

109TH CONGRESS  
1ST SESSION

# S. 1074

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

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IN THE SENATE OF THE UNITED STATES

MAY 18, 2005

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

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## A BILL

To improve the health of Americans and reduce health care costs by reorienting the Nation's health care system toward 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. Fresh fruit and vegetable program.
- Sec. 102. Child nutrition promotion and school lunch protection.
- Sec. 103. School nutrition environment enhancement grants.
- Sec. 104. Grants for the integration of schools and mental health systems.
- Sec. 105. Baby friendly hospital-center for breastfeeding excellence.
- Sec. 106. Intervention to strengthen families and build children's resilience.
- Sec. 107. Reservations for early head start programs.

## 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. National assessment of mental health needs.
- Sec. 215. Preventive medicine and public health training grant program.
- Sec. 216. Task force for the promotion of breastfeeding in the workplace.
- Sec. 217. Lactation accomodation and breastfeeding promotion at work.

## Subtitle C—Family Smoking Prevention and Control

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

## PART I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

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

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

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

## PART III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

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

TITLE III—RESPONSIBLE MARKETING AND CONSUMER  
AWARENESS

Subtitle A—General Provisions

- Sec. 301. Nutrition labeling of restaurant foods.
- Sec. 302. Rulemaking authority for advertising to children.
- Sec. 303. Label and disclosure requirements for infant formulas.
- Sec. 304. Food advertising in schools.
- Sec. 305. Disallowance of deductions for advertising and marketing expenses relating to tobacco product use.
- Sec. 306. 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. Recognition of school-based health centers as model for delivery of primary care for children under the medicaid and State children’s health insurance programs.
- Sec. 405. Preventive health care demonstration program.
- Sec. 406. Preventive health services for women.

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

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

TITLE VI—RESEARCH

- Sec. 601. Expansion of research regarding obesity.

**1 SEC. 2. FINDINGS.**

**2 Congress makes the following findings:**

- 3 (1) Health care costs in the United States are**
- 4 rising rapidly. Per capita health spending in the**
- 5 United States is 56 percent higher than the median**

1 country that is a member of the Organization for  
2 Economic Cooperation and Development.

3 (2) According to the Centers for Medicare and  
4 Medicaid Services, total health care spending in the  
5 United States in 2004 was \$1,800,000,000,000 and  
6 is expected to rise to \$3,600,000,000,000 by 2014.  
7 Furthermore, chronic disease accounts for approxi-  
8 mately 75 percent of health care costs annually.

9 (3) The United States spends less than 5 per-  
10 cent of annual health care expenditures on preven-  
11 tion

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

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

18 (6) The economic impact of chronic disease can  
19 be seen in the annual costs associated with cardio-  
20 vascular disease and stroke (\$352,000,000,000),  
21 obesity (\$117,000,000,000), cancer  
22 (\$171,600,000,000), and diabetes  
23 (\$132,000,000,000).

1           (7) Obesity related health conditions cost em-  
2           ployers nearly \$13,000,000,000 in health care and  
3           other indirect costs.

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

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

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

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

15          (12) Almost 40 percent of Americans are sed-  
16          entary. More than  $\frac{1}{3}$  of young people in grades 9  
17          through 12 do not regularly engage in vigorous-in-  
18          tensity physical activity.

19          (13) Only 1 in 5 young people eat the rec-  
20          ommended 5 daily servings of fruits and vegetables.

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

1           (15) Between 1977 and 1995, trips made by  
2 walking declined by 40 percent for adults while driv-  
3 ing trips increased to almost 90 percent of the total.

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

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

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

17           (19) Physical and mental health are inter-  
18 connected. Physical conditions often result in mental  
19 health complications and depression can manifest  
20 itself through physical symptoms.

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

1           (21) One of every 2 people who need mental  
2 health treatment in the United States does not re-  
3 ceive it. Of children and adolescents 6 to 17 years  
4 old who need mental health services, nearly 80 per-  
5 cent do not receive it.

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

10          (23) Children are at greater risk for mental  
11 health problems when they experience stressful fam-  
12 ily circumstances such as social or economic dis-  
13 advantage, severe marital discord, divorce, family vi-  
14 olence, parental substance abuse or other mental dis-  
15 order or physical illness, and parental absence due  
16 to military service, imprisonment, or death.

17          (24) The 2003 President's New Freedom Com-  
18 mission on Mental Health urged a transformation of  
19 the approach to mental health in the United States,  
20 including improving the mental health of children  
21 and promoting resilience and prevention.

22          (25) 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 (26) 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. FRESH FRUIT AND VEGETABLE PROGRAM.**

14 (a) **ADDITIONAL FUNDING FOR FRESH FRUIT AND**  
 15 **VEGETABLE PROGRAM.**—Section 18(g)(6)(B) of the Rich-  
 16 ard B. Russell National School Lunch Act (42 U.S.C.  
 17 1769(g)(6)(B)) is amended—

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

19 and

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

21 “(ii) **ADDITIONAL MANDATORY FUND-**  
 22 **ING.**—Out of any funds in the Treasury  
 23 not otherwise appropriated, the Secretary  
 24 of the Treasury shall transfer to the Sec-  
 25 retary of Agriculture to carry out and ex-

1           pand the program under this subsection, to  
2           remain available until expended—

3                   “(I) on October 1, 2005,  
4                   \$1,000,000,000; and

5                   “(II) on October 1, 2006, and on  
6                   each October 1 thereafter, the amount  
7                   made available for the previous fiscal  
8                   year, as adjusted under clause (iii).

9                   “(iii) ADJUSTMENT.—On October 1,  
10                  2006, and on each October 1 thereafter of  
11                  a fiscal year the amount made available  
12                  under subclause (I) of clause (ii) shall be  
13                  calculated by adjusting the amount made  
14                  available for the previous fiscal year to re-  
15                  flect changes in the Consumer Price Index  
16                  of the Bureau of Labor Statistics for fresh  
17                  fruits and vegetables, with the adjust-  
18                  ment—

19                   “(I) rounded down to the nearest  
20                   dollar increment; and

21                   “(II) based on the unrounded  
22                   amounts for the preceding 12-month  
23                   period.”.

1 (b) HEALTHY COOKING PILOT PROGRAM.—Section  
2 18(g) of the Richard B. Russell National School Lunch  
3 Act (42 U.S.C. 1769(g)) is amended—

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

6 (2) by inserting after paragraph (3) the fol-  
7 lowing:

8 “(4) HEALTHY COOKING PILOT PROGRAM.—

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

15 “(i) how to eat a nutritious diet;

16 “(ii) how to select foods to make a  
17 healthy meal; and

18 “(iii) how to prepare healthy meals.

19 “(B) SELECTION OF SCHOOLS.—In select-  
20 ing schools to participate in the pilot program,  
21 the Secretary shall ensure that—

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

1           “(ii) to the maximum extent prac-  
2           ticable, at least 75 percent of schools se-  
3           lected are schools in which at least 50 per-  
4           cent of the students enrolled are eligible  
5           for free or reduced price meals under this  
6           Act; and

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

9                   “(I) rural, urban, and suburban  
10                  schools; and

11                   “(II) elementary, middle, and  
12                  secondary schools.

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

19 **SEC. 102. CHILD NUTRITION PROMOTION AND SCHOOL**  
20 **LUNCH PROTECTION.**

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

23           (1) by striking the section heading and all that  
24           follows through “(a) The Secretary” and inserting  
25           the following:

1 **“SEC. 10. REGULATIONS.**

2 “(a) IN GENERAL.—The Secretary”; and

3 (2) by striking subsections (b) and (c) and in-  
4 sserting the following:

5 “(b) FOOD OF MINIMAL NUTRITIONAL VALUE.—

6 “(1) PROPOSED REGULATIONS.—

7 “(A) IN GENERAL.—Not later than 180  
8 days after the date of enactment of this para-  
9 graph, the Secretary shall promulgate proposed  
10 regulations—11 “(i) to revise the definition of ‘food of  
12 minimal nutritional value’ that is used to  
13 carry out this Act and the Richard B. Rus-  
14 sell National School Lunch Act (42 U.S.C.  
15 1751 et seq.); and16 “(ii) to rename the term ‘food of poor  
17 nutritional value’.18 “(B) REQUIREMENTS.—In revising the  
19 definition, the Secretary shall—

20 “(i) cover all foods made available—

21 “(I) outside the school meal pro-  
22 grams;

23 “(II) on the school campus; and

24 “(III) at any time during the  
25 school day;

1           “(ii) shall consider both the positive  
2           and negative contributions of nutrients, in-  
3           gredients, and foods (including calories,  
4           portion size, saturated fat, trans fat, so-  
5           dium, and added sugars) to the diets of  
6           children;

7           “(iii) consider evidence concerning the  
8           relationship between consumption of cer-  
9           tain nutrients, ingredients, and foods to  
10          both preventing and promoting the devel-  
11          opment of overweight, obesity, and other  
12          chronic illnesses; and

13          “(iv) consider recommendations made  
14          by authoritative scientific organizations  
15          concerning appropriate nutritional stand-  
16          ards for foods sold outside of the reimburs-  
17          able meal programs in schools.

18          “(2) IMPLEMENTATION.—

19                 “(A) EFFECTIVE DATE.—

20                         “(i) IN GENERAL.—Except as pro-  
21                         vided in clause (ii), the proposed regula-  
22                         tions shall take effect at the beginning of  
23                         the school year following the date on which  
24                         the regulations are finalized.

1           “(ii) EXCEPTION.—If the regulations  
2           are finalized on a date that is not more  
3           than 60 days before the beginning of the  
4           school year, the proposed regulations shall  
5           take effect at the beginning of the fol-  
6           lowing school year.

7           “(B) FAILURE TO PROMULGATE.—If, on  
8           the date that is 1 year after the date of enact-  
9           ment of this paragraph, the Secretary has not  
10          promulgated final regulations, the proposed reg-  
11          ulations shall be considered to be final regula-  
12          tions.”.

13 **SEC. 103. SCHOOL NUTRITION ENVIRONMENT ENHANCE-**  
14 **MENT GRANTS.**

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

18          “(1) HEALTHY SCHOOL NUTRITION ENVIRONMENT  
19 INCENTIVE GRANTS.—

20               “(1) IN GENERAL.—Following the publication  
21               of the recommendations of the Institute of Medicine  
22               study carried out using funds made available for  
23               public health improvement and leadership under the  
24               heading ‘CENTERS FOR DISEASE CONTROL AND  
25               PREVENTION’ in the Department of Labor Appro-

1        priations Act, 2005 (title I of division F of Public  
2        Law 108–447; 118 Stat. 3124) regarding appro-  
3        priate nutritional standards for the availability, sale,  
4        content, and consumption of food at school, with  
5        particular attention given to foods offered in com-  
6        petition with federally reimbursed meals and snacks,  
7        the Secretary may carry out a grant program to—

8                “(A) provide schools with technical assist-  
9                ance in implementing the recommendations of  
10              the Institute of Medicine regarding appropriate  
11              school nutrition standards; and

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

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

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

24              “(B) ensure that, of the schools selected to  
25              participate in the program, there is appropriate

1 representation of rural, urban, and suburban  
2 schools, as determined by the Secretary;

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

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

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

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

21 “(3) REQUIREMENTS.—

22 “(A) CRITERIA FOR HEALTHY SCHOOL EN-  
23 VIRONMENTS.—The Secretary shall establish  
24 criteria, based upon the recommendations of the  
25 Institute of Medicine described in paragraph

1 (1), under which schools may receive grants  
2 under this section.

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

5 “(i) submit to the Secretary a healthy  
6 school nutrition environment plan that de-  
7 scribes the actions the school will take to  
8 meet the criteria established under sub-  
9 paragraph (A); and

10 “(ii) take the actions described in the  
11 plan.

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

15 “(5) EVALUATIONS.—

16 “(A) IN GENERAL.—The Secretary, acting  
17 through the Administrator of the Food and Nu-  
18 trition Service, shall conduct an evaluation of a  
19 representative sample of schools that receive  
20 grants under this subsection.

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

24 “(i) overweight children and obesity;

25 “(ii) dietary intake;

1           “(iii) nutrition education and behav-  
2           ior;

3           “(iv) parental and student attitudes  
4           and participation; and

5           “(v) related funding issues, including  
6           the cost of maintaining a healthy school  
7           nutrition environment.

8           “(C) REPORTS.—The Secretary shall sub-  
9           mit to the Committee on Education and the  
10          Workforce of the House of Representatives and  
11          the Committee on Agriculture, Nutrition, and  
12          Forestry of the Senate—

13           “(i) an interim report on the activities  
14           of schools evaluated under this subsection;  
15           and

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

18          “(6) AUTHORIZATION OF APPROPRIATIONS.—

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

24           “(B) EVALUATIONS.—The Secretary may  
25           use not more than 10 percent of the total funds



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

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

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

9           “(A) an institution of higher education (in-  
10           cluding a graduate program in psychology, so-  
11           cial work, or education at an institution of  
12           higher education); and

13           “(B) private nonprofit community-based  
14           organizations that have experience in public  
15           education programs relating to mental health  
16           promotion and prevention.”.

17 **SEC. 105. BABY FRIENDLY HOSPITAL-CENTER FOR**  
18 **BREASTFEEDING EXCELLENCE.**

19           (a) ESTABLISHMENT OF PROGRAM.—The Director of  
20 the Office on Women’s Health of the Department of  
21 Health and Human Services (referred to in this section  
22 as the “Director”) shall establish a program to be known  
23 as the “Baby-Friendly Hospital Initiative” (referred to in  
24 this section and the “Initiative”).

1           (b) CERTIFICATION PROCESS.—Under the Initiative,  
2 the Director shall establish a certification process under  
3 which a hospital can apply for a certification as a “baby  
4 friendly hospital/center for breastfeeding excellence”. Such  
5 certification process shall be based upon the international  
6 guidelines of the Baby-Friendly Hospital Initiative estab-  
7 lished by the World Health Organization and United Na-  
8 tions Children’s Fund.

9           (c) REQUIREMENTS.—

10           (1) IN GENERAL.—To be certified as a baby  
11 friendly hospital/center for breastfeeding excellence,  
12 a hospital (as defined for purposes of this section by  
13 the Director, and which may include birth centers)  
14 shall carry out the following:

15           (A) The hospital shall maintain a written  
16 breastfeeding policy that is routinely commu-  
17 nicated to all of the healthcare staff of the hos-  
18 pital.

19           (B) The hospital shall provide training for  
20 all healthcare staff in the skills necessary to im-  
21 plement the policy described in subparagraph  
22 (A).

23           (C) The hospital shall ensure that all preg-  
24 nant women who are patients at the hospital

1 are informed about the benefits and manage-  
2 ment of breastfeeding.

3 (D) The hospital shall help mothers ini-  
4 tiate breastfeeding within one hour of birth.

5 (E) The hospital shall demonstrate to  
6 mothers how to breastfeed and how to maintain  
7 lactation, even if the mother is separated from  
8 her infant.

9 (F) The hospital shall give infants no food  
10 or drink other than breastmilk, unless medically  
11 indicated.

12 (G) The hospital shall implement a “room-  
13 ing in” policy by allowing mothers and infants  
14 to remain together 24 hours a day in the same  
15 hospital room.

16 (H) The hospital shall encourage unre-  
17 stricted breastfeeding.

18 (I) The hospital shall provide no pacifiers  
19 or artificial nipples to breastfeeding infants.

20 (J) The hospital shall foster the establish-  
21 ment of breastfeeding support groups and refer  
22 mothers to such groups on discharge from the  
23 hospital.

24 (2) INSPECTION.—A hospital shall be certified  
25 as a baby friendly hospital/center for breastfeeding

1 excellence only upon the completion of an on-site as-  
2 sessment by the Director through which the Director  
3 has determined that the hospital is in compliance  
4 with the guidelines used for certification under sub-  
5 section (b).

6 (3) VERIFICATION.—Upon being certified as a  
7 baby friendly hospital/center for breastfeeding excel-  
8 lence, a hospital shall agree to permit the Director  
9 to conduct on-site assessments to verify the contin-  
10 ued compliance of the hospital with the requirements  
11 of paragraph (1).

12 (d) AUTHORITY FOR AUTOMATIC CERTIFICATION.—  
13 The Director may automatically certify a hospital as a  
14 baby friendly hospital/center of breastfeeding excellence if  
15 such hospital has been designated as a baby-friendly hos-  
16 pital under the Baby-Friendly USA program.

17 (e) LIMITATION.—A hospital shall not make any  
18 claim that such hospital is a baby friendly hospital/center  
19 of breastfeeding excellence unless such hospital has been  
20 certified by the Director in accordance with this section.

21 (f) TECHNICAL ASSISTANCE.—The Director shall  
22 provide, at the request of a hospital seeking a certification  
23 as a baby friendly hospital/center of breastfeeding excel-  
24 lence, such technical assistance as appropriate to assist  
25 the requesting hospital to achieve such certification.

1           (g) CERTIFICATION COSTS.—Subject to the avail-  
2 ability of appropriations, the Director may provide to a  
3 hospital that has successfully been certified as a baby  
4 friendly hospital/center of breastfeeding excellence under  
5 this Act, a one time award of up to \$20,000 to offset the  
6 cost to such hospital of being certified as a baby friendly  
7 hospital/center of breastfeeding excellence.

8           (h) RECOMMENDATIONS FOR ACCREDITING ENTI-  
9 TIES.—Not later than 12 months after certifying the first  
10 baby friendly hospital/center for breastfeeding excellence  
11 under this section, the Director shall provide to the appro-  
12 priate organizations or entities that are engaged in the  
13 accreditation of healthcare organizations, recommenda-  
14 tions concerning steps that such accrediting entities may  
15 take to integrate the baby friendly hospital requirements  
16 used in the Baby Friendly Hospital Initiative into  
17 healthcare organization accreditation procedures and re-  
18 quirements.

19           (i) AUTHORIZATION OF APPROPRIATIONS.—There  
20 are authorized to be appropriated such sums as may be  
21 necessary to carry out this section.

1 **SEC. 106. INTERVENTION TO STRENGTHEN FAMILIES AND**  
 2 **BUILD CHILDREN'S RESILIENCE.**

3 Part B of title V of the Public Health Service Act  
 4 (42 3 U.S.C. 290bb et seq.) is amended by adding at the  
 5 end the following:

6 **"SEC. 520K. INTERVENTIONS TO STRENGTHEN FAMILIES**  
 7 **AND BUILD CHILDREN'S RESILIENCE.**

8 "(a) IN GENERAL.—The Secretary shall award  
 9 grants to eligible entities for the purpose of implementing  
 10 programs that strengthen families of children at risk for  
 11 emotional or behavioral problems due to family distress.

12 "(b) ELIGIBLE ENTITY.—Entities eligible to receive  
 13 funds under this section may include—

14 "(1) a local public entity, including a health de-  
 15 partment or local education agency;

16 "(2) an Indian tribal organization or agency;

17 "(3) a federally qualified health center;

18 "(4) a community-based organization; or

19 "(5) any other entity determined appropriate by  
 20 the Secretary, including a consortia or partnership  
 21 of entities eligible to receive funds under this sec-  
 22 tion.

23 "(c) USE OF FUNDS.—

24 "(1) IN GENERAL.—An eligible entity that re-  
 25 ceives a grant under this section shall use the funds  
 26 made available through the grant to carry out home-

1 based, school-based, and community-based activities  
2 that—

3 “(A) promote strong, supportive families  
4 and child resilience through parenting skills  
5 training and supports, or skill-building services  
6 with children, as well as provide other consult-  
7 ative services and support for family and other  
8 caregivers, such as child care providers, edu-  
9 cators, and after-school program staff;

10 “(B) enhance mental health promotion ac-  
11 tivities in domains where children live, play, and  
12 learn; and

13 “(C) enhance community wellness, and re-  
14 duce the incidence of preventable mental health  
15 problems among children.

