review in the Internal Rev-
8 enue Service Office of Appeals has been sent with
9 respect to a penalty to which this section applies,
10 only the Commissioner of Internal Revenue may
11 compromise all or any portion of such penalty.

12 “(2) APPLICABLE RULES.—The rules of para-
13 graphs (2), (3), (4), and (5) of section 6707A(d)
14 shall apply for purposes of paragraph (1).

15 “(e) COORDINATION WITH OTHER PENALTIES.—Ex-
16 cept as otherwise provided in this part, the penalty im-
17 posed by this section shall be in addition to any other pen-
18 alty imposed by this title.

19 “(f) CROSS REFERENCES.—

“**(1) For coordination of penalty with understatement-
ments 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).”.**

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

1 inserting after the item relating to section 6662A the fol-
 2 lowing new item:

“Sec. 6662B. Penalty for understatements attributable to trans-
 actions lacking economic substance, etc.”.

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

6 **SEC. 705. MODIFICATIONS OF SUBSTANTIAL UNDERSTATE-**
 7 **MENT PENALTY FOR NONREPORTABLE**
 8 **TRANSACTIONS.**

9 (a) SUBSTANTIAL UNDERSTATEMENT OF CORPORA-
 10 TIONS.—Section 6662(d)(1)(B) (relating to special rule
 11 for corporations) is amended to read as follows:

12 “(B) SPECIAL RULE FOR CORPORA-
 13 TIONS.—In the case of a corporation other than
 14 an S corporation or a personal holding company
 15 (as defined in section 542), there is a substan-
 16 tial understatement of income tax for any tax-
 17 able year if the amount of the understatement
 18 for the taxable year exceeds the lesser of—

19 “(i) 10 percent of the tax required to
 20 be shown on the return for the taxable
 21 year (or, if greater, \$10,000), or

22 “(ii) \$10,000,000.”.

1 (b) REDUCTION FOR UNDERSTATEMENT OF TAX-
2 PAYER DUE TO POSITION OF TAXPAYER OR DISCLOSED
3 ITEM.—

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

7 “(i) the tax treatment of any item by
8 the taxpayer if the taxpayer had reason-
9 able belief that the tax treatment was more
10 likely than not the proper treatment, or”.

11 (2) CONFORMING AMENDMENT.—Section
12 6662(d) is amended by adding at the end the fol-
13 lowing new paragraph:

14 “(3) SECRETARIAL LIST.—For purposes of this
15 subsection, section 6664(d)(2), and section
16 6694(a)(1), the Secretary may prescribe a list of po-
17 sitions for which the Secretary believes there is not
18 substantial authority or there is no reasonable belief
19 that the tax treatment is more likely than not the
20 proper tax treatment. Such list (and any revisions
21 thereof) shall be published in the Federal Register
22 or the Internal Revenue Bulletin.”.

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

1 **SEC. 706. TAX SHELTER EXCEPTION TO CONFIDENTIALITY**
2 **PRIVILEGES RELATING TO TAXPAYER COM-**
3 **MUNICATIONS.**

4 (a) IN GENERAL.—Section 7525(b) (relating to sec-
5 tion not to apply to communications regarding corporate
6 tax shelters) is amended to read as follows:

7 “(b) SECTION NOT TO APPLY TO COMMUNICATIONS
8 REGARDING TAX SHELTERS.—The privilege under sub-
9 section (a) shall not apply to any written communication
10 which is—

11 “(1) between a federally authorized tax practi-
12 tioner and—

13 “(A) any person,

14 “(B) any director, officer, employee, agent,
15 or representative of the person, or

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

18 “(2) in connection with the promotion of the di-
19 rect or indirect participation of the person in any
20 tax shelter (as defined in section 1274(b)(3)(C)).”.

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

24 **SEC. 707. DISCLOSURE OF REPORTABLE TRANSACTIONS.**

25 (a) IN GENERAL.—Section 6111 (relating to registra-
26 tion of tax shelters) is amended to read as follows:

1 **“SEC. 6111. DISCLOSURE OF REPORTABLE TRANSACTIONS.**

2 “(a) IN GENERAL.—Each material advisor with re-
3 spect to any reportable transaction shall make a return
4 (in such form as the Secretary may prescribe) setting
5 forth—

6 “(1) information identifying and describing the
7 transaction,

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

10 “(3) such other information as the Secretary
11 may prescribe.