16 “(2) INTERVENTION ACTIVITIES.—Intervention  
17 activities funded under this section shall—

18 “(A) be consumer and family driven, and  
19 use strengths-based approaches;

20 “(B) be designed to promote social and  
21 emotional competencies and increase children’s  
22 ability to successfully cope with stressful life  
23 circumstances;

24 “(C) be designed to strengthen children  
25 and their families by enhancing the knowledge,

1 social, emotional, and other life or work skills,  
2 and support of, parents or other significant  
3 caregivers;

4 “(D) emphasize and model a positive, sup-  
5 portive approach to working with children;

6 “(E) be evidence-based and provide in-  
7 depth and ongoing training and consultation in  
8 the adoption and use of evidence-based inter-  
9 ventions by schools, communities, and families;

10 “(F) include a rigorous evaluation compo-  
11 nent, including outcome measures suited to the  
12 intervention and the overall goals of the grant,  
13 as well as use of comparison groups and moder-  
14 ating and mediating process variables when-  
15 ever possible;

16 “(G) involve partnerships between commu-  
17 nities or schools and universities where possible  
18 to support effective implementation and evalua-  
19 tion of the intervention activities;

20 “(H) provide facilitated referrals for par-  
21 ents and other family members who need men-  
22 tal health, substance abuse, or social work serv-  
23 ices, and coordinate a referral network of pro-  
24 fessionals with affordable fees; and

1           “(I) emphasize local capacity-building to  
2           use evidence-based intervention, promote link-  
3           ages among individuals and groups that serve  
4           children and families, and develop community  
5           outreach to support coalition-building.

6           “(3) TARGET POPULATIONS.—Families targeted  
7           by these activities shall include those with children  
8           at risk for increased mental health problems due to  
9           stressful family circumstances, including—

10                   “(A) social or economic disadvantage;

11                   “(B) severe marital discord;

12                   “(C) divorce;

13                   “(D) family violence;

14                   “(E) parental substance abuse or other  
15           mental disorder or physical illness;

16                   “(F) parental death;

17                   “(G) parental absence due to military serv-  
18           ice;

19                   “(H) parental absence due to imprison-  
20           ment; and

21                   “(I) other family disruption determined ap-  
22           propriate by the Secretary.

23           “(d) PRIORITY FUNDING.—In awarding grants under  
24           subsection (a), the Secretary shall give priority to the fol-  
25           lowing:

1           “(1) Entities that provide non-Federal contribu-  
2           tions, either in cash or in kind.

3           “(2) Entities with demonstrated experience with  
4           community-based partnerships.

5           “(3) Entities with demonstrated experience and  
6           success with such interventions.

7           “(4) Entities with demonstrated experience  
8           working with families.

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

14          “(6) Entities that submit plans that exhibit co-  
15          operative plans that include the involvement of a  
16          broad range of stakeholders, including the following:

17               “(A) Community-based organizations.

18               “(B) Local governments.

19               “(C) Local educational agencies.

20               “(D) Local business and community asso-  
21               ciations.

22               “(E) Accredited colleges, universities, and  
23               community colleges.

24               “(F) Other entities determined appropriate  
25               by the Secretary.

1       “(e) EVALUATION.—Of the funds appropriated to  
2 carry out this section, the Secretary may reserve up to  
3 5 percent for each fiscal year for the purpose of carrying  
4 out evaluations of the activities carried out under this sec-  
5 tion, including a national cross-site evaluation. Within 90  
6 days of the completion of any evaluations, they shall be  
7 provided to the relevant authorizing committees and to the  
8 Committees on Appropriations of the Senate and the  
9 House of Representatives.

10       “(f) DURATION.—The Secretary shall award grants  
11 under this section for a period of not more than 5 years.

12       “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
13 is authorized to be appropriated to carry out this section,  
14 \$25,000,000 for fiscal year 2006, and such sums as may  
15 be necessary for each of fiscal years 2007 to 2010.”.

16 **SEC. 107. RESERVATIONS FOR EARLY HEAD START PRO-**  
17 **GRAMS.**

18       Section 640(a)(6)(A) of the Head Start Act (42  
19 U.S.C. 9835(a)(6)(A)) is amended by striking “7.5 per-  
20 cent” and all that follows and inserting “12 percent for  
21 fiscal year 2006, 14 percent for fiscal year 2007, 16 per-  
22 cent for fiscal year 2008, 18 percent for fiscal year 2009,  
23 and 20 percent for fiscal year 2010, of the amount appro-  
24 priated pursuant to section 639(a).”.

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 2005”.

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. 45J. 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  
5 and 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,  
7 “(G) depression,  
8 “(H) mental health promotion (including  
9 anxiety), and  
10 “(I) sleep (including sleep disorders and  
11 the consequences of sleep deprivation).

12 “(3) SUPPORTIVE ENVIRONMENT COMPO-  
13 NENT.—A supportive environment component which  
14 includes the following:

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

18 “(i) smoking at the worksite,

19 “(ii) the nutrition of food available at  
20 the worksite through cafeterias and vend-  
21 ing options,

22 “(iii) minimizing stress in the work-  
23 place,

24 “(iv) where applicable, accessible and  
25 attractive stairs,

1           “(v) the encouragement of physical  
2           activity during work hours,

3           “(vi) the promotion of fatigue coun-  
4           termeasures.

5           “(B) PARTICIPATION INCENTIVES.—

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

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

18          “(C) EMPLOYEE INPUT.—The opportunity  
19          for employees to participate in the management  
20          of any qualified wellness program or qualified  
21          small business wellness program to which this  
22          section applies.

23          “(d) PARTICIPATION REQUIREMENT.—

24          “(1) IN GENERAL.—No credit shall be allowed  
25          under subsection (a) unless the Secretary of Health

1 and Human Services certifies, as a part of any cer-  
2 tification described in subsection (b), that each  
3 wellness program component of the qualified  
4 wellness program or qualified small business  
5 wellness program applies to all qualified employees  
6 of the employer.

7 “(2) QUALIFIED EMPLOYEE.—For purposes of  
8 paragraph (1), the term ‘qualified employee’ means  
9 an employee who works an average of not less than  
10 25 hours per week during the taxable year.

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

13 “(1) EMPLOYEE AND EMPLOYER.—

14 “(A) PARTNERS AND PARTNERSHIPS.—  
15 The term ‘employee’ includes a partner and the  
16 term ‘employer’ includes a partnership.

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

19 “(2) SMALL BUSINESS EMPLOYER.—

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

1           “(B) CONTROLLED GROUPS.—For pur-  
2           poses of subparagraph (A), all persons treated  
3           as a single employer under subsection (b), (c),  
4           (m), or (o) of section 414 shall be treated as a  
5           single employer.

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

10           “(4) NO CREDIT WHERE GRANT AWARDED.—  
11           No credit shall be allowable under subsection (a) to  
12           any person who receives a grant under section 201  
13           of the Health Workforce Act of 2005.

14           “(f) PORTION OF CREDIT MADE REFUNDABLE.—

15           “(1) IN GENERAL.—In the case of an eligible  
16           employer of an employee, the aggregate credits al-  
17           lowed to a taxpayer under subpart C shall be in-  
18           creased by the lesser of—

19           “(A) the credit which would be allowed  
20           under this section without regard to this sub-  
21           section and the limitation under section 38(e),  
22           or

23           “(B) the amount by which the aggregate  
24           amount of credits allowed by this subpart (de-  
25           termined without regard to this subsection)

1 would increase if the limitation imposed by sec-  
2 tion 38(e) for any taxable year were increased  
3 by the amount of employer payroll taxes im-  
4 posed on the taxpayer during the calendar year  
5 in which the taxable year begins.

6 The amount of the credit allowed under this sub-  
7 section shall not be treated as a credit allowed under  
8 this subpart and shall reduce the amount of the  
9 credit otherwise allowable under subsection (a) with-  
10 out regard to section 38(c).

11 “(2) ELIGIBLE EMPLOYER.—For purposes of  
12 this subsection, the term ‘eligible employer’ means  
13 an employer or small business employer which is—

14 “(A) a State or political subdivision there-  
15 of, the District of Columbia, a possession of the  
16 United States, or an agency or instrumentality  
17 of any of the foregoing, or

18 “(B) any organization described in section  
19 501(c) of the Internal Revenue Code of 1986  
20 which is exempt from taxation under section  
21 501(a) of such Code.

22 “(3) EMPLOYER PAYROLL TAXES.—For pur-  
23 poses of this subsection—

24 “(A) IN GENERAL.—The term ‘employer  
25 payroll taxes’ means the taxes imposed by—

1 “(i) section 3111(b), and

2 “(ii) sections 3211(a) and 3221(a)  
3 (determined at a rate equal to the rate  
4 under section 3111(b)).

5 “(B) SPECIAL RULE.—A rule similar to  
6 the rule of section 24(d)(2)(C) shall apply for  
7 purposes of subparagraph (A).

8 “(g) TERMINATION.—This section shall not apply to  
9 any amount paid or incurred after December 31, 2015.”.

10 (b) TREATMENT AS GENERAL BUSINESS CREDIT.—  
11 Subsection (b) of section 38 of the Internal Revenue Code  
12 of 1986 (relating to general business credit) is amended  
13 by striking “plus” at the end of paragraph (18), by strik-  
14 ing the period at the end of paragraph (19) and inserting  
15 “, plus”, and by adding at the end the following:

16 “(20) the wellness program credit determined  
17 under section 45J.”.

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

22 “(e) WELLNESS PROGRAM CREDIT.—

23 “(1) IN GENERAL.—No deduction shall be al-  
24 lowed for that portion of the costs paid or incurred  
25 for a qualified wellness program (within the meaning

1 of section 45J) or a qualified small business wellness  
2 program (within the meaning of such section) allow-  
3 able as a deduction for the taxable year which is  
4 equal to the amount of the credit allowable for the  
5 taxable year under section 45J.

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

8 “(A) the amount of the credit determined  
9 for the taxable year under section 45J, exceeds

10 “(B) the amount allowable as a deduction  
11 for such taxable year for a qualified wellness  
12 program or a qualified small business wellness  
13 program,

14 the amount chargeable to capital account for the  
15 taxable year for such expenses shall be reduced by  
16 the amount of such excess.

17 “(3) CONTROLLED GROUPS.—In the case of a  
18 corporation which is a member of a controlled group  
19 of corporations (within the meaning of section  
20 41(f)(5)) or a trade or business which is treated as  
21 being under common control with other trades or  
22 business (within the meaning of section  
23 41(f)(1)(B)), this subsection shall be applied under  
24 rules prescribed by the Secretary similar to the rules

1 applicable under subparagraphs (A) and (B) of sec-  
2 tion 41(f)(1).”.

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

“Sec. 45J. Wellness program credit.”.

7 (e) EFFECTIVE DATE.—The amendments made by  
8 this section shall apply to taxable years beginning after  
9 December 31, 2005.

10 (f) OUTREACH.—

11 (1) IN GENERAL.—The Secretary of the Treas-  
12 ury, in conjunction with the Director of the Centers  
13 for Disease Control and members of the business  
14 community, shall institute an outreach program to  
15 inform businesses about the availability of the  
16 wellness program credit under section 45J of the In-  
17 ternal Revenue Code of 1986.

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

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

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

3 “In the case of taxable years beginning after 2005,  
4 the last item in the fourth column in the preceding  
5 table shall be applied by substituting ‘39.6%’ for  
6 ‘35.0%’.”.

7 (b) EFFECTIVE DATE.—The amendment made by  
8 this section shall apply to taxable years beginning after  
9 December 31, 2004.

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

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

16 “(A) IN GENERAL.—Gross income shall  
17 not include—

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

21 “(ii) fees or membership expenses  
22 paid by an employer to an athletic or fit-  
23 ness facility described in subparagraph (C)  
24 on behalf of its employees, but only to the

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

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

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

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

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

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

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

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

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

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

11           (1) IN GENERAL.—Paragraph (3) of section  
12          274(a) of such Code (relating to denial of deduction  
13          for club dues) is amended—

14           (A) by striking “Notwithstanding” and in-  
15           serting the following:

16           “(A) IN GENERAL.—Notwithstanding”,  
17           and

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

20           “(B) EXCEPTION FOR ATHLETIC FACILI-  
21           TIES.—This paragraph shall not apply to fees  
22           or dues paid to athletic or fitness facilities  
23           (within the meaning of section 132(j)(4)(C)) to  
24           the extent that such fees or dues do not exceed  
25           \$900 for any membership.”.





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 **Subtitle B—Healthy Communities**

17 **SEC. 211. HEALTHY COMMUNITY GRANTS.**

18 Part P of title III of the Public Health Service Act  
19 (42 U.S.C. 280g et seq.) is amended by adding at the end  
20 the following:

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

22 “(a) ESTABLISHMENT.—The Secretary, acting  
23 through the Director of the Centers for Disease Control  
24 and Prevention and in coordination with the Directors of  
25 other appropriate Federal agencies, shall award competi-  
26 tive grants to eligible entities for the purpose of planning

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

4 “(b) ELIGIBILITY.—

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

7 “(A) be—

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

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

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

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

15 “(v) a local health department;

16 “(vi) a health care provider;

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

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

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

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

5           “(2) APPLICATION.—

6           “(A) IN GENERAL.—An entity desiring a  
7 grant under this section shall submit an appli-  
8 cation to the Secretary at such time, in such  
9 manner, and containing such information as the  
10 Secretary may require, including a plan that  
11 meets the requirements of subparagraph (B).

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

15           “(i)(I) programs or community-based  
16 activities that the applicant proposes to  
17 carry out with funds received under this  
18 section and which seek to prevent and re-  
19 duce the incidence of—

20           “(aa) overweight and obesity, or  
21 chronic diseases associated with over-  
22 weight and obesity;

23           “(bb) tobacco use; or

24           “(cc) mental illness; or

1           “(II) other such activities, as deter-  
2           mined appropriate by the Secretary, that  
3           are consistent with the goals of promoting  
4           individual and community health and pre-  
5           venting chronic disease; and

6           “(ii) the manner in which the appli-  
7           cant will evaluate the effectiveness of the  
8           program or activities carried out under this  
9           section.

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

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

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

24           “(A) being overweight or obese;

25           “(B) tobacco use; or

1                   “(C) mental illness; or

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

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

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

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

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

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

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

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

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

10              “(7) entities that submit plans that exhibit  
11       multisectoral, cooperative conduct that includes the  
12       involvement of a broad range of stakeholders, includ-  
13       ing—

14                      “(A) community-based organizations;

15                      “(B) local governments;

16                      “(C) local educational agencies;

17                      “(D) the private sector;

18                      “(E) State or local departments of health;

19                      “(F) accredited colleges, universities, and  
20       community colleges;

21                      “(G) health care providers;

22                      “(H) State and local departments of trans-  
23       portation and city planning; and

24                      “(I) other entities determined appropriate  
25       by the Secretary.

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

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

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

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

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

4 **SEC. 212. LIVING WELL WITH A DISABILITY AND WORKING**  
5 **WELL WITH A DISABILITY PROGRAMS.**

6       Part P of title III of the Public Health Service Act  
7 (42 U.S.C. 280g et seq.), as amended by section 211, is  
8 further amended by adding at the end the following:

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

10       “(a) DEFINITIONS.—In this section:

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

15           “(2) DISABILITY.—The term ‘disability’ has the  
16 meaning given the term in section 3 of the Ameri-  
17 cans with Disabilities Act of 1990 (42 U.S.C.  
18 12102).

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

23       “(b) GRANTS.—The Secretary, acting through the  
24 Director of the Centers for Disease Control and Preven-  
25 tion, may make grants to eligible entities on a competitive

1 basis, to assist the entities in implementing Living Well  
2 With a Disability Programs, designed—

3           “(1) to increase health-promoting behavior,  
4           such as engaging in exercise, eating nutritious food,  
5           and using stress management techniques, among in-  
6           dividuals with disabilities; and

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

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

11           “(1) shall be a nonprofit organization that  
12           serves individuals with disabilities;

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

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

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

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

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

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

3           “(e) PREFERENCE AND DISTRIBUTION.—

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

7                   “(A) are currently (as of the date of sub-  
8 mission of the application) serving individuals  
9 with disabilities and implementing training and  
10 peer support programs;

11                   “(B) indicate a commitment and ability to  
12 continue to train participants over several  
13 years; and

14                   “(C) have not previously provided training  
15 through a Living Well With a Disability Pro-  
16 gram.

17           “(2) DISTRIBUTION.—In making grants under  
18 this section, the Secretary shall, to the extent prac-  
19 ticable, ensure an equitable geographic distribution  
20 of the grants.

21           “(f) CURRICULUM, TRAINING, AND TECHNICAL AS-  
22 SISTANCE.—An entity that receives a grant under this sec-  
23 tion may use funds made available through the grant to  
24 acquire a curriculum, training, or technical assistance for  
25 the program carried out through the grant from an entity

1 qualified to implement, and train participants in, a Living  
2 Well With a Disability program.

3 “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
4 are authorized to be appropriated to carry out this section  
5 \$2,000,000 for each of fiscal years 2005 through 2009.

6 **“SEC. 399R. WORKING WELL WITH A DISABILITY PRO-**  
7 **GRAMS.**

8 “(a) DEFINITIONS.—In this section, the terms ‘cen-  
9 ter for independent living’, ‘disability’, and ‘independent  
10 living services’ have the meanings given the terms in sec-  
11 tion 399Q.

12 “(b) AUTHORIZATION.—The Secretary, acting  
13 through the Director of the Centers for Disease Control  
14 and Prevention, may establish a demonstration program  
15 promoting the health and wellness of individuals with dis-  
16 abilities in the workplace.

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

22 “(1) gathering data on the positive effects of  
23 healthy behaviors on retention and productivity of  
24 individuals with disabilities who are employees or po-  
25 tential employees;

1           “(2) building relationships between vocational  
2           rehabilitation programs and health promotion pro-  
3           grams;

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

7           “(4) training individuals in methods of imple-  
8           menting the program;

9           “(5) implementing the program; and

10          “(6) measuring the impact of the program on  
11          health and employment outcomes.

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

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

16                 “(2) demonstrate that the entity is qualified  
17                 and able to adapt the program to establish a Work-  
18                 ing Well With a Disability Program, and implement  
19                 the program.

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

24                 “(1) shall be nonprofit organizations that serve  
25                 individuals with disabilities;



1 cials and the Institute of Transportation Engineers,  
2 shall develop recommended enhanced standards for  
3 the design of roads and intersection controls (includ-  
4 ing associated bicycle paths, bicycle lanes, and walk-  
5 ways) to improve pedestrian and bicycle safety.

6 “(2) ACCOMMODATION OF BICYCLES AND PE-  
7 DESTRIANS.—The standards under paragraph (1)  
8 shall—

9 “(A) cover all common types of facilities  
10 where pedestrians or bicycles are allowed on a  
11 road or on associated walkways and bicycle  
12 paths or lanes; and

13 “(B) specify that generally, when the in-  
14 creased cost is not excessive, as an element of  
15 good highway design for new construction or re-  
16 construction facilities on which bicycles or pe-  
17 destrians are permitted, the design shall include  
18 appropriate provisions to accommodate bicycles  
19 or pedestrians.

20 “(3) INCREASED APPORTIONMENT.—

21 “(A) IN GENERAL.—Beginning with the  
22 first fiscal year that begins after the date that  
23 is 2 years after the date of enactment of this  
24 subsection, if a State accepts the recommended  
25 enhanced standards for the State and local

1 units of government to meet, the State shall re-  
2 ceive a 4 percent increase in the amount of  
3 funds made available to the State under this  
4 section for each fiscal year, if, at least 10 days  
5 before the beginning of the fiscal year, the  
6 State—

7 “(i) agrees to follow the enhanced  
8 standards; or

9 “(ii) establishes an alternative en-  
10 hanced standard that the Secretary ap-  
11 proves.

12 “(B) SIGNIFICANT COMMITMENT.—In de-  
13 termining the significance of the required com-  
14 mitment of funds under subparagraph (A), the  
15 Secretary shall take into consideration the ef-  
16 fectiveness of the criteria required and an esti-  
17 mation of increased costs.

18 “(4) CONSTRUCTION REQUIREMENTS.—The  
19 Secretary and a State may establish differing re-  
20 quirements for the construction of new facilities, for  
21 the rehabilitation of facilities, and for modifications  
22 specifically to improve safety and for facilities based  
23 on the level of expected pedestrian and bicycle traf-  
24 fic.”.

1 (b) NONMOTORIZED TRANSPORTATION SAFETY.—  
2 Section 120(c) of title 23, United States Code, is amend-  
3 ed—

4 (1) in the first sentence, by striking “The Fed-  
5 eral” and inserting the following:

6 “(2) FEDERAL SHARE.—The Federal”;

7 (2) in the second sentence, by striking “In this  
8 subsection, the term” and inserting the following:

9 “(1) DEFINITIONS.—In this subsection:

10 “(A) BICYCLE AND PEDESTRIAN SAFE-  
11 TY.—The term ‘bicycle and pedestrian safety’  
12 means any improvement that—

13 “(i) promotes the safety of bicyclists  
14 and pedestrians (including people with dis-  
15 abilities); and

16 “(ii) is consistent with sections 134  
17 and 135.

18 “(B) SAFETY REST AREA.—The term”;

19 (3) by moving paragraph (1) (as added by para-  
20 graph (2)) so as to appear before paragraph (2) (as  
21 added by paragraph (1)); and

22 (4) by adding at the end the following:

23 “(3) STATEMENT OF POLICY BY STATE TRANS-  
24 PORTATION DEPARTMENTS.—

1           “(A) IN GENERAL.—Each State transpor-  
2           tation department shall adopt a statement of  
3           policy ensuring that the needs and safety of all  
4           road users (including the need for pedestrian  
5           and bicycle safety) are fully integrated into the  
6           planning, design, operation and maintenance of  
7           the transportation system of the State transpor-  
8           tation department.

9           “(B) BASIS.—In the case of bicycle and  
10          pedestrian safety, the statement of policy shall  
11          be based on the design guidance on accommo-  
12          dating bicyclists and pedestrians of the Federal  
13          Highway Administration adopted in February  
14          2000.

15          “(C) REPORTS.—Not later 1 year after the  
16          date of enactment of this paragraph, and each  
17          year thereafter, the Secretary shall submit to  
18          Congress a report on the statements of policy  
19          adopted under this paragraph.

20          “(4)       NONMOTORIZED       TRANSPORTATION  
21          GOAL.—

22          “(A) IN GENERAL.—The Secretary shall  
23          take such actions as are necessary to, to the  
24          maximum extent practicable, double the per-  
25          centage of trips made by foot or bicycle while

1 simultaneously reducing crashes involving  
2 bicyclists and pedestrians by 10 percent, in a  
3 manner consistent with the goals of the na-  
4 tional bicycling and walking study conducted  
5 during 1994.

6 “(B) ADMINISTRATION.—Not later than 1  
7 year after the date of enactment of this para-  
8 graph, the Secretary shall establish such base-  
9 line and completion dates as are necessary to  
10 carry out subparagraph (A).

11 “(5) RESEARCH FOR NONMOTORIZED USERS.—

12 “(A) FINDINGS.—Congress finds that—

13 “(i) it is in the national interest to  
14 meet the goals of the national bicycling  
15 and walking study by the completion date  
16 established under paragraph (4)(B);

17 “(ii) research into the safety and op-  
18 eration of the transportation system for  
19 nonmotorized users is inadequate, given  
20 that almost 1 in 10 trips are made by foot  
21 or bicycle and 1 in 8 traffic fatalities in-  
22 volves a bicyclist or pedestrian; and

23 “(iii) inadequate data collection, espe-  
24 cially on exposure rates and infrastructure  
25 needs, are hampering efforts to improve bi-

1 cycle and pedestrian safety and use to  
2 meet local transportation needs.

3 “(B) ALLOCATION OF RESEARCH FUNDS  
4 FOR NONMOTORIZED USERS.—

5 “(i) IN GENERAL.—The Secretary  
6 shall submit to Congress an annual report  
7 on the percentage of research funds that  
8 are allocated (for the most recent fiscal  
9 year for which data are available) to re-  
10 search that directly benefits the planning,  
11 design, operation, and maintenance of the  
12 transportation system for nonmotorized  
13 users—

14 “(I) by the Department of Trans-  
15 portation; and

16 “(II) by State transportation de-  
17 partments.

18 “(ii) NATIONAL COOPERATIVE HIGH-  
19 WAY RESEARCH PROGRAM.—The Transpor-  
20 tation Research Board of the National  
21 Academy of Sciences shall submit to Con-  
22 gress an annual report on the percentage  
23 of research funds under the National Co-  
24 operative Highway Research Program that  
25 are allocated (for the most recent fiscal

1 year for which data are available) to re-  
2 search that directly benefits the planning,  
3 design, operation, and maintenance of the  
4 transportation system for nonmotorized  
5 users.

6 “(iii) DEPARTMENT OF TRANSPOR-  
7 TATION ALLOCATION.—Effective beginning  
8 with the third full fiscal year that begins  
9 after the date of enactment of this para-  
10 graph, the Secretary shall allocate at least  
11 10 percent of the research funds that are  
12 allocated by the Department of Transpor-  
13 tation for each fiscal year to research that  
14 directly benefits the planning, design, oper-  
15 ation, and maintenance of the transpor-  
16 tation system for nonmotorized users.

17 “(6) METROPOLITAN PLANNING ORGANIZA-  
18 TIONS.—

19 “(A) BICYCLE/PEDESTRIAN COORDINA-  
20 TORS.—A metropolitan planning organization  
21 shall designate a bicycle/pedestrian coordi-  
22 nator to coordinate bicycle and pedestrian pro-  
23 grams and activities carried out in the area  
24 served by the organization.

1           “(B) CERTIFICATION.—A metropolitan  
2 planning organization shall certify to the Sec-  
3 retary, as part of the certification review,  
4 that—

5           “(i) the needs of bicyclists and pedes-  
6 trians (including people who use wheel-  
7 chairs and people with vision impairment)  
8 have been adequately addressed by the  
9 long-range transportation plan of the orga-  
10 nization; and

11           “(ii) the bicycle and pedestrian  
12 projects to implement the plan in a timely  
13 manner are included in the transportation  
14 improvement program of the organization.

15           “(C) LONG-RANGE TRANSPORTATION  
16 PLANS.—

17           “(i) IN GENERAL.—Except as pro-  
18 vided in clause (ii), a metropolitan plan-  
19 ning organization shall develop and adopt  
20 a long-range transportation plan that—

21           “(I) includes the most recent  
22 data available on the percentage of  
23 trips made by foot and by bicycle in  
24 each jurisdiction;

1                   “(II) includes a target level for  
2                   bicycle and pedestrian trips that is  
3                   commensurate with the national goal  
4                   of doubling the percentage of trips  
5                   made by foot and bicycle established  
6                   under paragraph (4); and

7                   “(III) identify the contribution  
8                   made by each project under the trans-  
9                   portation improvement program of the  
10                  organization toward meeting the goal  
11                  of doubling the percentage of trips  
12                  made by foot and bicycle.

13                  “(ii) APPLICATION.—Clause (i) does  
14                  not apply to a metropolitan planning orga-  
15                  nization that adopts the design guidance  
16                  described in paragraph (3)(B) for all  
17                  transportation projects carried out by the  
18                  organization.

19                  “(D) LOCAL JURISDICTIONS.—A metro-  
20                  politan planning organization shall strongly en-  
21                  courage local jurisdictions that are served by  
22                  the organization to maximize the efforts of the  
23                  local jurisdictions to include sidewalks,  
24                  bikepaths, and road intersections that maximize

1 bicycle and pedestrian safety in the local trans-  
2 portation systems of the local jurisdictions.”.

3 (c) SAFE ROUTES TO SCHOOLS PROGRAM.—

4 (1) IN GENERAL.—Subchapter I of chapter I of  
5 title 23, United States Code, is amended by insert-  
6 ing after section 149 the following:

7 **“§ 150. Safe routes to schools program**

8 “(a) DEFINITIONS.—In this section:

9 “(1) IN THE VICINITY OF SCHOOLS.—The term  
10 ‘in the vicinity of schools’ means, with respect to pri-  
11 mary and middle schools, the area within bicycling  
12 and walking distance of the primary and middle  
13 schools (approximately 2 miles).

14 “(2) PRIMARY AND MIDDLE SCHOOLS.—The  
15 term ‘primary and middle schools’ means schools  
16 providing education from kindergarten through  
17 eighth grade.

18 “(b) ESTABLISHMENT.—The Secretary shall estab-  
19 lish and carry out a safe routes to schools program for  
20 the benefit of children in primary and middle schools.

21 “(c) PURPOSES.—The purposes of the program are—

22 “(1) to enable and encourage children, includ-  
23 ing children with disabilities, to walk and bicycle to  
24 primary and middle schools;

1           “(2) to make bicycling and walking to primary  
2           and middle schools a safer and more appealing  
3           transportation alternative, thereby encouraging a  
4           healthy and active lifestyle from an early age; and

5           “(3) to facilitate the planning, development,  
6           and implementation of projects and activities that  
7           will improve safety and reduce traffic, fuel consump-  
8           tion, and air pollution in the vicinity of primary and  
9           middle schools.

10          “(d) APPORTIONMENT OF FUNDS.—

11           “(1) IN GENERAL.—Subject to paragraphs (2)  
12           and (3), amounts made available to carry out this  
13           subsection for a fiscal year shall be apportioned  
14           among the States in the ratio that—

15           “(A) the total student enrollment in pri-  
16           mary and middle schools in each State; bears to

17           “(B) the total student enrollment in pri-  
18           mary and middle schools in all the States.

19           “(2) MINIMUM APPORTIONMENT.—No State  
20           shall receive an apportionment under this section for  
21           a fiscal year of less than \$2,000,000.

22           “(3) SET-ASIDE.—Before apportioning amounts  
23           made available to carry out this section under this  
24           subsection for a fiscal year, the Secretary shall set  
25           aside not more than 2 percent of those amounts to

1 pay the administrative expenses incurred by the Sec-  
2 retary in carrying out this section.

3 “(4) DETERMINATION OF STUDENT ENROLL-  
4 MENTS.—Determinations under this subsection con-  
5 cerning student enrollments shall be made by the  
6 Secretary.

7 “(e) ADMINISTRATION OF AMOUNTS.—Amounts ap-  
8 portioned to a State under this section shall be adminis-  
9 tered by the applicable State transportation department.

10 “(f) ELIGIBLE RECIPIENTS.—Amounts apportioned  
11 to a State under this section shall be used by the State  
12 to provide financial assistance to State, local, and regional  
13 agencies, including nonprofit organizations, that dem-  
14 onstrate an ability to meet the requirements of this sec-  
15 tion.

16 “(g) ELIGIBLE PROJECTS AND ACTIVITIES.—

17 “(1) INFRASTRUCTURE-RELATED PROJECTS.—

18 “(A) IN GENERAL.—Amounts apportioned  
19 to a State under this section may be used for  
20 the planning, design, and construction of infra-  
21 structure-related projects that will substantially  
22 improve the ability of students to walk and bi-  
23 cycle to primary and middle schools in the vi-  
24 cinity of primary and middle schools, includ-  
25 ing—

- 1 “(i) sidewalk improvements;
- 2 “(ii) traffic calming and speed reduc-
- 3 tion improvements;
- 4 “(iii) pedestrian and bicycle crossing
- 5 improvements;
- 6 “(iv) on-street bicycle facilities;
- 7 “(v) off-street bicycle and pedestrian
- 8 facilities;
- 9 “(vi) secure bicycle parking facilities;
- 10 and
- 11 “(vii) traffic diversion improvements.

12 “(B) LOCATION OF PROJECTS.—An infra-

13 structure-related project under subparagraph

14 (A) may be carried out on any public road or

15 any bicycle or pedestrian pathway or trail in the

16 vicinity of a primary or middle school.

17 “(2) NONINFRASTRUCTURE-RELATED ACTIVI-

18 TIES.—

19 “(A) IN GENERAL.—In addition to projects

20 described in paragraph (1), amounts appor-

21 tioned to a State under this section may be

22 used for noninfrastructure-related activities to

23 encourage walking and bicycling to primary and

24 middle schools, including—

1                   “(i) public awareness campaigns and  
2                   outreach to press and community leaders;

3                   “(ii) traffic education and enforce-  
4                   ment in the vicinity of primary and middle  
5                   schools;

6                   “(iii) student sessions on bicycle and  
7                   pedestrian safety, health, and environment;  
8                   and

9                   “(iv) funding for training, volunteers,  
10                  and managers of safe routes to schools  
11                  programs.

12                  “(B) ALLOCATION.—Not less than 10 per-  
13                  cent and not more than 30 percent of the  
14                  amount apportioned to a State under this sub-  
15                  section for a fiscal year shall be used for non-  
16                  infrastructure-related activities under this para-  
17                  graph.

18                  “(3) SAFE ROUTES TO SCHOOL COORDI-  
19                  NATOR.—Each State receiving an apportionment  
20                  under this section for a fiscal year shall use a suffi-  
21                  cient amount of the apportionment to fund a full-  
22                  time position of coordinator of the safe routes to  
23                  schools program of the State.

24                  “(h) CLEARINGHOUSE.—

1           “(1) IN GENERAL.—The Secretary shall make  
2 grants to a national nonprofit organization engaged  
3 in promoting safe routes to schools to—

4           “(A) operate a national safe routes to  
5 school clearinghouse;

6           “(B) develop information and educational  
7 programs on safe routes to schools; and

8           “(C) provide technical assistance and dis-  
9 seminate techniques and strategies used for  
10 successful safe routes to schools programs.

11          “(2) FUNDING.—The Secretary shall carry out  
12 this subsection using amounts set aside for adminis-  
13 trative expenses under subsection (d)(3).

14          “(i) TASK FORCE.—

15           “(1) IN GENERAL.—The Secretary shall estab-  
16 lish a national safe routes to schools task force com-  
17 posed of leaders in health, transportation, and edu-  
18 cation, including representatives of appropriate Fed-  
19 eral agencies, to study and develop a strategy for ad-  
20 vancing safe routes to schools programs nationwide.

21           “(2) REPORT.—Not later than March 31, 2006,  
22 the Secretary shall submit to Congress a report con-  
23 taining—

1           “(A) the results of the study conducted,  
2           and a description of the strategy developed,  
3           under paragraph (1); and

4           “(B) information regarding the use of  
5           funds for infrastructure-related and noninfra-  
6           structure-related activities under paragraphs  
7           (1) and (2) of subsection (g).

8           “(3) FUNDING.—The Secretary shall carry out  
9           this subsection using amounts set aside for adminis-  
10          trative expenses under subsection (d)(3).

11          “(j) APPLICABILITY.—

12           “(1) IN GENERAL.—Except as otherwise pro-  
13          vided in this subsection, funds made available to  
14          carry out this section shall be available for obligation  
15          in the same manner as funds apportioned under this  
16          chapter.

17           “(2) AVAILABILITY.—Funds made available to  
18          carry out this section shall not be transferable and  
19          shall remain available until expended.

20           “(3) FEDERAL SHARE.—The Federal share of  
21          the cost of a project or activity under this section  
22          shall be 100 percent.

23           “(4) FEDERAL-AID SYSTEM.—Notwithstanding  
24          any other provision of law, a project assisted under

1 this section shall be treated as a project on a Fed-  
 2 eral-aid system under this chapter.”.

3 (2) AUTHORIZATIONS OF APPROPRIATIONS.—

4 There are authorized to be appropriated from the  
 5 Highway Trust Fund (other than the Mass Transit  
 6 Account) for the safe routes to schools programs  
 7 under section 150 of title 23, United States Code  
 8 (as added by paragraph (1))—

9 (A) \$175,000,000 for fiscal year 2006;

10 (B) \$200,000,000 for fiscal year 2007;

11 (C) \$200,000,000 for fiscal year 2008;

12 (D) \$200,000,000 for fiscal year 2009;

13 and

14 (E) \$225,000,000 for fiscal year 2010.

15 (3) CONFORMING AMENDMENTS.—The analysis  
 16 for subchapter I of chapter 1 of title 23, United  
 17 States Code is amended by inserting after the item  
 18 relating to section 149 the following:

“150. Safe routes to schools program.”.

19 (d) NONMOTORIZED TRANSPORTATION PILOT PRO-  
 20 GRAM.—

21 (1) ESTABLISHMENT.—The Secretary of Trans-  
 22 portation shall establish and carry out a non-  
 23 motorized transportation pilot program to construct,  
 24 in 4 communities selected by the Secretary, a net-  
 25 work of nonmotorized transportation infrastructure

1 facilities (including sidewalks, bicycle lanes, and pe-  
2 destrian and bicycle trails) that connect directly with  
3 transit stations, schools, residences, businesses,  
4 recreation areas, and other community activity cen-  
5 ters.

6 (2) PURPOSE.—The purpose of the program  
7 shall be to demonstrate the extent to which bicycling  
8 and walking can ease the burden on transportation  
9 systems, and represent a major portion of the trans-  
10 portation needs that are met, within selected com-  
11 munities.

12 (3) GRANTS.—

13 (A) IN GENERAL.—In carrying out the  
14 program, the Secretary may make grants to  
15 State, local, and regional agencies that the Sec-  
16 retary determines are suitably equipped and or-  
17 ganized to carry out the objectives and require-  
18 ments of this subsection.

19 (B) SUBALLOCATION.—An agency that re-  
20 ceives a grant under this section may suballo-  
21 cate grant funds to a nonprofit organization to  
22 carry out the program under this subsection.

23 (4) APPLICABILITY OF TITLE 23.—

24 (A) IN GENERAL.—Except as otherwise  
25 provided in this paragraph, funds made avail-

1           able to carry out this subsection shall be avail-  
2           able for obligation in the same manner as if the  
3           funds were apportioned under chapter 1 of title  
4           23, United States Code.

5           (B) AVAILABILITY.—Funds made available  
6           to carry out this subsection shall not be trans-  
7           ferable and shall remain available until ex-  
8           pended.

9           (C) FEDERAL SHARE.—The Federal share  
10          of the cost of a project carried out under this  
11          subsection shall be 80 percent.

12          (5) STATISTICAL INFORMATION.—In carrying  
13          out the program, the Secretary shall—

14                (A) develop statistical information on  
15                changes in motor vehicle, nonmotorized trans-  
16                portation, and public transportation usage in  
17                communities participating in the program; and

18                (B) assess how the changes—

19                    (i) decrease congestion and energy  
20                    usage;

21                    (ii) increase the frequency of biking  
22                    and walking; and

23                    (iii) promote better health and a  
24                    cleaner environment.