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

14 “(b) DEFINITIONS.—For purposes of this section—

15 “(1) MATERIAL ADVISOR.—

16 “(A) IN GENERAL.—The term ‘material
17 advisor’ means any person—

18 “(i) who provides any material aid,
19 assistance, or advice with respect to orga-
20 nizing, managing, promoting, selling, im-
21 plementing, insuring, or carrying out any
22 reportable transaction, and

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

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

3 “(i) \$50,000 in the case of a report-
4 able transaction substantially all of the tax
5 benefits from which are provided to nat-
6 ural persons, and

7 “(ii) \$250,000 in any other case.

8 “(2) REPORTABLE TRANSACTION.—The term
9 ‘reportable transaction’ has the meaning given to
10 such term by section 6707A(c).

11 “(c) REGULATIONS.—The Secretary may prescribe
12 regulations which provide—

13 “(1) that only 1 person shall be required to
14 meet the requirements of subsection (a) in cases in
15 which 2 or more persons would otherwise be re-
16 quired to meet such requirements,

17 “(2) exemptions from the requirements of this
18 section, and

19 “(3) such rules as may be necessary or appro-
20 priate to carry out the purposes of this section.”.

21 (b) CONFORMING AMENDMENTS.—

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

 “Sec. 6111. Disclosure of reportable transactions.”.

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

3 **“SEC. 6112. MATERIAL ADVISORS OF REPORTABLE TRANS-**
4 **ACTIONS MUST KEEP LISTS OF ADVISEES.**

5 “(a) IN GENERAL.—Each material advisor (as de-
6 fined in section 6111) with respect to any reportable
7 transaction (as defined in section 6707A(c)) shall main-
8 tain, in such manner as the Secretary may by regulations
9 prescribe, a list—

10 “(1) identifying each person with respect to
11 whom such advisor acted as such a material advisor
12 with respect to such transaction, and

13 “(2) containing such other information as the
14 Secretary may by regulations require.

15 This section shall apply without regard to whether a mate-
16 rial advisor is required to file a return under section 6111
17 with respect to such transaction.”.

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

20 (C) Section 6112(b), as redesignated by sub-
21 paragraph (B), is amended—

22 (i) by inserting “written” before “request”
23 in paragraph (1)(A), and

24 (ii) by striking “shall prescribe” in para-
25 graph (2) and inserting “may prescribe”.

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

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

4 (3)(A) The heading for section 6708 is amend-
 5 ed to read as follows:

6 **“SEC. 6708. FAILURE TO MAINTAIN LISTS OF ADVISEES**
 7 **WITH RESPECT TO REPORTABLE TRANS-**
 8 **ACTIONS.”.**

9 (B) The item relating to section 6708 in the
 10 table of sections for part I of subchapter B of chap-
 11 ter 68 is amended to read as follows:

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

12 (c) REQUIRED DISCLOSURE NOT SUBJECT TO CLAIM
 13 OF CONFIDENTIALITY.—Subparagraph (A) of section
 14 6112(b)(1), as redesignated by subsection (b)(2)(B), is
 15 amended by adding at the end the following new flush sen-
 16 tence:

17 “For purposes of this section, the identity of any
 18 person on such list shall not be privileged.”.

19 (d) EFFECTIVE DATE.—

20 (1) IN GENERAL.—Except as provided in para-
 21 graph (2), the amendments made by this section
 22 shall apply to transactions with respect to which ma-
 23 terial aid, assistance, or advice referred to in section

1 6111(b)(1)(A)(i) of the Internal Revenue Code of
2 1986 (as added by this section) is provided after the
3 date of the enactment of this Act.

4 (2) NO CLAIM OF CONFIDENTIALITY AGAINST
5 DISCLOSURE.—The amendment made by subsection
6 (c) shall take effect as if included in the amend-
7 ments made by section 142 of the Deficit Reduction
8 Act of 1984.