1           (6) REPORTS.—The Secretary shall submit to  
2 Congress an interim report not later than September  
3 30, 2007, and a final report not later than Sep-  
4 tember 30, 2010, on the results of the program.

5           (7) AUTHORIZATIONS OF APPROPRIATIONS.—  
6 There is authorized to be appropriated from the  
7 Highway Trust Fund (other than the Mass Transit  
8 Account) to carry out the nonmotorized pilot pro-  
9 gram under this subsection \$25,000,000 for each of  
10 fiscal years 2006 through 2010.

11 **SEC. 214. NATIONAL ASSESSMENT OF MENTAL HEALTH**  
12 **NEEDS.**

13 Title V of the Public Health Service Act (42 U.S.C.  
14 290aa et seq.) is amended by inserting after section 506B  
15 (42 U.S.C. 290aa–5b) the following:

16 **“SEC. 506C. NATIONAL ASSESSMENT OF MENTAL HEALTH**  
17 **NEEDS.**

18           “(a) IN GENERAL.—The Secretary, acting through  
19 the Administrator, and in consultation with the Centers  
20 for Disease Control and Prevention and the Director of  
21 the National Institutes of Health, shall establish and im-  
22 plement public health monitoring measures to address the  
23 mental and behavioral health needs of the population of  
24 the United States and other populations served by the Ad-  
25 ministration, that include—

1           “(1) monitoring the mental health status of the  
2           population, including incidence and prevalence rates  
3           of mental and behavioral health problems through-  
4           out the lifespan;

5           “(2) monitoring mental and behavioral health  
6           risks;

7           “(3) enhancing existing public health moni-  
8           toring systems to include data on mental and behav-  
9           ioral health status and risks; and

10          “(4) monitoring the immediate and long-term  
11          impact of environmental factors to collect data on  
12          the prevalence of mental and behavioral health prob-  
13          lems throughout the lifespan with the aim of encour-  
14          aging early intervention and treatment.

15          “(b) DISTINGUISHING AMONG AGE GROUPS.—In de-  
16          signing and implementing the measures described in sub-  
17          section (a) the Secretary shall ensure that methods of  
18          monitoring and reporting data distinguish among different  
19          age groups, including when identifying groups of children,  
20          and very young children under age 3, together with their  
21          parents.

22          “(c) REPORT.—Not later than 1 year after the date  
23          of enactment of this section, the Secretary shall submit  
24          a report to Congress that describes the progress on the

1 implementation of the monitoring measures described in  
2 subsection (a).

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
4 is authorized to be appropriated to carry out this section  
5 \$5,000,000 for fiscal year 2006 and such sums as may  
6 be necessary for each of the following fiscal years.”.

7 **SEC. 215. PREVENTIVE MEDICINE AND PUBLIC HEALTH**  
8 **TRAINING GRANT PROGRAM.**

9 Part C of title VII of the Public Health Service Act  
10 is amended by inserting after section 747 (42 U.S.C.  
11 293k) the following:

12 **“SEC. 747A. PREVENTIVE MEDICINE AND PUBLIC HEALTH**  
13 **TRAINING GRANT PROGRAM.**

14 “(a) GRANTS.—The Secretary may award grants to,  
15 or enter into contracts with, eligible entities to provide  
16 training to graduate medical residents in preventive medi-  
17 cine and public health.

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

20 “(1) be a school of public health, public health  
21 department, school of medicine or osteopathic medi-  
22 cine, public or private hospital, or public or private  
23 non-profit entity; and

1           “(2) submit to the Secretary an application at  
2 such time, in such manner, and containing such in-  
3 formation as the Secretary may require.

4           “(c) PREFERENCE AND SPECIAL CONSIDERATION.—

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

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

21           “(d) USE OF FUNDS.—Amounts received under a  
22 grant or contract under this section shall be used to—

23           “(1) to plan, develop, and operate residency  
24 programs for preventive medicine or public health;



1 (b) MEMBERSHIP.—The Task Force shall be com-  
2 posed of members who are—

3 (1) expert staff from the Department of Labor  
4 with expertise in workforce issues;

5 (2) expert staff from the Department of Health  
6 and Human Services with expertise in the areas of  
7 breastfeeding and breastfeeding promotion;

8 (3) members of the United States Breastfeeding  
9 Committee;

10 (4) expert staff from the Department of Agri-  
11 culture; and

12 (5) appointed by the Secretary of Health and  
13 Human Services and the Secretary of Labor, includ-  
14 ing—

15 (A) working mothers who have experience  
16 in working and breastfeeding; and

17 (B) representatives of the human resource  
18 departments of both large and small employers  
19 that have successfully promoted breastfeeding  
20 and breastmilk pumping support at work.

21 (c) PERIOD OF APPOINTMENT; VACANCIES.—Mem-  
22 bers shall be appointed for the life of the Task Force. Any  
23 vacancy in the Task Force shall not affects its powers,  
24 but shall be filled in the same manner as the original ap-  
25 pointment.

1 (d) CHAIR.—The Task Force shall be chaired jointly  
2 by the Secretary of Health and Human Services and the  
3 Secretary of Labor, or their designees.

4 (e) DUTIES OF THE TASK FORCE.—

5 (1) EXAMINATION.—Consistent with the De-  
6 partment of Health and Human Services Blueprint  
7 for Action on Breastfeeding (2000), the Task Force  
8 shall examine the following issues:

9 (A) The challenges that mothers face with  
10 continuing breastfeeding when the mothers re-  
11 turn to work after giving birth.

12 (B) The challenges that employers face in  
13 accommodating mothers who seek to continue  
14 to breastfeed or to express milk when the moth-  
15 ers re-enter the workforce, including different  
16 challenges that mothers of varying socio-eco-  
17 nomic status and in different professions may  
18 face.

19 (C) The benefits that accrue to mothers,  
20 babies, and to employers when mothers are able  
21 to continue to breastfeed or to express  
22 breastmilk at work after the mothers have re-  
23 entered the workforce.

24 (D) Federal and State statutes that may  
25 have the effect of reducing breastfeeding and

1 breastfeeding retention rates among working  
2 mothers.

3 (2) REPORTS.—

4 (A) IN GENERAL.—Not later than 1 year  
5 after the date of enactment of this section, the  
6 Task Force shall issue a public report with rec-  
7 ommendations on the following:

8 (i) Steps that can be taken to promote  
9 breastfeeding among working mothers and  
10 to remove barriers to breastfeeding among  
11 working mothers.

12 (ii) Potential ways in which the Fed-  
13 eral Government can work with employers  
14 to promote breastfeeding among working  
15 mothers.

16 (iii) Areas in which changes to exist-  
17 ing Federal, State, or local laws would  
18 likely have the effect of making it easier  
19 for working mothers to breastfeed or would  
20 remove impediments to breastfeeding that  
21 currently exist in such laws.

22 (iv) Whether or not increased rates of  
23 breastfeeding among working mothers  
24 would likely have the result of reducing  
25 health care costs among such mothers and

1           their children, and, in particular, whether  
2           increased rates of breastfeeding would be  
3           likely to result in lower Federal expendi-  
4           tures on health care for such mothers and  
5           their children.

6           (v) Areas in which the Federal Gov-  
7           ernment, through additional appropria-  
8           tions, increased efforts by Federal agen-  
9           cies, or changes to existing Federal law,  
10          can and should increase the Federal Gov-  
11          ernment's efforts to promote breastfeeding  
12          among working mothers.

13          (B) COPY TO CONGRESS.—Upon comple-  
14          tion of the report described in subparagraph  
15          (A), the Task Force shall submit a copy of the  
16          report to the Committee on Health, Education,  
17          Labor, and Pensions of the Senate, the Com-  
18          mittee on Appropriations of the Senate, the  
19          Committee on Education and the Workforce of  
20          the House of Representatives, and the Com-  
21          mittee on Appropriations of the House of Rep-  
22          resentatives.

23          (f) POWERS OF THE TASK FORCE.—

24           (1) HEARINGS.—The Task Force may hold  
25          such hearings, sit and act at such times and places,

1 take such testimony, and receive such evidence as  
2 the Task Force considers advisable to carry out this  
3 section.

4 (2) INFORMATION FROM FEDERAL AGENCIES.—

5 The Task Force may secure directly from any Fed-  
6 eral department or agency such information as the  
7 Task Force considers necessary to carry out this  
8 section. Upon request of the Chair of the Task  
9 Force, the head of such department or agency shall  
10 furnish such information to the task Force.

11 (3) POSTAL SERVICES.—The Task Force may

12 use the United States mails in the same manner and  
13 under the same conditions as other departments and  
14 agencies of the Federal Government.

15 (4) GIFTS.—The Task Force may accept, use,  
16 and dispose of gifts or donations of services or prop-  
17 erty.

18 (g) OPERATING EXPENSES.—The operating expenses

19 of the Task Force, including travel expenses for members  
20 of the Task Force, shall be paid for from the general oper-  
21 ating expenses funds of the Secretary of Health and  
22 Human Services and the Secretary of Labor.

1 **SEC. 217. LACTATION ACCOMMODATION AND BREASTFEED-**  
 2 **ING PROMOTION AT WORK.**

3 (a) BREASTFEEDING AT WORK GENERAL REQUIRE-  
 4 MENTS.—The Family and Medical Leave Act of 1993 (29  
 5 U.S.C. 2611 et seq.) is amended by inserting after title  
 6 IV the following:

7 **“TITLE V—LACTATION PERIODS**  
 8 **AND FACILITIES**

9 **“SEC. 501. DEFINITIONS.**

10 “In this title:

11 “(1) ELIGIBLE CHILD.—The term ‘eligible  
 12 child’, used with respect to an eligible employee,  
 13 means a son or daughter (as defined in section 101)  
 14 who is a child of the employee.

15 “(2) ELIGIBLE EMPLOYEE.—The term ‘eligible  
 16 employee’ has the meaning given the term in section  
 17 101, except that the limitations established in  
 18 clauses (i) and (ii) of section 101(2)(A) shall not  
 19 apply. The term ‘eligible employee’ does not include  
 20 any Federal officer or employee covered under sub-  
 21 chapter VII of chapter 63 of title 5, United States  
 22 Code, but does include a State employee described in  
 23 section 304(a) of the Government Employee Rights  
 24 Act of 1991 (42 U.S.C. 2000e–16c(a)).

25 “(3) EMPLOYER.—The term ‘employer’ has the  
 26 meaning given the term in section 101, and includes

1 an entity employing a State employee described in  
2 section 304(a) of the Government Employee Rights  
3 Act of 1991.

4 “(4) UNDUE HARDSHIP.—The term ‘undue  
5 hardship’ means an action requiring significant dif-  
6 ficulty or expense.

7 **“SEC. 502. LACTATION PERIODS.**

8 “(a) IN GENERAL.—An employer shall provide an ap-  
9 propriate number of lactation periods, of reasonable  
10 length, for an eligible employee during each workday, to  
11 permit the employee to express milk for, or breastfeed, an  
12 eligible child.

13 “(b) BREAK TIME.—

14 “(1) UNPAID BREAK PERIODS.—Except as pro-  
15 vided in paragraph (2), the lactation periods may  
16 consist of unpaid break periods.

17 “(2) COMBINED BREAK PERIODS.—To the ex-  
18 tent practicable, an employer shall combine break  
19 periods by providing the lactation periods for an eli-  
20 gible employee at the same time as the employer  
21 provides other break periods for the employee. If the  
22 employer combines the break periods, the employee  
23 shall receive the same compensation for a combined  
24 break period as the employee would have received for  
25 an original break period.

1 “(c) LIMITATION.—

2 “(1) UNDUE HARDSHIP.—An employer shall  
3 not be required to provide a lactation period under  
4 this section if the employer demonstrates that pro-  
5 viding the period would impose an undue hardship  
6 on the employer, subject to paragraph (2).

7 “(2) REASONABLE EFFORTS.—An employer  
8 who maintains that an undue hardship would result  
9 from providing a lactation period to an eligible em-  
10 ployee shall demonstrate that the employer made  
11 reasonable efforts to comply with subsections (a)  
12 and (b).

13 **“SEC. 503. LACTATION FACILITIES.**

14 “(a) IN GENERAL.—An employer shall provide an ap-  
15 propriate lactation facility for an eligible employee, within  
16 a reasonable distance from the employee’s usual work loca-  
17 tion, to permit the employee to express milk for, or  
18 breastfeed, an eligible child.

19 “(b) LIMITATION.—

20 “(1) UNDUE HARDSHIP.—An employer shall  
21 not be required to provide a lactation facility under  
22 this section if the employer demonstrates that pro-  
23 viding the facility would impose an undue hardship  
24 on the employer, subject to paragraph (2).

1           “(2) REASONABLE EFFORTS.—An employer  
2           who maintains that an undue hardship would result  
3           from providing a lactation facility to an eligible em-  
4           ployee shall demonstrate that the employer made  
5           reasonable efforts to comply with subsection (a).

6   **“SEC. 504. ENFORCEMENT AND REMEDIES.**

7           “(a) ENFORCEMENT PROCESS.—The Secretary of  
8           Labor shall establish or designate a process through  
9           which—

10           “(1) an individual may file a complaint regard-  
11           ing a violation of this title; and

12           “(2) an office designated by the Secretary in  
13           the Department of Labor shall receive, investigate,  
14           make determinations regarding, and administer rem-  
15           edies with respect to such complaints.

16           “(b) REMEDIES.—The Secretary of Labor shall es-  
17           tablish remedies for violations of this title.

18           “(c) GOVERNMENT ACCOUNTABILITY OFFICE AND  
19           LIBRARY OF CONGRESS.—In the case of the Government  
20           Accountability Office and the Library of Congress, the au-  
21           thority of the Secretary of Labor under this title shall be  
22           exercised respectively by the Comptroller General of the  
23           United States and the Librarian of Congress.

1 **“SEC. 505. REGULATIONS.**

2 “The Secretary of Labor shall issue regulations to  
3 carry out this title, including provisions prescribing—

4 “(1) an appropriate number and reasonable  
5 length of lactation periods, for purposes of section  
6 502;

7 “(2) an appropriate lactation facility (which  
8 shall not be a restroom or a portion of a restroom)  
9 and a reasonable distance from a usual work loca-  
10 tion, for purposes of section 503; and

11 “(3) the process and remedies described in sec-  
12 tion 504.”.

13 (b) **BREASTFEEDING AT WORK FOR CIVIL SERVICE**  
14 **EMPLOYEES.**—Chapter 63 of title 5, United States Code,  
15 is amended by adding at the end:

16 “**SUBCHAPTER VII—LACTATION PERIODS AND**  
17 **FACILITIES**

18 **“§ 6392. Definitions**

19 “For the purpose of this subchapter—

20 “(1) the term ‘eligible child’, used with respect  
21 to an employee, means a son or daughter (as defined  
22 in section 6381) who is a child of the employee;

23 “(2) the term ‘employee’ means any individual  
24 who is an ‘employee’, as defined by section 6301(2),  
25 including any individual employed in a position re-  
26 ferred to in clause (v) or (ix) of section 6301(2), but

1 excluding any individual employed by the govern-  
2 ment of the District of Columbia, any individual em-  
3 ployed on a temporary or intermittent basis, and any  
4 employee of the General Accounting Office or the Li-  
5 brary of Congress; and

6 “(3) the term ‘undue hardship’ means an action  
7 requiring significant difficulty or expense.

8 **“§ 6392A. Lactation periods**

9 “(a) An employing agency shall provide an appro-  
10 priate number of lactation periods, of reasonable length,  
11 for an employee during each workday, to permit the em-  
12 ployee to express milk for, or breastfeed, an eligible child.

13 “(b)(1) Except as provided in paragraph (2), the lac-  
14 tation periods may consist of unpaid break periods.

15 “(2) To the extent practicable, an employing agency  
16 shall combine break periods by providing the lactation pe-  
17 riods for an employee at the same time as the employing  
18 agency provides other break periods for the employee. If  
19 the employing agency combines the break periods, the em-  
20 ployee shall receive the same compensation for a combined  
21 break period as the employee would have received for an  
22 original break period.

23 “(c)(1) An employing agency shall not be required to  
24 provide a lactation period under this section if the employ-  
25 ing agency demonstrates that providing the period would

1 impose an undue hardship on the employing agency, sub-  
2 ject to paragraph (2).

3 “(2) An employing agency who maintains that an  
4 undue hardship would result from providing a lactation  
5 period to an employee shall demonstrate that the employ-  
6 ing agency made reasonable efforts to comply with sub-  
7 sections (a) and (b).

8 **“§ 6392B. Lactation facilities**

9 “(a) An employing agency shall provide an appro-  
10 priate lactation facility for an employee, within a reason-  
11 able distance from the employee’s usual work location, to  
12 permit the employee to express milk for, or breastfeed, an  
13 eligible child.

14 “(b)(1) An employing agency shall not be required  
15 to provide a lactation facility under this section if the em-  
16 ploying agency demonstrates that providing the facility  
17 would impose an undue hardship on the employing agency,  
18 subject to paragraph (2).

19 “(2) An employing agency who maintains that an  
20 undue hardship would result from providing a lactation  
21 facility to an employee shall demonstrate that the employ-  
22 ing agency made reasonable efforts to comply with sub-  
23 section (a).

1 **“§ 6392C. Remedies**

2 “(a) The Office of Personnel Management shall es-  
3 tablish or designate a process through which—

4 “(1) an individual may file a complaint regard-  
5 ing a violation of this subchapter; and

6 “(2) an office designated by the Director of the  
7 Office of Personnel Management shall receive, inves-  
8 tigate, make determinations regarding, and admin-  
9 ister remedies with respect to such complaints.

10 “(b) The Office of Personnel Management shall es-  
11 tablish remedies for violations of this subchapter.

12 **“§ 6392D. Regulations**

13 “(a) The Office of Personnel Management shall issue  
14 regulations to carry out this subchapter, including provi-  
15 sions prescribing—

16 “(1) an appropriate number and reasonable  
17 length of lactation periods, for purposes of section  
18 6392A;

19 “(2) an appropriate lactation facility (which  
20 shall not be a restroom or a portion of a restroom)  
21 and a reasonable distance from a usual work loca-  
22 tion, for purposes of section 6392B; and

23 “(3) the process and remedies described in sec-  
24 tion 6392C.

25 “(b) The regulations prescribed under this sub-  
26 chapter shall, to the extent appropriate, be consistent with

1 the regulations prescribed by the Secretary of Labor to  
 2 carry out title V of the Family and Medical Leave Act  
 3 of 1993.”.

4 (c) BREASTFEEDING AT WORK FOR CONGRESSIONAL  
 5 EMPLOYEES.—

6 (1) APPLICATION OF LAWS.—Section 102(a) of  
 7 the Congressional Accountability Act of 1995 (2  
 8 U.S.C. 1302(a)) is amended—

9 (A) in paragraph (5), by striking “The”  
 10 and inserting “Title I of the”; and

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

12 “(12) Title V of the Family and Medical Leave  
 13 Act of 1993.”.