9 **SEC. 708. MODIFICATIONS TO PENALTY FOR FAILURE TO**
10 **REGISTER TAX SHELTERS.**

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

14 **“SEC. 6707. FAILURE TO FURNISH INFORMATION REGARD-**
15 **ING REPORTABLE TRANSACTIONS.**

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

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

21 “(2) files false or incomplete information with
22 the Secretary with respect to such transaction,
23 such person shall pay a penalty with respect to such return
24 in the amount determined under subsection (b).

25 “(b) AMOUNT OF PENALTY.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), the penalty imposed under subsection (a)
3 with respect to any failure shall be \$50,000.

4 “(2) LISTED TRANSACTIONS.—The penalty im-
5 posed under subsection (a) with respect to any listed
6 transaction shall be an amount equal to the greater
7 of—

8 “(A) \$200,000, or

9 “(B) 50 percent of the gross income de-
10 rived by such person with respect to aid, assist-
11 ance, or advice which is provided with respect
12 to the listed transaction before the date the re-
13 turn including the transaction is filed under
14 section 6111.

15 Subparagraph (B) shall be applied by substituting
16 ‘75 percent’ for ‘50 percent’ in the case of an inten-
17 tional failure or act described in subsection (a).

18 “(c) CERTAIN RULES TO APPLY.—The provisions of
19 section 6707A(d) shall apply to any penalty imposed under
20 this section.

21 “(d) REPORTABLE AND LISTED TRANSACTIONS.—
22 The terms ‘reportable transaction’ and ‘listed transaction’
23 have the respective meanings given to such terms by sec-
24 tion 6707A(c).”.

1 (b) CLERICAL AMENDMENT.—The item relating to
 2 section 6707 in the table of sections for part I of sub-
 3 chapter B of chapter 68 is amended by striking “tax shel-
 4 ters” and inserting “reportable transactions”.

5 (c) EFFECTIVE DATE.—The amendments made by
 6 this section shall apply to returns the due date for which
 7 is after the date of the enactment of this Act.

8 **SEC. 709. MODIFICATION OF PENALTY FOR FAILURE TO**
 9 **MAINTAIN LISTS OF INVESTORS.**

10 (a) IN GENERAL.—Subsection (a) of section 6708 is
 11 amended to read as follows:

12 “(a) IMPOSITION OF PENALTY.—

13 “(1) IN GENERAL.—If any person who is re-
 14 quired to maintain a list under section 6112(a) fails
 15 to make such list available upon written request to
 16 the Secretary in accordance with section
 17 6112(b)(1)(A) within 20 business days after the
 18 date of the Secretary’s request, such person shall
 19 pay a penalty of \$10,000 for each day of such fail-
 20 ure after such 20th day.

21 “(2) REASONABLE CAUSE EXCEPTION.—No
 22 penalty shall be imposed by paragraph (1) with re-
 23 spect to the failure on any day if such failure is due
 24 to reasonable cause.”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 this section shall apply to requests made after the date
3 of the enactment of this Act.

4 **SEC. 710. MODIFICATION OF ACTIONS TO ENJOIN CERTAIN**
5 **CONDUCT RELATED TO TAX SHELTERS AND**
6 **REPORTABLE TRANSACTIONS.**

7 (a) IN GENERAL.—Section 7408 (relating to action
8 to enjoin promoters of abusive tax shelters, etc.) is amend-
9 ed by redesignating subsection (c) as subsection (d) and
10 by striking subsections (a) and (b) and inserting the fol-
11 lowing new subsections:

12 “(a) AUTHORITY TO SEEK INJUNCTION.—A civil ac-
13 tion in the name of the United States to enjoin any person
14 from further engaging in specified conduct may be com-
15 menced at the request of the Secretary. Any action under
16 this section shall be brought in the district court of the
17 United States for the district in which such person resides,
18 has his principal place of business, or has engaged in spec-
19 ified conduct. The court may exercise its jurisdiction over
20 such action (as provided in section 7402(a)) separate and
21 apart from any other action brought by the United States
22 against such person.

23 “(b) ADJUDICATION AND DECREE.—In any action
24 under subsection (a), if the court finds—

1 “(1) that the person has engaged in any speci-
2 fied conduct, and

3 “(2) that injunctive relief is appropriate to pre-
4 vent recurrence of such conduct,

5 the court may enjoin such person from engaging in such
6 conduct or in any other activity subject to penalty under
7 this title.