14 (2) EXTENSION OF RIGHTS AND PROTEC-  
 15 TIONS.—Part A of title II of the Congressional Ac-  
 16 countability Act of 1995 (2 U.S.C. 1311 et seq.) is  
 17 amended—

18 (A) in section 202 (2 U.S.C. 1312), by  
 19 striking the title and inserting the following:

20 **“SEC. 202. RIGHTS AND PROTECTIONS UNDER TITLE I OF**  
 21 **THE FAMILY AND MEDICAL LEAVE ACT OF**  
 22 **1993.”;**

23 (B) by redesignating section 207 as section  
 24 208; and

1 (C) by inserting after section 206 the fol-  
2 lowing:

3 **“SEC. 207. RIGHTS AND PROTECTIONS UNDER TITLE V OF**  
4 **THE FAMILY AND MEDICAL LEAVE ACT OF**  
5 **1993.**

6 “(a) BREASTFEEDING RIGHTS AND PROTECTIONS  
7 PROVIDED.—

8 “(1) IN GENERAL.—The rights and protections  
9 established by sections 501 through 503 of the Fam-  
10 ily and Medical Leave Act of 1993 shall apply to  
11 covered employees.

12 “(2) DEFINITION.—For purposes of the appli-  
13 cation described in paragraph (1)—

14 “(A) the term ‘employer’ as used in the  
15 Family and Medical Leave Act of 1993 means  
16 any employing office; and

17 “(B) the term ‘eligible employee’ as used  
18 in the Family and Medical Leave Act of 1993  
19 means a covered employee who has been em-  
20 ployed in any employing office.

21 “(b) REMEDY.—The remedy for a violation of sub-  
22 section (a) shall be such remedy as would be appropriate  
23 if awarded under section 504 of the Family and Medical  
24 Leave Act of 1993.

25 “(c) REGULATIONS.—

1           “(1) IN GENERAL.—The Board shall, pursuant  
2 to section 304, issue regulations to implement the  
3 rights and protections under this section.

4           “(2) AGENCY REGULATIONS.—The regulations  
5 issued under paragraph (1) shall be the same as  
6 substantive regulations promulgated by the Sec-  
7 retary of Labor to implement the statutory provi-  
8 sions referred to in subsections (a) and (b), except  
9 insofar as the Board may determine, for good cause  
10 shown and stated together with the issued regula-  
11 tions, that a modification of such promulgated regu-  
12 lations would be more effective for the implementa-  
13 tion of the rights and protections under this sec-  
14 tion.”.

15           “(3) TABLE OF CONTENTS.—The table of con-  
16 tents for the Congressional Accountability Act of  
17 1995 is amended by striking the item relating to  
18 section 207 and inserting the following:

“Sec. 207. Rights and protections under title V of the Family and Medical  
Leave Act of 1993.

“Sec. 208. Prohibition of intimidation or reprisal.”.

19           “(d) BREASTFEEDING AT WORK FOR EMPLOYEES IN  
20 PRESIDENTIAL OFFICES.—

21           “(1) APPLICATION OF LAWS.—Section 402 of  
22 title 3, United States Code, is amended—

23                   “(A) in paragraph (5), by striking “The”  
24                   and inserting “Title I of the”; and

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

2 “(12) Title V of the Family and Medical Leave  
3 Act of 1993.”.

4 (2) EXTENSION OF RIGHTS AND PROTEC-  
5 TIONS.—Subchapter II of chapter 5 of title 3,  
6 United States Code, is amended—

7 (A) in section 412, by striking the title and  
8 inserting the following:

9 **“SEC. 412. RIGHTS AND PROTECTIONS UNDER TITLE I OF**  
10 **THE FAMILY AND MEDICAL LEAVE ACT OF**  
11 **1993.”;**

12 (B) by redesignating section 417 as section  
13 418; and

14 (C) by inserting after section 416 the fol-  
15 lowing:

16 **“SEC. 417. RIGHTS AND PROTECTIONS UNDER TITLE V OF**  
17 **THE FAMILY AND MEDICAL LEAVE ACT OF**  
18 **1993.**

19 “(a) BREASTFEEDING RIGHTS AND PROTECTIONS  
20 PROVIDED.—

21 “(1) IN GENERAL.—The rights and protections  
22 established by sections 501 through 503 of the Fam-  
23 ily and Medical Leave Act of 1993 shall apply to  
24 covered employees.

1           “(2) DEFINITION.—For purposes of the appli-  
2           cation described in paragraph (1)—

3                   “(A) the term ‘employer’ as used in the  
4           Family and Medical Leave Act of 1993 means  
5           any employing office; and

6                   “(B) the term ‘eligible employee’ as used  
7           in the Family and Medical Leave Act of 1993  
8           means a covered employee.

9           “(b) REMEDY.—The remedy for a violation of sub-  
10          section (a) shall be such remedy as would be appropriate  
11          if awarded under section 504 of the Family and Medical  
12          Leave Act of 1993.

13          “(c) REGULATIONS.—

14                   “(1) IN GENERAL.—The President, or the des-  
15          ignee of the President, shall issue regulations to im-  
16          plement this section.

17                   “(2) AGENCY REGULATIONS.—The regulations  
18          issued under paragraph (1) shall be the same as  
19          substantive regulations promulgated by the Sec-  
20          retary of Labor to implement the statutory provi-  
21          sions referred to in subsections (a) and (b)—

22                           “(A) except to the extent that the Presi-  
23          dent or designee may determine, for good cause  
24          shown and stated together with the issued regu-  
25          lations, that a modification of such promulgated

1 regulations would be more effective for the im-  
2 plementation of the rights and protections  
3 under this section; and

4 “(B) except that the President or designee  
5 may, at the discretion of the President or des-  
6 ignee, issue regulations to implement a provi-  
7 sion of subchapter VII of chapter 63 of title 5,  
8 United States Code, that applies to employees  
9 in the executive branch of the Federal Govern-  
10 ment in lieu of an analogous statutory provision  
11 referred to in subsection (a) or (b), if the  
12 issuance of such regulations—

13 “(i) would be equally effective for the  
14 implementation of the rights and protec-  
15 tions under this section; and

16 “(ii) would promote uniformity in the  
17 application of Federal law to employees in  
18 the executive branch of the Federal Gov-  
19 ernment.”.

20 (3) CONFORMING AMENDMENT.—Section  
21 411(e) of title 3, United States Code, is amended by  
22 striking “417” and inserting “418”.

23 (4) TABLE OF CONTENTS.—The table of con-  
24 tents for chapter 5 of title 3, United States Code,

1 is amended by striking the item relating to section  
2 417 and inserting the following:

“417. Rights and protections under title V of the Family and Medical Leave Act of 1993.

“418. Prohibition of intimidation or reprisal.”.

3 (e) EFFECTIVE DATES.—

4 (1) IN GENERAL.—Except as provided in para-  
5 graph (2), this section and the amendments made by  
6 this section take effect 18 months after the date of  
7 enactment of this Act.

8 (2) REGULATIONS.—Section 505 of the Family  
9 and Medical Leave Act of 1993 (as added by sub-  
10 section (a)), section 6392D of title 5, United States  
11 Code (as added by subsection (b)), section 207(c) of  
12 the Congressional Accountability Act of 1995 (as  
13 added by subsection (c)), and section 417(c) of title  
14 3, United States Code (as added by subsection (d))  
15 take effect on the date of enactment of this Act.

16 **Subtitle C—Family Smoking**  
17 **Prevention and Control**

18 **SEC. 221. SHORT TITLE.**

19 This subtitle may be cited as the “Family Smoking  
20 Prevention and Tobacco Control Act”.

21 **SEC. 222. FINDINGS.**

22 The Congress finds the following:

23 (1) The use of tobacco products by the Nation’s  
24 children is a pediatric disease of considerable pro-

1 portions that results in new generations of tobacco-  
2 dependent children and adults.

3 (2) A consensus exists within the scientific and  
4 medical communities that tobacco products are in-  
5 herently dangerous and cause cancer, heart disease,  
6 and other serious adverse health effects.

7 (3) Nicotine is an addictive drug.

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

11 (5) Tobacco advertising and marketing con-  
12 tribute significantly to the use of nicotine-containing  
13 tobacco products by adolescents.

14 (6) Because past efforts to restrict advertising  
15 and marketing of tobacco products have failed ade-  
16 quately to curb tobacco use by adolescents, com-  
17 prehensive restrictions on the sale, promotion, and  
18 distribution of such products are needed.

19 (7) Federal and State governments have lacked  
20 the legal and regulatory authority and resources  
21 they need to address comprehensively the public  
22 health and societal problems caused by the use of to-  
23 bacco products.

24 (8) Federal and State public health officials,  
25 the public health community, and the public at large

1 recognize that the tobacco industry should be subject  
2 to ongoing oversight.

3 (9) Under article I, section 8 of the Constitu-  
4 tion, the Congress is vested with the responsibility  
5 for regulating interstate commerce and commerce  
6 with Indian tribes.

7 (10) The sale, distribution, marketing, adver-  
8 tising, and use of tobacco products are activities in  
9 and substantially affecting interstate commerce be-  
10 cause they are sold, marketed, advertised, and dis-  
11 tributed in interstate commerce on a nationwide  
12 basis, and have a substantial effect on the Nation's  
13 economy.

14 (11) The sale, distribution, marketing, adver-  
15 tising, and use of such products substantially affect  
16 interstate commerce through the health care and  
17 other costs attributable to the use of tobacco prod-  
18 ucts.

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

1           (13) Tobacco use is the foremost preventable  
2           cause of premature death in America. It causes over  
3           400,000 deaths in the United States each year and  
4           approximately 8,600,000 Americans have chronic ill-  
5           nesses related to smoking.

6           (14) Reducing the use of tobacco by minors by  
7           50 percent would prevent well over 10,000,000 of to-  
8           day's children from becoming regular, daily smokers,  
9           saving over 3,000,000 of them from premature  
10          death due to tobacco induced disease. Such a reduc-  
11          tion in youth smoking would also result in approxi-  
12          mately \$75,000,000,000 in savings attributable to  
13          reduced health care costs.

14          (15) Advertising, marketing, and promotion of  
15          tobacco products have been especially directed to at-  
16          tract young persons to use tobacco products and  
17          these efforts have resulted in increased use of such  
18          products by youth. Past efforts to oversee these ac-  
19          tivities have not been successful in adequately pre-  
20          venting such increased use.

21          (16) In 2002, the tobacco industry spent more  
22          than \$12,466,000,000 to attract new users, retain  
23          current users, increase current consumption, and  
24          generate favorable long-term attitudes toward smok-  
25          ing and tobacco use.

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

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

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

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

19           (21) The use of tobacco products in motion pic-  
20 tures and other mass media glamorizes its use for  
21 young people and encourages them to use tobacco  
22 products.

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

1 tobacco products including tobacco use by young peo-  
2 ple.

3 (23) Children are more influenced by tobacco  
4 advertising than adults, they smoke the most adver-  
5 tised brands.

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

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

15 (26) Restrictions on advertising are necessary  
16 to prevent unrestricted tobacco advertising from un-  
17 dermining legislation prohibiting access to young  
18 people and providing for education about tobacco  
19 use.

20 (27) International experience shows that adver-  
21 tising regulations that are stringent and comprehen-  
22 sive have a greater impact on overall tobacco use  
23 and young people's use than weaker or less com-  
24 prehensive ones.

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

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

8           (30) The final regulations promulgated by the  
9           Secretary of Health and Human Services in the Au-  
10          gust 28, 1996, issue of the Federal Register (61  
11          Fed. Reg. 44615–44618) for inclusion as part 897  
12          of title 21, Code of Federal Regulations, are con-  
13          sistent with the First Amendment to the United  
14          States Constitution and with the standards set forth  
15          in the amendments made by this subtitle for the reg-  
16          ulation of tobacco products by the Food and Drug  
17          Administration and the restriction on the sale and  
18          distribution, including access to and the advertising  
19          and promotion of, tobacco products contained in  
20          such regulations are substantially related to accom-  
21          plishing the public health goals of this Act.

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

1       rettes and smokeless tobacco and in preventing the  
2       life-threatening health consequences associated with  
3       tobacco use. An overwhelming majority of Americans  
4       who use tobacco products begin using such products  
5       while they are minors and become addicted to the  
6       nicotine in those products before reaching the age of  
7       18. Tobacco advertising and promotion plays a cru-  
8       cial role in the decision of these minors to begin  
9       using tobacco products. Less restrictive and less  
10      comprehensive approaches have not and will not be  
11      effective in reducing the problems addressed by such  
12      regulations. The reasonable restrictions on the ad-  
13      vertising and promotion of tobacco products con-  
14      tained in such regulations will lead to a significant  
15      decrease in the number of minors using and becom-  
16      ing addicted to those products.

17           (32) The regulations described in paragraph  
18      (30) impose no more extensive restrictions on com-  
19      munication by tobacco manufacturers and sellers  
20      than are necessary to reduce the number of children  
21      and adolescents who use cigarettes and smokeless to-  
22      bacco and to prevent the life-threatening health con-  
23      sequences associated with tobacco use. Such regula-  
24      tions are narrowly tailored to restrict those adver-  
25      tising and promotional practices which are most like-

1 ly to be seen or heard by youth and most likely to  
2 entice them into tobacco use, while affording tobacco  
3 manufacturers and sellers ample opportunity to con-  
4 vey information about their products to adult con-  
5 sumers.

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

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

12 (35) Tobacco products have been used to facili-  
13 tate and finance criminal activities both domestically  
14 and internationally. Illicit trade of tobacco products  
15 has been linked to organized crime and terrorist  
16 groups.

17 (36) It is essential that the Food and Drug Ad-  
18 ministration review products sold or distributed for  
19 use to reduce risks or exposures associated with to-  
20 bacco products and that it be empowered to review  
21 any advertising and labeling for such products. It is  
22 also essential that manufacturers, prior to marketing  
23 such products, be required to demonstrate that such  
24 products will meet a series of rigorous criteria, and  
25 will benefit the health of the population as a whole,

1 taking into account both users of tobacco products  
2 and persons who do not currently use tobacco prod-  
3 ucts.

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

21 (38) As the National Cancer Institute has  
22 found, many smokers mistakenly believe that “low  
23 tar” and “light” cigarettes cause fewer health prob-  
24 lems than other cigarettes. As the National Cancer  
25 Institute has also found, mistaken beliefs about the

1 health consequences of smoking “low tar” and  
2 “light” cigarettes can reduce the motivation to quit  
3 smoking entirely and thereby lead to disease and  
4 death.

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

10 (40) The dangers of products sold or distrib-  
11 uted as modified risk tobacco products that do not  
12 in fact reduce risk are so high that there is a com-  
13 pelling governmental interest in insuring that state-  
14 ments about modified risk tobacco products are com-  
15 plete, accurate, and relate to the overall disease risk  
16 of the product.

17 (41) As the Federal Trade Commission has  
18 found, consumers have misinterpreted advertise-  
19 ments in which one product is claimed to be less  
20 harmful than a comparable product, even in the  
21 presence of disclosures and advisories intended to  
22 provide clarification.

23 (42) Permitting manufacturers to make unsub-  
24 stantiated statements concerning modified risk to-  
25 bacco products, whether express or implied, even if

1 accompanied by disclaimers would be detrimental to  
2 the public health.

3 (43) The only way to effectively protect the  
4 public health from the dangers of unsubstantiated  
5 modified risk tobacco products is to empower the  
6 Food and Drug Administration to require that prod-  
7 ucts that tobacco manufacturers sold or distributed  
8 for risk reduction be approved in advance of mar-  
9 keting, and to require that the evidence relied on to  
10 support approval of these products is rigorous.

11 **SEC. 223. PURPOSE.**

12 The purposes of this Act are—

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

20 (2) to ensure that the Food and Drug Adminis-  
21 tration has the authority to address issues of par-  
22 ticular concern to public health officials, especially  
23 the use of tobacco by young people and dependence  
24 on tobacco;

1           (3) to authorize the Food and Drug Adminis-  
2           tration to set national standards controlling the  
3           manufacture of tobacco products and the identity,  
4           public disclosure, and amount of ingredients used in  
5           such products;

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

10          (5) to vest the Food and Drug Administration  
11          with the authority to regulate the levels of tar, nico-  
12          tine, and other harmful components of tobacco prod-  
13          ucts;

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

20          (7) to continue to permit the sale of tobacco  
21          products to adults in conjunction with measures to  
22          ensure that they are not sold or accessible to under-  
23          age purchasers;

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

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

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

6 **SEC. 224. SCOPE AND EFFECT.**

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

9           (1) establish a precedent with regard to any  
10          other industry, situation, circumstance, or legal ac-  
11          tion; or

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

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

22 **SEC. 225. SEVERABILITY.**

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

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

5 **PART I—AUTHORITY OF THE FOOD AND DRUG**  
6 **ADMINISTRATION**

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

9 (a) DEFINITION OF TOBACCO PRODUCTS.—Section  
10 201 of the Federal Food, Drug, and Cosmetic Act (21  
11 U.S.C. 321) is amended by adding at the end the fol-  
12 lowing:

13 “(m)(1) The term ‘tobacco product’ means any prod-  
14 uct made or derived from tobacco that is intended for  
15 human consumption, including any component, part, or  
16 accessory of a tobacco product (except for raw materials  
17 other than tobacco used in manufacturing a component,  
18 part, or accessory of a tobacco product).

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

20 “(A) a product in the form of conventional food  
21 (including water and chewing gum), a product rep-  
22 resented for use as or for use in a conventional food,  
23 or a product that is intended for ingestion in cap-  
24 sule, tablet, softgel, or liquid form; or

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

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

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

11           (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—  
12 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 301 et seq.) is amended—

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

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

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

18           **“CHAPTER IX—TOBACCO PRODUCTS**

19           **“SEC. 900. DEFINITIONS.**

20           “In this chapter:

21           “(1) ADDITIVE.—The term ‘additive’ means  
22 any substance the intended use of which results or  
23 may reasonably be expected to result, directly or in-  
24 directly, in its becoming a component or otherwise  
25 affecting the characteristic of any tobacco product

1 (including any substances intended for use as a fla-  
2 voring, coloring or in producing, manufacturing,  
3 packing, processing, preparing, treating, packaging,  
4 transporting, or holding), except that such term does  
5 not include tobacco or a pesticide chemical residue  
6 in or on raw tobacco or a pesticide chemical.

7 “(2) BRAND.—The term ‘brand’ means a vari-  
8 ety of tobacco product distinguished by the tobacco  
9 used, tar content, nicotine content, flavoring used,  
10 size, filtration, or packaging, logo, registered trade-  
11 mark or brand name, identifiable pattern of colors,  
12 or any combination of such attributes.

13 “(3) CIGARETTE.—The term ‘cigarette’ has the  
14 meaning given that term by section 3(1) of the Fed-  
15 eral Cigarette Labeling and Advertising Act (15  
16 U.S.C. 1332(1)), but also includes tobacco, in any  
17 form, that is functional in the product, which, be-  
18 cause of its appearance, the type of tobacco used in  
19 the filler, or its packaging and labeling, is likely to  
20 be offered to, or purchased by, consumers as a ciga-  
21 rette or as roll-your-own tobacco.

22 “(4) CIGARETTE TOBACCO.—The term ‘ciga-  
23 rette tobacco’ means any product that consists of  
24 loose tobacco that is intended for use by consumers  
25 in a cigarette. Unless otherwise stated, the require-

1       ments for cigarettes shall also apply to cigarette to-  
2       bacco.

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

7               “(6) COUNTERFEIT TOBACCO PRODUCT.—The  
8       term ‘counterfeit tobacco product’ means a tobacco  
9       product (or the container or labeling of such a prod-  
10      uct) that, without authorization, bears the trade-  
11      mark, trade name, or other identifying mark, im-  
12      print or device, or any likeness thereof, of a tobacco  
13      product listed in a registration under section  
14      905(i)(1).

15              “(7) DISTRIBUTOR.—The term ‘distributor’ as  
16      regards a tobacco product means any person who  
17      furthers the distribution of a tobacco product,  
18      whether domestic or imported, at any point from the  
19      original place of manufacture to the person who sells  
20      or distributes the product to individuals for personal  
21      consumption. Common carriers are not considered  
22      distributors for purposes of this chapter.

23              “(8) ILLICIT TRADE.—The term ‘illicit trade’  
24      means any practice or conduct prohibited by law  
25      which relates to production, shipment, receipt, pos-

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

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

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

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

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

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

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

7           “(15) SMOKE CONSTITUENT.—The term ‘smoke  
8           constituent’ means any chemical or chemical com-  
9           pound in mainstream or sidestream tobacco smoke  
10          that either transfers from any component of the cig-  
11          arette to the smoke or that is formed by the combus-  
12          tion or heating of tobacco, additives, or other compo-  
13          nent of the tobacco product.

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

19          “(17) STATE.—The term ‘State’ means any  
20          State of the United States and, for purposes of this  
21          chapter, includes the District of Columbia, the Com-  
22          monwealth of Puerto Rico, Guam, the Virgin Is-  
23          lands, American Samoa, Wake Island, Midway Is-  
24          lands, Kingman Reef, Johnston Atoll, the Northern

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

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

6 “(A) manufactures, fabricates, assembles,  
7 processes, or labels a tobacco product; or

8 “(B) imports a finished cigarette or  
9 smokeless tobacco product for sale or distribu-  
10 tion in the United States.

11 “(19) UNITED STATES.—The term ‘United  
12 States’ means the 50 States of the United States of  
13 America and the District of Columbia, the Common-  
14 wealth of Puerto Rico, Guam, the Virgin Islands,  
15 American Samoa, Wake Island, Midway Islands,  
16 Kingman Reef, Johnston Atoll, the Northern Mar-  
17 iana Islands, and any other trust territory or posses-  
18 sion of the United States.

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

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

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

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

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

7 “(b) APPLICABILITY.—This chapter shall apply to all  
8 tobacco products subject to the regulations referred to in  
9 section 232 of the Family Smoking Prevention and To-  
10 bacco Control Act, and to any other tobacco products that  
11 the Secretary by regulation deems to be subject to this  
12 chapter.

13 “(c) SCOPE.—

14 “(1) IN GENERAL.—Nothing in this chapter, or  
15 any policy issued or regulation promulgated there-  
16 under, or the Family Smoking Prevention and To-  
17 bacco Control Act, shall be construed to affect the  
18 Secretary’s authority over, or the regulation of,  
19 products under this Act that are not tobacco prod-  
20 ucts under chapter V or any other chapter.

21 “(2) LIMITATION OF AUTHORITY.—

22 “(A) IN GENERAL.—The provisions of this  
23 chapter shall not apply to tobacco leaf that is  
24 not in the possession of a manufacturer of to-  
25 bacco products, or to the producers of tobacco

1 leaf, including tobacco growers, tobacco ware-  
2 houses, and tobacco grower cooperatives, nor  
3 shall any employee of the Food and Drug Ad-  
4 ministration have any authority to enter onto a  
5 farm owned by a producer of tobacco leaf with-  
6 out the written consent of such producer.

7 “(B) EXCEPTION.—Notwithstanding any  
8 other provision of this subparagraph, if a pro-  
9 ducer of tobacco leaf is also a tobacco product  
10 manufacturer or controlled by a tobacco prod-  
11 uct manufacturer, the producer shall be subject  
12 to this chapter in the producer’s capacity as a  
13 manufacturer.

14 “(C) RULE OF CONSTRUCTION.—Nothing  
15 in this chapter shall be construed to grant the  
16 Secretary authority to promulgate regulations  
17 on any matter that involves the production of  
18 tobacco leaf or a producer thereof, other than  
19 activities by a manufacturer affecting produc-  
20 tion.

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

22 “A tobacco product shall be deemed to be adulterated  
23 if—

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

1 contaminated by any added poisonous or added dele-  
2 terious substance that may render the product inju-  
3 rious to health;

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

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

11 “(4) it is, or purports to be or is represented  
12 as, a tobacco product which is subject to a tobacco  
13 product standard established under section 907 un-  
14 less such tobacco product is in all respects in con-  
15 formity with such standard;

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

19 “(B) it is in violation of the order approving  
20 such an application;

21 “(6) the methods used in, or the facilities or  
22 controls used for, its manufacture, packing or stor-  
23 age are not in conformity with applicable require-  
24 ments under section 906(e)(1) or an applicable con-

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

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

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

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

7            “(1) if its labeling is false or misleading in any  
8        particular;

9            “(2) if in package form unless it bears a label  
10       containing—

11            “(A) the name and place of business of the  
12       tobacco product manufacturer, packer, or dis-  
13       tributor;

14            “(B) an accurate statement of the quantity  
15       of the contents in terms of weight, measure, or  
16       numerical count;

17            “(C) an accurate statement of the percent-  
18       age of the tobacco used in the product that is  
19       domestically grown tobacco and the percentage  
20       that is foreign grown tobacco; and

21            “(D) the statement required under section  
22       921(a), except that under subparagraph (B)  
23       reasonable variations shall be permitted, and  
24       exemptions as to small packages shall be estab-

1           lished, by regulations prescribed by the Sec-  
2           retary;

3           “(3) if any word, statement, or other informa-  
4           tion required by or under authority of this chapter  
5           to appear on the label or labeling is not prominently  
6           placed thereon with such conspicuousness (as com-  
7           pared with other words, statements or designs in the  
8           labeling) and in such terms as to render it likely to  
9           be read and understood by the ordinary individual  
10          under customary conditions of purchase and use;

11          “(4) if it has an established name, unless its  
12          label bears, to the exclusion of any other nonpropri-  
13          etary name, its established name prominently print-  
14          ed in type as required by the Secretary by regula-  
15          tion;

16          “(5) if the Secretary has issued regulations re-  
17          quiring that its labeling bear adequate directions for  
18          use, or adequate warnings against use by children,  
19          that are necessary for the protection of users unless  
20          its labeling conforms in all respects to such regula-  
21          tions;

22          “(6) if it was manufactured, prepared, propa-  
23          gated, compounded, or processed in any State in an  
24          establishment not duly registered under section  
25          905(b), 905(c), 905(d), or 905(h), if it was not in-

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

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

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

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

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

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

24                   “(B) a brief statement of—

1           “(i) the uses of the tobacco product  
2           and relevant warnings, precautions, side  
3           effects, and contraindications; and

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

15          “(9) if it is a tobacco product subject to a to-  
16          bacco product standard established under section  
17          907, unless it bears such labeling as may be pre-  
18          scribed in such tobacco product standard; or

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

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

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

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

25          The Secretary may, by regulation, require prior approval

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

15 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**  
16 **SECRETARY.**

17 “(a) REQUIREMENT.—Not later than 6 months after  
18 the date of enactment of the Family Smoking Prevention  
19 and Tobacco Control Act, each tobacco product manufac-  
20 turer or importer, or agents thereof, shall submit to the  
21 Secretary the following information:

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

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

3           “(2) A description of the content, delivery, and  
4       form of nicotine in each tobacco product measured  
5       in milligrams of nicotine in accordance with regula-  
6       tions promulgated by the Secretary in accordance  
7       with section 4(a)(4) of the Federal Cigarette Label-  
8       ing and Advertising Act.

9           “(3) A listing of all constituents, including  
10      smoke constituents as applicable, identified by the  
11      Secretary as harmful or potentially harmful to  
12      health in each tobacco product, and as applicable in  
13      the smoke of each tobacco product, by brand and by  
14      quantity in each brand and subbrand. Effective be-  
15      ginning 2 years after the date of enactment of this  
16      chapter, the manufacturer, importer, or agent shall  
17      comply with regulations promulgated under section  
18      916 in reporting information under this paragraph,  
19      where applicable.

20          “(4) All documents developed after the date of  
21      enactment of the Family Smoking Prevention and  
22      Tobacco Control Act that relate to health, toxi-  
23      cological, behavioral, or physiologic effects of current  
24      or future tobacco products, their constituents (in-

1 including smoke constituents), ingredients, compo-  
2 nents, and additives.

3 “(b) DATA SUBMISSION.—At the request of the Sec-  
4 retary, each tobacco product manufacturer or importer of  
5 tobacco products, or agents thereof, shall submit the fol-  
6 lowing:

7 “(1) Any or all documents (including under-  
8 lying scientific information) relating to research ac-  
9 tivities, and research findings, conducted, supported,  
10 or possessed by the manufacturer (or agents thereof)  
11 on the health, toxicological, behavioral, or physio-  
12 logic effects of tobacco products and their constitu-  
13 ents (including smoke constituents), ingredients,  
14 components, and additives.

15 “(2) Any or all documents (including under-  
16 lying scientific information) relating to research ac-  
17 tivities, and research findings, conducted, supported,  
18 or possessed by the manufacturer (or agents thereof)  
19 that relate to the issue of whether a reduction in  
20 risk to health from tobacco products can occur upon  
21 the employment of technology available or known to  
22 the manufacturer.

23 “(3) Any or all documents (including under-  
24 lying scientific or financial information) relating to  
25 marketing research involving the use of tobacco

1 products or marketing practices and the effective-  
2 ness of such practices used by tobacco manufactur-  
3 ers and distributors.

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

7 “(c) TIME FOR SUBMISSION.—

8 “(1) IN GENERAL.—At least 90 days prior to  
9 the delivery for introduction into interstate com-  
10 merce of a tobacco product not on the market on the  
11 date of enactment of the Family Smoking Preven-  
12 tion and Tobacco Control Act, the manufacturer of  
13 such product shall provide the information required  
14 under subsection (a).

15 “(2) DISCLOSURE OF ADDITIVE.—If at any  
16 time a tobacco product manufacturer adds to its to-  
17 bacco products a new tobacco additive or increases  
18 the quantity of an existing tobacco additive, the  
19 manufacturer shall, except as provided in paragraph  
20 (3), at least 90 days prior to such action so advise  
21 the Secretary in writing.

22 “(3) DISCLOSURE OF OTHER ACTIONS.—If at  
23 any time a tobacco product manufacturer eliminates  
24 or decreases an existing additive, or adds or in-  
25 creases an additive that has by regulation been des-

1       ignated by the Secretary as an additive that is not  
2       a human or animal carcinogen, or otherwise harmful  
3       to health under intended conditions of use, the man-  
4       ufacturer shall within 60 days of such action so ad-  
5       vise the Secretary in writing.

6       “(d) DATA LIST.—

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

15              “(2) CONSUMER RESEARCH.—The Secretary  
16      shall conduct periodic consumer research to ensure  
17      that the list published under paragraph (1) is not  
18      misleading to lay persons. Not later than 5 years  
19      after the date of enactment of the Family Smoking  
20      Prevention and Tobacco Control Act, the Secretary  
21      shall submit to the appropriate committees of Con-  
22      gress a report on the results of such research, to-  
23      gether with recommendations on whether such publi-  
24      cation should be continued or modified.

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

12 **“SEC. 905. ANNUAL REGISTRATION.**

13       “(a) DEFINITIONS.—In this section:

14           “(1)       MANUFACTURE,       PREPARATION,  
15       COMPOUNDING, OR PROCESSING.—The term ‘manu-  
16       facture, preparation, compounding, or processing’  
17       shall include repackaging or otherwise changing the  
18       container, wrapper, or labeling of any tobacco prod-  
19       uct package in furtherance of the distribution of the  
20       tobacco product from the original place of manufac-  
21       ture to the person who makes final delivery or sale  
22       to the ultimate consumer or user.

23           “(2) NAME.—The term ‘name’ shall include in  
24       the case of a partnership the name of each partner  
25       and, in the case of a corporation, the name of each

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

3 “(b) REGISTRATION BY OWNERS AND OPERATORS.—

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

10 “(c) REGISTRATION OF NEW OWNERS AND OPERA-

11 TORS.—Every person upon first engaging in the manufac-  
12 ture, preparation, compounding, or processing of a tobacco  
13 product or tobacco products in any establishment owned  
14 or operated in any State by that person shall immediately  
15 register with the Secretary that person’s name, place of  
16 business, and such establishment.

17 “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—

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

24 “(e) UNIFORM PRODUCT IDENTIFICATION SYS-

25 TEM.—The Secretary may by regulation prescribe a uni-

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

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

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

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

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

12 “(i) REGISTRATION INFORMATION.—

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

1           “(A) in the case of a tobacco product con-  
2           tained in the applicable list with respect to  
3           which a tobacco product standard has been es-  
4           tablished under section 907 or which is subject  
5           to section 910, a reference to the authority for  
6           the marketing of such tobacco product and a  
7           copy of all labeling for such tobacco product;

8           “(B) in the case of any other tobacco prod-  
9           uct contained in an applicable list, a copy of all  
10          consumer information and other labeling for  
11          such tobacco product, a representative sampling  
12          of advertisements for such tobacco product,  
13          and, upon request made by the Secretary for  
14          good cause, a copy of all advertisements for a  
15          particular tobacco product; and

16          “(C) if the registrant filing a list has de-  
17          termined that a tobacco product contained in  
18          such list is not subject to a tobacco product  
19          standard established under section 907, a brief  
20          statement of the basis upon which the reg-  
21          istrant made such determination if the Sec-  
22          retary requests such a statement with respect  
23          to that particular tobacco product.

24          “(2) BIENNIAL REPORT OF ANY CHANGE IN  
25          PRODUCT LIST.—Each person who registers with the

1 Secretary under this section shall report to the Sec-  
2 retary once during the month of June of each year  
3 and once during the month of December of each  
4 year the following:

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

14 “(B) If since the date the registrant last  
15 made a report under this paragraph that person  
16 has discontinued the manufacture, preparation,  
17 compounding, or processing for commercial dis-  
18 tribution of a tobacco product included in a list  
19 filed under subparagraph (A) or paragraph (1),  
20 notice of such discontinuance, the date of such  
21 discontinuance, and the identity of its estab-  
22 lished name.

23 “(C) If since the date the registrant re-  
24 ported under subparagraph (B) a notice of dis-  
25 continuance that person has resumed the manu-

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

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

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

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

1 such form and manner as the Secretary shall pre-  
2 scribe)—

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

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

13 “(2) APPLICATION TO CERTAIN POST JUNE 1,  
14 2003 PRODUCTS.—A report under this subsection for  
15 a tobacco product that was first introduced or deliv-  
16 ered for introduction into interstate commerce for  
17 commercial distribution in the United States after  
18 June 1, 2003, and prior to the date that is 15  
19 months after the date of enactment of the Family  
20 Smoking Prevention and Tobacco Control Act shall  
21 be submitted to the Secretary not later than 15  
22 months after such date of enactment.

23 “(3) EXEMPTIONS.—

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

1 this subsection tobacco products that are modi-  
2 fied by adding or deleting a tobacco additive, or  
3 increasing or decreasing the quantity of an ex-  
4 isting tobacco additive, if the Secretary deter-  
5 mines that—

6 “(i) such modification would be a  
7 minor modification of a tobacco product  
8 authorized for sale under this Act;

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

14 “(iii) an exemption is otherwise appro-  
15 priate.

16 “(B) REGULATIONS.—Not later than 9  
17 months after the date of enactment of the Fam-  
18 ily Smoking Prevention and Tobacco Control  
19 Act, the Secretary shall issue regulations to im-  
20 plement this paragraph.

21 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**  
22 **OF TOBACCO PRODUCTS.**

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

1 the applicability of the requirement to the tobacco product  
2 has been changed by action taken under section 907, sec-  
3 tion 910, section 911, or subsection (d) of this section,  
4 and any requirement established by or under section 902,  
5 903, 905, or 909 which is inconsistent with a requirement  
6 imposed on such tobacco product under section 907, sec-  
7 tion 910, section 911, or subsection (d) of this section  
8 shall not apply to such tobacco product.

9       “(b) INFORMATION ON PUBLIC ACCESS AND COM-  
10 MENT.—Each notice of proposed rulemaking under section  
11 907, 908, 909, 910, or 911 or under this section, any  
12 other notice which is published in the Federal Register  
13 with respect to any other action taken under any such sec-  
14 tion and which states the reasons for such action, and  
15 each publication of findings required to be made in con-  
16 nection with rulemaking under any such section shall set  
17 forth—

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

21               “(2) the period within which interested persons  
22       may present their comments on the notice or find-  
23       ings (including the need therefore) orally or in writ-  
24       ing, which period shall be at least 60 days but may  
25       not exceed 90 days unless the time is extended by

1 the Secretary by a notice published in the Federal  
2 Register stating good cause therefore.

3 “(c) LIMITED CONFIDENTIALITY OF INFORMA-  
4 TION.—Any information reported to or otherwise obtained  
5 by the Secretary or the Secretary’s representative under  
6 section 903, 904, 907, 908, 909, 910, 911, or 704, or  
7 under subsection (e) or (f) of this section, which is exempt  
8 from disclosure under subsection (a) of section 552 of title  
9 5, United States Code, by reason of subsection (b)(4) of  
10 that section shall be considered confidential and shall not  
11 be disclosed, except that the information may be disclosed  
12 to other officers or employees concerned with carrying out  
13 this chapter, or when relevant in any proceeding under  
14 this chapter.

15 “(d) RESTRICTIONS.—

16 “(1) IN GENERAL.—The Secretary may by reg-  
17 ulation require restrictions on the sale and distribu-  
18 tion of a tobacco product, including restrictions on  
19 the access to, and the advertising and promotion of,  
20 the tobacco product, if the Secretary determines that  
21 such regulation would be appropriate for the protec-  
22 tion of the public health. The Secretary may by reg-  
23 ulation impose restrictions on the advertising and  
24 promotion of a tobacco product consistent with and  
25 to full extent permitted by the first amendment to

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

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

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

13 No such regulation may require that the sale or dis-  
14 tribution of a tobacco product be limited to the writ-  
15 ten or oral authorization of a practitioner licensed  
16 by law to prescribe medical products.

17 “(2) LABEL STATEMENTS.—The label of a to-  
18 bacco product shall bear such appropriate state-  
19 ments of the restrictions required by a regulation  
20 under subsection (a) as the Secretary may in such  
21 regulation prescribe.

22 “(3) LIMITATIONS.—

23 “(A) IN GENERAL.—No restrictions under  
24 paragraph (1) may—

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

4           “(ii) establish a minimum age of sale  
5           of tobacco products to any person older  
6           than 18 years of age.

7           “(B) MATCHBOOKS.—For purposes of any  
8           regulations issued by the Secretary, matchbooks  
9           of conventional size containing not more than  
10          20 paper matches, and which are customarily  
11          given away for free with the purchase of to-  
12          bacco products shall be considered as adult  
13          written publications which shall be permitted to  
14          contain advertising. Notwithstanding the pre-  
15          ceding sentence, if the Secretary finds that such  
16          treatment of matchbooks is not appropriate for  
17          the protection of the public health, the Sec-  
18          retary may determine by regulation that match-  
19          books shall not be considered adult written pub-  
20          lications.