8 “(c) SPECIFIED CONDUCT.—For purposes of this
9 section, the term ‘specified conduct’ means any action, or
10 failure to take action, which is—

11 “(1) subject to penalty under section 6700,
12 6701, 6707, or 6708, or

13 “(2) in violation of any requirement under reg-
14 ulations issued under section 320 of title 31, United
15 States Code.”.

16 (b) CONFORMING AMENDMENTS.—

17 (1) The heading for section 7408 is amended to
18 read as follows:

19 **“SEC. 7408. ACTIONS TO ENJOIN SPECIFIED CONDUCT RE-**
20 **LATED TO TAX SHELTERS AND REPORTABLE**
21 **TRANSACTIONS.”.**

22 (2) The table of sections for subchapter A of
23 chapter 67 is amended by striking the item relating
24 to section 7408 and inserting the following new
25 item:

“Sec. 7408. Actions to enjoin specified conduct related to tax shelters and reportable transactions.”.

1 (c) EFFECTIVE DATE.—The amendment made by
2 this section shall take effect on the day after the date of
3 the enactment of this Act.

4 **SEC. 711. PENALTY FOR PROMOTING ABUSIVE TAX SHEL-**
5 **TERS.**

6 (a) PENALTY FOR PROMOTING ABUSIVE TAX SHEL-
7 TERS.—Section 6700 (relating to promoting abusive tax
8 shelters, etc.) is amended—

9 (1) by redesignating subsections (b) and (c) as
10 subsections (d) and (e), respectively,

11 (2) by striking “a penalty” and all that follows
12 through the period in the first sentence of subsection
13 (a) and inserting “a penalty determined under sub-
14 section (b)”, and

15 (3) by inserting after subsection (a) the fol-
16 lowing new subsections:

17 “(b) AMOUNT OF PENALTY; CALCULATION OF PEN-
18 ALTY; LIABILITY FOR PENALTY.—

19 “(1) AMOUNT OF PENALTY.—The amount of
20 the penalty imposed by subsection (a) shall not ex-
21 ceed 100 percent of the gross income derived (or to
22 be derived) from such activity by the person or per-
23 sons subject to such penalty.

1 “(2) CALCULATION OF PENALTY.—The penalty
2 amount determined under paragraph (1) shall be
3 calculated with respect to each instance of an activ-
4 ity described in subsection (a), each instance in
5 which income was derived by the person or persons
6 subject to such penalty, and each person who par-
7 ticipated in such an activity.

8 “(3) LIABILITY FOR PENALTY.—If more than 1
9 person is liable under subsection (a) with respect to
10 such activity, all such persons shall be jointly and
11 severally liable for the penalty under such sub-
12 section.

13 “(c) PENALTY NOT DEDUCTIBLE.—The payment of
14 any penalty imposed under this section or the payment
15 of any amount to settle or avoid the imposition of such
16 penalty shall not be deductible by the person who is sub-
17 ject to such penalty or who makes such payment.”.

18 (b) EFFECTIVE DATE.—The amendments made by
19 this section shall apply to activities after the date of the
20 enactment of this Act.

1 **SEC. 712. STATUTE OF LIMITATIONS FOR TAXABLE YEARS**
2 **FOR WHICH REQUIRED LISTED TRANS-**
3 **ACTIONS NOT REPORTED.**

4 (a) IN GENERAL.—Section 6501(c) (relating to ex-
5 ceptions) is amended by adding at the end the following
6 new paragraph:

7 “(10) LISTED TRANSACTIONS.—If a taxpayer
8 fails to include on any return or statement for any
9 taxable year any information with respect to a listed
10 transaction (as defined in section 6707A(c)(2))
11 which is required under section 6011 to be included
12 with such return or statement, the time for assess-
13 ment of any tax imposed by this title with respect
14 to such transaction shall not expire before the date
15 which is 1 year after the earlier of—

16 “(A) the date on which the Secretary is
17 furnished the information so required; or

18 “(B) the date that a material advisor (as
19 defined in section 6111) meets the requirements
20 of section 6112 with respect to a request by the
21 Secretary under section 6112(b) relating to
22 such transaction with respect to such tax-
23 payer.”.