21          “(e) GOOD MANUFACTURING PRACTICE REQUIRE-  
22          MENTS.—

23                 “(1) METHODS, FACILITIES, AND CONTROLS TO  
24          CONFORM.—

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

18           “(B) REQUIREMENTS.—The Secretary  
19 shall—

20                   “(i) before promulgating any regula-  
21 tion under subparagraph (A), afford the  
22 Tobacco Products Scientific Advisory Com-  
23 mittee an opportunity to submit rec-  
24 ommendations with respect to the regula-  
25 tion proposed to be promulgated;

1           “(ii) before promulgating any regula-  
2           tion under subparagraph (A), afford oppor-  
3           tunity for an oral hearing;

4           “(iii) provide the advisory committee a  
5           reasonable time to make its recommenda-  
6           tion with respect to proposed regulations  
7           under subparagraph (A); and

8           “(iv) in establishing the effective date  
9           of a regulation promulgated under this  
10          subsection, take into account the dif-  
11          ferences in the manner in which the dif-  
12          ferent types of tobacco products have his-  
13          torically been produced, the financial re-  
14          sources of the different tobacco product  
15          manufacturers, and the state of their exist-  
16          ing manufacturing facilities, and shall pro-  
17          vide for a reasonable period of time for  
18          such manufacturers to conform to good  
19          manufacturing practices.

20          “(2) EXEMPTIONS; VARIANCES.—

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

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

3 “(i) in the case of a petition for an ex-  
4 emption from a requirement, set forth the  
5 basis for the petitioner’s determination  
6 that compliance with the requirement is  
7 not required to assure that the tobacco  
8 product will be in compliance with this  
9 chapter;

10 “(ii) in the case of a petition for a  
11 variance from a requirement, set forth the  
12 methods proposed to be used in, and the  
13 facilities and controls proposed to be used  
14 for, the manufacture, packing, and storage  
15 of the tobacco product in lieu of the meth-  
16 ods, facilities, and controls prescribed by  
17 the requirement; and

18 “(iii) contain such other information  
19 as the Secretary shall prescribe.

20 “(B) REFERRAL TO THE TOBACCO PROD-  
21 UCTS SCIENTIFIC ADVISORY COMMITTEE.—The  
22 Secretary may refer to the Tobacco Products  
23 Scientific Advisory Committee any petition sub-  
24 mitted under subparagraph (A). The Tobacco  
25 Products Scientific Advisory Committee shall

1 report its recommendations to the Secretary  
2 with respect to a petition referred to it within  
3 60 days after the date of the petition's referral.

4 Within 60 days after—

5 “(i) the date the petition was sub-  
6 mitted to the Secretary under subpara-  
7 graph (A); or

8 “(ii) the day after the petition was re-  
9 ferred to the Tobacco Products Scientific  
10 Advisory Committee, whichever occurs  
11 later, the Secretary shall by order either  
12 deny the petition or approve it.

13 “(C) APPROVAL.—The Secretary may ap-  
14 prove—

15 “(i) a petition for an exemption for a  
16 tobacco product from a requirement if the  
17 Secretary determines that compliance with  
18 such requirement is not required to assure  
19 that the tobacco product will be in compli-  
20 ance with this chapter; and

21 “(ii) a petition for a variance for a to-  
22 bacco product from a requirement if the  
23 Secretary determines that the methods to  
24 be used in, and the facilities and controls  
25 to be used for, the manufacture, packing,

1 and storage of the tobacco product in lieu  
2 of the methods, controls, and facilities pre-  
3 scribed by the requirement are sufficient to  
4 assure that the tobacco product will be in  
5 compliance with this chapter.

6 “(D) CONDITIONS.—An order of the Sec-  
7 retary approving a petition for a variance shall  
8 prescribe such conditions respecting the meth-  
9 ods used in, and the facilities and controls used  
10 for, the manufacture, packing, and storage of  
11 the tobacco product to be granted the variance  
12 under the petition as may be necessary to as-  
13 sure that the tobacco product will be in compli-  
14 ance with this chapter.

15 “(E) HEARING.—After the issuance of an  
16 order under subparagraph (B) respecting a pe-  
17 tition, the petitioner shall have an opportunity  
18 for an informal hearing on such order.

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

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

1 onstrations respecting tobacco products and may obtain  
2 tobacco products for research, testing, and demonstration  
3 purposes without regard to section 3324(a) and (b) of title  
4 31, United States Code, and section 5 of title 41, United  
5 States Code.

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

7 “(a) IN GENERAL.—

8 “(1) SPECIAL RULE FOR CIGARETTES.—A ciga-  
9 rette or any of its component parts (including the  
10 tobacco, filter, or paper) shall not contain, as a con-  
11 stituent (including a smoke constituent) or additive,  
12 an artificial or natural flavor (other than tobacco or  
13 menthol) or an herb or spice, including strawberry,  
14 grape, orange, clove, cinnamon, pineapple, vanilla,  
15 coconut, licorice, cocoa, chocolate, cherry, or coffee,  
16 that is a characterizing flavor of the tobacco product  
17 or tobacco smoke. Nothing in this subparagraph  
18 shall be construed to limit the Secretary’s authority  
19 to take action under this section or other sections of  
20 this Act applicable to menthol or any artificial or  
21 natural flavor, herb, or spice not specified in this  
22 paragraph.

23 “(2) REVISION OF TOBACCO PRODUCT STAND-  
24 ARDS.—The Secretary may revise the tobacco prod-

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

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

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

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

18           “(4) CONTENT OF TOBACCO PRODUCT STAND-  
19      ARDS.—A tobacco product standard established  
20      under this section for a tobacco product—

21           “(A) shall include provisions that are ap-  
22      propriate for the protection of the public health,  
23      including provisions, where appropriate—

24           “(i) for the reduction of nicotine  
25      yields of the product;

1           “(ii) for the reduction or elimination  
2 of other constituents, including smoke con-  
3 stituents, or harmful components of the  
4 product; or

5           “(iii) relating to any other require-  
6 ment under (B);

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

9           “(i) provisions respecting the con-  
10 struction, components, ingredients, addi-  
11 tives, constituents, including smoke con-  
12 stituents, and properties of the tobacco  
13 product;

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

17           “(iii) provisions for the measurement  
18 of the tobacco product characteristics of  
19 the tobacco product;

20           “(iv) provisions requiring that the re-  
21 sults of each or of certain of the tests of  
22 the tobacco product required to be made  
23 under clause (ii) show that the tobacco  
24 product is in conformity with the portions

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

3 “(v) a provision requiring that the  
4 sale and distribution of the tobacco prod-  
5 uct be restricted but only to the extent  
6 that the sale and distribution of a tobacco  
7 product may be restricted under a regula-  
8 tion under section 906(d); and

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

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

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

23 “(A) use personnel, facilities, and other  
24 technical support available in other Federal  
25 agencies;

1           “(B) consult with other Federal agencies  
2 concerned with standard-setting and other na-  
3 tionally or internationally recognized standard-  
4 setting entities; and

5           “(C) invite appropriate participation,  
6 through joint or other conferences, workshops,  
7 or other means, by informed persons represent-  
8 ative of scientific, professional, industry, agri-  
9 cultural, or consumer organizations who in the  
10 Secretary’s judgment can make a significant  
11 contribution.

12       “(b) ESTABLISHMENT OF STANDARDS.—

13           “(1) NOTICE.—

14           “(A) IN GENERAL.—The Secretary shall  
15 publish in the Federal Register a notice of pro-  
16 posed rulemaking for the establishment, amend-  
17 ment, or revocation of any tobacco product  
18 standard.

19           “(B) REQUIREMENTS OF NOTICE.—A no-  
20 tice of proposed rulemaking for the establish-  
21 ment or amendment of a tobacco product stand-  
22 ard for a tobacco product shall—

23           “(i) set forth a finding with sup-  
24 porting justification that the tobacco prod-

1           uct standard is appropriate for the protec-  
2           tion of the public health;

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

7           “(iii) invite interested persons to sub-  
8           mit an existing tobacco product standard  
9           for the tobacco product, including a draft  
10          or proposed tobacco product standard, for  
11          consideration by the Secretary.

12          “(C) STANDARD.—Upon a determination  
13          by the Secretary that an additive, constituent  
14          (including smoke constituent), or other compo-  
15          nent of the product that is the subject of the  
16          proposed tobacco product standard is harmful,  
17          it shall be the burden of any party challenging  
18          the proposed standard to prove that the pro-  
19          posed standard will not reduce or eliminate the  
20          risk of illness or injury.

21          “(D) FINDING.—A notice of proposed rule-  
22          making for the revocation of a tobacco product  
23          standard shall set forth a finding with sup-  
24          porting justification that the tobacco product

1 standard is no longer appropriate for the pro-  
2 tection of the public health.

3 “(E) CONSIDERATION BY SECRETARY.—

4 The Secretary shall consider all information  
5 submitted in connection with a proposed stand-  
6 ard, including information concerning the coun-  
7 tervailing effects of the tobacco product stand-  
8 ard on the health of adolescent tobacco users,  
9 adult tobacco users, or non-tobacco users, such  
10 as the creation of a significant demand for con-  
11 traband or other tobacco products that do not  
12 meet the requirements of this chapter and the  
13 significance of such demand, and shall issue the  
14 standard if the Secretary determines that the  
15 standard would be appropriate for the protec-  
16 tion of the public health.

17 “(F) COMMENT.—The Secretary shall pro-  
18 vide for a comment period of not less than 60  
19 days.

20 “(2) PROMULGATION.—

21 “(A) IN GENERAL.—After the expiration of  
22 the period for comment on a notice of proposed  
23 rulemaking published under paragraph (1) re-  
24 specting a tobacco product standard and after  
25 consideration of such comments and any report

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

3 “(i) promulgate a regulation estab-  
4 lishing a tobacco product standard and  
5 publish in the Federal Register findings on  
6 the matters referred to in paragraph (1);  
7 or

8 “(ii) publish a notice terminating the  
9 proceeding for the development of the  
10 standard together with the reasons for  
11 such termination.

12 “(B) EFFECTIVE DATE.—A regulation es-  
13 tablishing a tobacco product standard shall set  
14 forth the date or dates upon which the standard  
15 shall take effect, but no such regulation may  
16 take effect before 1 year after the date of its  
17 publication unless the Secretary determines  
18 that an earlier effective date is necessary for  
19 the protection of the public health. Such date or  
20 dates shall be established so as to minimize,  
21 consistent with the public health, economic loss  
22 to, and disruption or dislocation of, domestic  
23 and international trade.

24 “(3) POWER RESERVED TO CONGRESS.—Be-  
25 cause of the importance of a decision of the Sec-

1       retary to issue a regulation establishing a tobacco  
2       product standard—

3               “(A) banning all cigarettes, all smokeless  
4               tobacco products, all little cigars, all cigars  
5               other than little cigars, all pipe tobacco, or all  
6               roll your own tobacco products; or

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

9       Congress expressly reserves to itself such power.

10              “(4) AMENDMENT; REVOCATION.—

11              “(A) AUTHORITY.—The Secretary, upon  
12              the Secretary’s own initiative or upon petition  
13              of an interested person may by a regulation,  
14              promulgated in accordance with the require-  
15              ments of paragraphs (1) and (2)(B), amend or  
16              revoke a tobacco product standard.

17              “(B) EFFECTIVE DATE.—The Secretary  
18              may declare a proposed amendment of a to-  
19              bacco product standard to be effective on and  
20              after its publication in the Federal Register and  
21              until the effective date of any final action taken  
22              on such amendment if the Secretary determines  
23              that making it so effective is in the public inter-  
24              est.

1           “(5) REFERENCE TO ADVISORY COMMITTEE.—

2           The Secretary may—

3                   “(A) on the Secretary’s own initiative,  
4                   refer a proposed regulation for the establish-  
5                   ment, amendment, or revocation of a tobacco  
6                   product standard; or

7                   “(B) upon the request of an interested per-  
8                   son which demonstrates good cause for referral  
9                   and which is made before the expiration of the  
10                  period for submission of comments on such pro-  
11                  posed regulation, refer such proposed regulation  
12                  to the Tobacco Products Scientific Advisory  
13                  Committee, for a report and recommendation  
14                  with respect to any matter involved in the pro-  
15                  posed regulation which requires the exercise of  
16                  scientific judgment. If a proposed regulation is  
17                  referred under this paragraph to the Tobacco  
18                  Products Scientific Advisory Committee, the  
19                  Secretary shall provide the advisory committee  
20                  with the data and information on which such  
21                  proposed regulation is based. The Tobacco  
22                  Products Scientific Advisory Committee shall,  
23                  within 60 days after the referral of a proposed  
24                  regulation and after independent study of the  
25                  data and information furnished to it by the Sec-

1           retary and other data and information before it,  
2           submit to the Secretary a report and rec-  
3           ommendation respecting such regulation, to-  
4           gether with all underlying data and information  
5           and a statement of the reason or basis for the  
6           recommendation. A copy of such report and rec-  
7           ommendation shall be made public by the Sec-  
8           retary.

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

10       “(a) NOTIFICATION.—If the Secretary determines  
11 that—

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

16           “(2) notification under this subsection is nec-  
17           essary to eliminate the unreasonable risk of such  
18           harm and no more practicable means is available  
19           under the provisions of this chapter (other than this  
20           section) to eliminate such risk, the Secretary may  
21           issue such order as may be necessary to assure that  
22           adequate notification is provided in an appropriate  
23           form, by the persons and means best suited under  
24           the circumstances involved, to all persons who  
25           should properly receive such notification in order to

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

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

14 “(c) RECALL AUTHORITY.—

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

1 portunity for an informal hearing, to be held not  
2 later than 10 days after the date of the issuance of  
3 the order, on the actions required by the order and  
4 on whether the order should be amended to require  
5 a recall of such tobacco product. If, after providing  
6 an opportunity for such a hearing, the Secretary de-  
7 termines that inadequate grounds exist to support  
8 the actions required by the order, the Secretary shall  
9 vacate the order.

10 “(2) AMENDMENT OF ORDER TO REQUIRE RE-  
11 CALL.—

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

24 “(B) NOTICE.—An amended order under  
25 subparagraph (A)—

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

3                   “(ii) shall provide for notice to per-  
4                   sons subject to the risks associated with  
5                   the use of such tobacco product.

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

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

15                  **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**  
16                  **UCTS.**

17                  “(a) IN GENERAL.—Every person who is a tobacco  
18                  product manufacturer or importer of a tobacco product  
19                  shall establish and maintain such records, make such re-  
20                  ports, and provide such information, as the Secretary may  
21                  by regulation reasonably require to assure that such to-  
22                  bacco product is not adulterated or misbranded and to  
23                  otherwise protect public health. Regulations prescribed  
24                  under the preceding sentence—

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

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

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

20           “(4) when prescribing the procedure for making  
21          requests for reports or information, shall require  
22          that each request made under such regulations for  
23          submission of a report or information to the Sec-  
24          retary state the reason or purpose for such request

1 and identify to the fullest extent practicable such re-  
2 port or information;

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

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

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

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

23 “(1) IN GENERAL.—Except as provided in para-  
24 graph (2), the Secretary shall by regulation require  
25 a tobacco product manufacturer or importer of a to-

1 tobacco product to report promptly to the Secretary  
2 any corrective action taken or removal from the  
3 market of a tobacco product undertaken by such  
4 manufacturer or importer if the removal or correc-  
5 tion was undertaken—

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

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

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

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

21 **“SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TO-**  
22 **BACCO PRODUCTS.**

23 “(a) IN GENERAL.—

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

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

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

16           “(2) PREMARKET APPROVAL REQUIRED.—

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

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

23           “(ii) the Secretary has issued an order  
24 that the tobacco product—

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

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

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

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

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

23          “(ii) for which a report was submitted  
24          under section 905(j) within such 15-month  
25          period, until the Secretary issues an order

1           that the tobacco product is not substan-  
2           tially equivalent.

3           “(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

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

11                   “(i) has the same characteristics as  
12                   the predicate tobacco product; or

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

21           “(B) CHARACTERISTICS.—In subpara-  
22           graph (A), the term ‘characteristics’ means the  
23           materials, ingredients, design, composition,  
24           heating source, or other features of a tobacco  
25           product.

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

7           “(4) HEALTH INFORMATION.—

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

16           “(B) REQUIRED INFORMATION.—Any sum-  
17 mary under subparagraph (A) respecting a to-  
18 bacco product shall contain detailed information  
19 regarding data concerning adverse health ef-  
20 fects and shall be made available to the public  
21 by the Secretary within 30 days of the issuance  
22 of a determination that such tobacco product is  
23 substantially equivalent to another tobacco  
24 product.

25           “(b) APPLICATION.—

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

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

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

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

19           “(D) an identifying reference to any to-  
20 bacco product standard under section 907  
21 which would be applicable to any aspect of such  
22 tobacco product, and either adequate informa-  
23 tion to show that such aspect of such tobacco  
24 product fully meets such tobacco product stand-

1           ard or adequate information to justify any devi-  
2           ation from such standard;

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

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

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

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

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

17               “(B) may, upon the request of an appli-  
18               cant, refer such application to the Tobacco  
19               Products Scientific Advisory Committee for ref-  
20               erence and for submission (within such period  
21               as the Secretary may establish) of a report and  
22               recommendation respecting approval of the ap-  
23               plication, together with all underlying data and  
24               the reasons or basis for the recommendation.

25          “(c) ACTION ON APPLICATION.—

1 “(1) DEADLINE.—

2 “(A) IN GENERAL.—As promptly as pos-  
3 sible, but in no event later than 180 days after  
4 the receipt of an application under subsection  
5 (b), the Secretary, after considering the report  
6 and recommendation submitted under para-  
7 graph (2) of such subsection, shall—

8 “(i) issue an order approving the ap-  
9 plication if the Secretary finds that none of  
10 the grounds for denying approval specified  
11 in paragraph (2) of this subsection applies;  
12 or

13 “(ii) deny approval of the application  
14 if the Secretary finds (and sets forth the  
15 basis for such finding as part of or accom-  
16 panying such denial) that 1 or more  
17 grounds for denial specified in paragraph  
18 (2) of this subsection apply.

19 “(B) RESTRICTIONS ON SALE AND DIS-  
20 TRIBUTION.—An order approving an application  
21 for a tobacco product may require as a condi-  
22 tion to such approval that the sale and distribu-  
23 tion of the tobacco product be restricted but  
24 only to the extent that the sale and distribution

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

3 “(2) DENIAL OF APPROVAL.—The Secretary  
4 shall deny approval of an application for a tobacco  
5 product if, upon the basis of the information sub-  
6 mitted to the Secretary as part of the application  
7 and any other information before the Secretary with  
8 respect to such tobacco product, the Secretary finds  
9 that—

10 “(A) there is a lack of a showing that per-  
11 mitting such tobacco product to be marketed  
12 would be appropriate for the protection of the  
13 public health;

14 “(B) the methods used in, or the facilities  
15 or controls used for, the manufacture, proc-  
16 essing, or packing of such tobacco product do  
17 not conform to the requirements of section  
18 906(e);

19 “(C) based on a fair evaluation of all mate-  
20 rial facts, the proposed labeling is false or mis-  
21 leading in any particular; or

22 “(D) such tobacco product is not shown to  
23 conform in all respects to a tobacco product  
24 standard in effect under section 907, compli-  
25 ance with which is a condition to approval of

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

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

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

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

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

25          “(5) BASIS FOR ACTION.—

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

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

18           “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

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

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

4           “(B) that the application contained or was  
5 accompanied by an untrue statement of a mate-  
6 rial fact;

7           “(C) that the applicant—

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

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

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

18           “(D) on the basis of new information be-  
19 fore the Secretary with respect to such tobacco  
20 product, evaluated together with the evidence  
21 before the Secretary when the application was  
22 approved, that the methods used in, or the fa-  
23 cilities and controls used for, the manufacture,  
24 processing, packing, or installation of such to-  
25 bacco product do not conform with the require-

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

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

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

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

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

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

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

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

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

1       plicant’s last known address in the records of the  
2       Secretary.