24 (b) EFFECTIVE DATE.—The amendment made by
25 this section shall apply to taxable years with respect to

1 which the period for assessing a deficiency did not expire
 2 before the date of the enactment of this Act.

3 **SEC. 713. DENIAL OF DEDUCTION FOR INTEREST ON UN-**
 4 **DERPAYMENTS ATTRIBUTABLE TO NONDIS-**
 5 **CLOSED REPORTABLE AND NONECONOMIC**
 6 **SUBSTANCE TRANSACTIONS.**

7 (a) IN GENERAL.—Section 163 (relating to deduction
 8 for interest) is amended by redesignating subsection (m)
 9 as subsection (n) and by inserting after subsection (l) the
 10 following new subsection:

11 “(m) INTEREST ON UNPAID TAXES ATTRIBUTABLE
 12 TO NONDISCLOSED REPORTABLE TRANSACTIONS AND
 13 NONECONOMIC SUBSTANCE TRANSACTIONS.—No deduc-
 14 tion shall be allowed under this chapter for any interest
 15 paid or accrued under section 6601 on any underpayment
 16 of tax which is attributable to—

17 “(1) the portion of any reportable transaction
 18 understatement (as defined in section 6662A(b))
 19 with respect to which the requirement of section
 20 6664(d)(2)(A) is not met, or

21 “(2) any noneconomic substance transaction
 22 understatement (as defined in section 6662B(c)).”.

23 (b) EFFECTIVE DATE.—The amendments made by
 24 this section shall apply to transactions in taxable years
 25 beginning after the date of the enactment of this Act.

1 **SEC. 714. PENALTY FOR AIDING AND ABETTING THE UN-**
2 **DERSTATEMENT OF TAX LIABILITY.**

3 (a) IN GENERAL.—Section 6701(a) (relating to impo-
4 sition of penalty) is amended—

5 (1) by inserting “the tax liability or” after “re-
6 spect to,” in paragraph (1),

7 (2) by inserting “aid, assistance, procurement,
8 or advice with respect to such” before “portion”
9 both places it appears in paragraphs (2) and (3),
10 and

11 (3) by inserting “instance of aid, assistance,
12 procurement, or advice or each such” before “docu-
13 ment” in the matter following paragraph (3).

14 (b) AMOUNT OF PENALTY.—Subsection (b) of section
15 6701 (relating to penalties for aiding and abetting under-
16 statement of tax liability) is amended to read as follows:

17 “(b) AMOUNT OF PENALTY; CALCULATION OF PEN-
18 ALTY; LIABILITY FOR PENALTY.—

19 “(1) AMOUNT OF PENALTY.—The amount of
20 the penalty imposed by subsection (a) shall not ex-
21 ceed 100 percent of the gross income derived (or to
22 be derived) from such aid, assistance, procurement,
23 or advice provided by the person or persons subject
24 to such penalty.

25 “(2) CALCULATION OF PENALTY.—The penalty
26 amount determined under paragraph (1) shall be

1 calculated with respect to each instance of aid, as-
 2 sistance, procurement, or advice described in sub-
 3 section (a), each instance in which income was de-
 4 rived by the person or persons subject to such pen-
 5 alty, and each person who made such an understatement of the liability for tax.

7 “(3) LIABILITY FOR PENALTY.—If more than 1
 8 person is liable under subsection (a) with respect to
 9 providing such aid, assistance, procurement, or ad-
 10 vice, all such persons shall be jointly and severally
 11 liable for the penalty under such subsection.”.

12 (c) PENALTY NOT DEDUCTIBLE.—Section 6701 is
 13 amended by adding at the end the following new sub-
 14 section:

15 “(g) PENALTY NOT DEDUCTIBLE.—The payment of
 16 any penalty imposed under this section or the payment
 17 of any amount to settle or avoid the imposition of such
 18 penalty shall not be deductible by the person who is sub-
 19 ject to such penalty or who makes such payment.”.

20 (d) EFFECTIVE DATE.—The amendments made by
 21 this section shall apply to activities after the date of the
 22 enactment of this Act.