3       “(f) RECORDS.—

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

16              “(2) ACCESS TO RECORDS.—Each person re-  
17      quired under this section to maintain records, and  
18      each person in charge or custody thereof, shall, upon  
19      request of an officer or employee designated by the  
20      Secretary, permit such officer or employee at all rea-  
21      sonable times to have access to and copy and verify  
22      such records.

23              “(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMP-  
24      TION FOR INVESTIGATIONAL USE.—The Secretary may  
25      exempt tobacco products intended for investigational use

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

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

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

9 “(b) DEFINITIONS.—In this section:

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

16 “(2) SOLD OR DISTRIBUTED.—

17 “(A) IN GENERAL.—With respect to a to-  
18 bacco product, the term ‘sold or distributed for  
19 use to reduce harm or the risk of tobacco-re-  
20 lated disease associated with commercially mar-  
21 keted tobacco products’ means a tobacco prod-  
22 uct—

23 “(i) the label, labeling, or advertising  
24 of which represents explicitly or implicitly  
25 that—

1           “(I) the tobacco product presents  
2           a lower risk of tobacco-related disease  
3           or is less harmful than one or more  
4           other commercially marketed tobacco  
5           products;

6           “(II) the tobacco product or its  
7           smoke contains a reduced level of a  
8           substance or presents a reduced expo-  
9           sure to a substance; or

10          “(III) the tobacco product or its  
11          smoke does not contain or is free of a  
12          substance;

13          “(ii) the label, labeling, or advertising  
14          of which uses the descriptors ‘light’, ‘mild’,  
15          or ‘low’ or similar descriptors; or

16          “(iii) the tobacco product manufac-  
17          turer of which has taken any action di-  
18          rected to consumers through the media or  
19          otherwise, other than by means of the to-  
20          bacco product’s label, labeling or adver-  
21          tising, after the date of enactment of the  
22          Family Smoking Prevention and Tobacco  
23          Control Act, respecting the product that  
24          would be reasonably expected to result in  
25          consumers believing that the tobacco prod-

1           uct or its smoke may present a lower risk  
2           of disease or is less harmful than one or  
3           more commercially marketed tobacco prod-  
4           ucts, or presents a reduced exposure to, or  
5           does not contain or is free of, a substance  
6           or substances.

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

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

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

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

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

24                 “(3) the formulation of the product;

25                 “(4) sample product labels and labeling;

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

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

12           “(7) such other information as the Secretary  
13           may require.

14           “(e) PUBLIC AVAILABILITY.—The Secretary shall  
15           make the application described in subsection (d) publicly  
16           available (except matters in the application which are  
17           trade secrets or otherwise confidential, commercial infor-  
18           mation) and shall request comments by interested persons  
19           on the information contained in the application and on the  
20           label, labeling, and advertising accompanying such appli-  
21           cation.

22           “(f) ADVISORY COMMITTEE.—

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

1           “(2) RECOMMENDATIONS.—Not later than 60  
2 days after the date an application is referred to an  
3 advisory committee under paragraph (1), the advi-  
4 sory committee shall report its recommendations on  
5 the application to the Secretary.

6           “(g) APPROVAL.—

7           “(1) MODIFIED RISK PRODUCTS.—Except as  
8 provided in paragraph (2), the Secretary shall ap-  
9 prove an application for a modified risk tobacco  
10 product filed under this section only if the Secretary  
11 determines that the applicant has demonstrated that  
12 such product, as it is actually used by consumers,  
13 will—

14           “(A) significantly reduce harm and the  
15 risk of tobacco-related disease to individual to-  
16 bacco users; and

17           “(B) benefit the health of the population  
18 as a whole taking into account both users of to-  
19 bacco products and persons who do not cur-  
20 rently use tobacco products.

21           “(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

22           “(A) IN GENERAL.—The Secretary may  
23 approve an application for a tobacco product  
24 that has not been approved as a modified risk  
25 tobacco product pursuant to paragraph (1) if

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

4 “(i) the approval of the application  
5 would be appropriate to promote the public  
6 health;

7 “(ii) any aspect of the label, labeling,  
8 and advertising for such product that  
9 would cause the tobacco product to be a  
10 modified risk tobacco product under sub-  
11 section (b)(2) is limited to an explicit or  
12 implicit representation that such tobacco  
13 product or its smoke contains or is free of  
14 a substance or contains a reduced level of  
15 a substance, or presents a reduced expo-  
16 sure to a substance in tobacco smoke;

17 “(iii) scientific evidence is not avail-  
18 able and, using the best available scientific  
19 methods, cannot be made available without  
20 conducting long-term epidemiological stud-  
21 ies for an application to meet the stand-  
22 ards set forth in paragraph (1); and

23 “(iv) the scientific evidence that is  
24 available without conducting long-term epi-  
25 demiological studies demonstrates that a

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

5 “(B) ADDITIONAL FINDINGS REQUIRED.—

6 In order to approve an application under sub-  
7 paragraph (A) the Secretary must also find  
8 that the applicant has demonstrated that—

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

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

1           tion in overall morbidity and mortality  
2           among individual tobacco users;

3           “(iii) testing of actual consumer per-  
4           ception shows that, as the applicant pro-  
5           poses to label and market the product, con-  
6           sumers will not be misled into believing  
7           that the product—

8                   “(I) is or has been demonstrated  
9                   to be less harmful; or

10                   “(II) presents or has been dem-  
11                   onstrated to present less of a risk of  
12                   disease than 1 or more other commer-  
13                   cially marketed tobacco products; and

14           “(iv) approval of the application is ex-  
15           pected to benefit the health of the popu-  
16           lation as a whole taking into account both  
17           users of tobacco products and persons who  
18           do not currently use tobacco products.

19           “(C) CONDITIONS OF APPROVAL.—

20                   “(i) IN GENERAL.—Applications ap-  
21                   proved under this paragraph shall be lim-  
22                   ited to a term of not more than 5 years,  
23                   but may be renewed upon a finding by the  
24                   Secretary that the requirements of this

1 paragraph continue to be satisfied based  
2 on the filing of a new application.

3 “(ii) AGREEMENTS BY APPLICANT.—  
4 Applications approved under this para-  
5 graph shall be conditioned on the appli-  
6 cant’s agreement to conduct post-market  
7 surveillance and studies and to submit to  
8 the Secretary the results of such surveil-  
9 lance and studies to determine the impact  
10 of the application approval on consumer  
11 perception, behavior, and health and to en-  
12 able the Secretary to review the accuracy  
13 of the determinations upon which the ap-  
14 proval was based in accordance with a pro-  
15 tocol approved by the Secretary.

16 “(iii) ANNUAL SUBMISSION.—The re-  
17 sults of such post-market surveillance and  
18 studies described in clause (ii) shall be  
19 submitted annually.

20 “(3) BASIS.—The determinations under para-  
21 graphs (1) and (2) shall be based on—

22 “(A) the scientific evidence submitted by  
23 the applicant; and

24 “(B) scientific evidence and other informa-  
25 tion that is available to the Secretary.

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

5                   “(A) the relative health risks to individuals  
6                   of the tobacco product that is the subject of the  
7                   application;

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

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

17                  “(D) the risks and benefits to persons  
18                  from the use of the tobacco product that is the  
19                  subject of the application as compared to the  
20                  use of products for smoking cessation approved  
21                  under chapter V to treat nicotine dependence;  
22                  and

23                  “(E) comments, data, and information  
24                  submitted by interested persons.

25           “(h) ADDITIONAL CONDITIONS FOR APPROVAL.—

1           “(1) MODIFIED RISK PRODUCTS.—The Sec-  
2           retary shall require for the approval of an applica-  
3           tion under this section that any advertising or label-  
4           ing concerning modified risk products enable the  
5           public to comprehend the information concerning  
6           modified risk and to understand the relative signifi-  
7           cance of such information in the context of total  
8           health and in relation to all of the diseases and  
9           health-related conditions associated with the use of  
10          tobacco products.

11          “(2) COMPARATIVE CLAIMS.—

12                 “(A) IN GENERAL.—The Secretary may re-  
13                 quire for the approval of an application under  
14                 this subsection that a claim comparing a to-  
15                 bacco product to 1 or more other commercially  
16                 marketed tobacco products shall compare the  
17                 tobacco product to a commercially marketed to-  
18                 bacco product that is representative of that type  
19                 of tobacco product on the market (for example  
20                 the average value of the top 3 brands of an es-  
21                 tablished regular tobacco product).

22                 “(B) QUANTITATIVE COMPARISONS.—The  
23                 Secretary may also require, for purposes of sub-  
24                 paragraph (A), that the percent (or fraction) of  
25                 change and identity of the reference tobacco

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

5 “(3) LABEL DISCLOSURE.—

6 “(A) IN GENERAL.—The Secretary may re-  
7 quire the disclosure on the label of other sub-  
8 stances in the tobacco product, or substances  
9 that may be produced by the consumption of  
10 that tobacco product, that may affect a disease  
11 or health-related condition or may increase the  
12 risk of other diseases or health-related condi-  
13 tions associated with the use of tobacco prod-  
14 ucts.

15 “(B) CONDITIONS OF USE.—If the condi-  
16 tions of use of the tobacco product may affect  
17 the risk of the product to human health, the  
18 Secretary may require the labeling of conditions  
19 of use.

20 “(4) TIME.—The Secretary shall limit an ap-  
21 proval under subsection (g)(1) for a specified period  
22 of time.

23 “(5) ADVERTISING.—The Secretary may re-  
24 quire that an applicant, whose application has been  
25 approved under this subsection, comply with require-

1       ments relating to advertising and promotion of the  
2       tobacco product.

3       “(i) POSTMARKET SURVEILLANCE AND STUDIES.—

4               “(1) IN GENERAL.—The Secretary shall require  
5       that an applicant under subsection (g)(1) conduct  
6       post market surveillance and studies for a tobacco  
7       product for which an application has been approved  
8       to determine the impact of the application approval  
9       on consumer perception, behavior, and health, to en-  
10      able the Secretary to review the accuracy of the de-  
11      terminations upon which the approval was based,  
12      and to provide information that the Secretary deter-  
13      mines is otherwise necessary regarding the use or  
14      health risks involving the tobacco product. The re-  
15      sults of post-market surveillance and studies shall be  
16      submitted to the Secretary on an annual basis.

17              “(2) SURVEILLANCE PROTOCOL.—Each appli-  
18      cant required to conduct a surveillance of a tobacco  
19      product under paragraph (1) shall, within 30 days  
20      after receiving notice that the applicant is required  
21      to conduct such surveillance, submit, for the ap-  
22      proval of the Secretary, a protocol for the required  
23      surveillance. The Secretary, within 60 days of the  
24      receipt of such protocol, shall determine if the prin-  
25      cipal investigator proposed to be used in the surveil-

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

6 “(j) WITHDRAWAL OF APPROVAL.—The Secretary,  
7 after an opportunity for an informal hearing, shall with-  
8 draw the approval of an application under this section if  
9 the Secretary determines that—

10 “(1) the applicant, based on new information,  
11 can no longer make the demonstrations required  
12 under subsection (g), or the Secretary can no longer  
13 make the determinations required under subsection  
14 (g);

15 “(2) the application failed to include material  
16 information or included any untrue statement of ma-  
17 terial fact;

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

21 “(A) a tobacco product standard is estab-  
22 lished pursuant to section 907;

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

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

3 “(C) any postmarket surveillance or stud-  
4 ies reveal that the approval of the application is  
5 no longer consistent with the protection of the  
6 public health;

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

10 “(5) the applicant failed to meet a condition  
11 imposed under subsection (h).

12 “(k) CHAPTER IV OR V.—A product approved in ac-  
13 cordance with this section shall not be subject to chapter  
14 IV or V.

15 “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

16 “(1) SCIENTIFIC EVIDENCE.—Not later than 2  
17 years after the date of enactment of the Family  
18 Smoking Prevention and Tobacco Control Act, the  
19 Secretary shall issue regulations or guidance (or any  
20 combination thereof) on the scientific evidence re-  
21 quired for assessment and ongoing review of modi-  
22 fied risk tobacco products. Such regulations or guid-  
23 ance shall—

24 “(A) establish minimum standards for sci-  
25 entific studies needed prior to approval to show

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

4 “(B) include validated biomarkers, inter-  
5 mediate clinical endpoints, and other feasible  
6 outcome measures, as appropriate;

7 “(C) establish minimum standards for post  
8 market studies, that shall include regular and  
9 long-term assessments of health outcomes and  
10 mortality, intermediate clinical endpoints, con-  
11 sumer perception of harm reduction, and the  
12 impact on quitting behavior and new use of to-  
13 bacco products, as appropriate;

14 “(D) establish minimum standards for re-  
15 quired postmarket surveillance, including ongo-  
16 ing assessments of consumer perception; and

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

21 “(2) CONSULTATION.—The regulations or guid-  
22 ance issued under paragraph (1) shall be developed  
23 in consultation with the Institute of Medicine, and  
24 with the input of other appropriate scientific and

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

3 “(3) REVISION.—The regulations or guidance  
4 under paragraph (1) shall be revised on a regular  
5 basis as new scientific information becomes avail-  
6 able.

7 “(4) NEW TOBACCO PRODUCTS.—Not later  
8 than 2 years after the date of enactment of the  
9 Family Smoking Prevention and Tobacco Control  
10 Act, the Secretary shall issue a regulation or guid-  
11 ance that permits the filing of a single application  
12 for any tobacco product that is a new tobacco prod-  
13 uct under section 910 and for which the applicant  
14 seeks approval as a modified risk tobacco product  
15 under this section.

16 “(m) DISTRIBUTORS.—No distributor may take any  
17 action, after the date of enactment of the Family Smoking  
18 Prevention and Tobacco Control Act, with respect to a to-  
19 bacco product that would reasonably be expected to result  
20 in consumers believing that the tobacco product or its  
21 smoke may present a lower risk of disease or is less harm-  
22 ful than one or more commercially marketed tobacco prod-  
23 ucts, or presents a reduced exposure to, or does not con-  
24 tain or is free of, a substance or substances.

1 **“SEC. 912. JUDICIAL REVIEW.**

2 “(a) RIGHT TO REVIEW.—

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

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

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

16 “(2) REQUIREMENTS.—

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

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

1           “(i) the record of the proceedings on  
2           which the regulation or order was based;  
3           and

4           “(ii) a statement of the reasons for  
5           the issuance of such a regulation or order.

6           “(C) DEFINITION OF RECORD.—In this  
7           section, the term ‘record’ means—

8           “(i) all notices and other matter pub-  
9           lished in the Federal Register with respect  
10          to the regulation or order reviewed;

11          “(ii) all information submitted to the  
12          Secretary with respect to such regulation  
13          or order;

14          “(iii) proceedings of any panel or ad-  
15          visory committee with respect to such reg-  
16          ulation or order;

17          “(iv) any hearing held with respect to  
18          such regulation or order; and

19          “(v) any other information identified  
20          by the Secretary, in the administrative pro-  
21          ceeding held with respect to such regula-  
22          tion or order, as being relevant to such  
23          regulation or order.

24          “(b) STANDARD OF REVIEW.—Upon the filing of the  
25          petition under subsection (a) for judicial review of a regu-

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

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

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

17       “(e) REGULATIONS AND ORDERS MUST RECITE  
18 BASIS IN RECORD.—To facilitate judicial review, a regula-  
19 tion or order issued under section 906, 907, 908, 909,  
20 910, or 916 shall contain a statement of the reasons for  
21 the issuance of such regulation or order in the record of  
22 the proceedings held in connection with its issuance.

23 **“SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.**

24       “The Secretary shall issue regulations to require that  
25 retail establishments for which the predominant business

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

4 **“SEC. 914. JURISDICTION OF AND COORDINATION WITH**  
5 **THE FEDERAL TRADE COMMISSION.**

6 “(a) JURISDICTION.—

7 “(1) IN GENERAL.—Except where expressly  
8 provided in this chapter, nothing in this chapter  
9 shall be construed as limiting or diminishing the au-  
10 thority of the Federal Trade Commission to enforce  
11 the laws under its jurisdiction with respect to the  
12 advertising, sale, or distribution of tobacco products.

13 “(2) ENFORCEMENT.—Any advertising that vio-  
14 lates this chapter or a provision of the regulations  
15 referred to in section 232 of the Family Smoking  
16 Prevention and Tobacco Control Act, is an unfair or  
17 deceptive act or practice under section 5(a) of the  
18 Federal Trade Commission Act (15 U.S.C. 45(a))  
19 and shall be considered a violation of a rule promul-  
20 gated under section 18 of that Act (15 U.S.C. 57a).

21 “(b) COORDINATION.—With respect to the require-  
22 ments of section 4 of the Federal Cigarette Labeling and  
23 Advertising Act (15 U.S.C. 1333) and section 3 of the  
24 Comprehensive Smokeless Tobacco Health Education Act  
25 of 1986 (15 U.S.C. 4402)—

1           “(1) the Chairman of the Federal Trade Com-  
2           mission shall coordinate with the Secretary con-  
3           cerning the enforcement of such Act as such enforce-  
4           ment relates to unfair or deceptive acts or practices  
5           in the advertising of cigarettes or smokeless tobacco;  
6           and

7           “(2) the Secretary shall consult with the Chair-  
8           man of such Commission in revising the label state-  
9           ments and requirements under such sections.

10 **“SEC. 915. CONGRESSIONAL REVIEW PROVISIONS.**

11           “In accordance with section 801 of title 5, United  
12 States Code, Congress shall review, and may disapprove,  
13 any rule under this chapter that is subject to section 801.  
14 This section and section 801 do not apply to the regula-  
15 tions referred to in section 232 of the Family Smoking  
16 Prevention and Tobacco Control Act.

17 **“SEC. 916. REGULATION REQUIREMENT.**

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

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

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

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

22       “(a) IN GENERAL.—

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

1 (including the Armed Forces), a State or political  
2 subdivision of a State, or the government of an In-  
3 dian tribe to enact, adopt, promulgate, and enforce  
4 any law, rule, regulation, or other measure with re-  
5 spect to tobacco products that is in addition to, or  
6 more stringent than, requirements established under  
7 this chapter, including a law, rule, regulation, or  
8 other measure relating to or prohibiting the sale,  
9 distribution, possession, exposure to, access to, ad-  
10 vertising and promotion of, or use of tobacco prod-  
11 ucts by individuals of any age, information reporting  
12 to the State, or measures relating to fire safety  
13 standards for tobacco products. No provision of this  
14 chapter shall limit or otherwise affect any State,  
15 Tribal, or local taxation of tobacco products.

16 “(2) PREEMPTION OF CERTAIN STATE AND  
17 LOCAL REQUIREMENTS.—

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



1 11-member advisory committee, to be known as the ‘To-  
2 bacco Products Scientific Advisory Committee’.

3 “(b) MEMBERSHIP.—

4 “(1) IN GENERAL.—

5 “(A) MEMBERS.—The Secretary shall ap-  
6 point as members of the Tobacco Products Sci-  
7 entific Advisory Committee individuals who are  
8 technically qualified by training and experience  
9 in the medicine, medical ethics, science, or tech-  
10 nology involving the manufacture, evaluation, or  
11 use of tobacco products, who are of appro-  
12 priately diversified professional backgrounds.  
13 The committee shall be composed of—

14 “(i) 7 individuals who are physicians,  
15 dentists, scientists, or health care profes-  
16 sionals practicing in the area of oncology,  
17 pulmonology, cardiology, toxicology, phar-  
18 macology, addiction, or any other relevant  
19 specialty;

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

23 “(iii) 1 individual as a representative  
24 of the general public;

1                   “(iv) 1 individual as a representative  
2                   of the interests in the tobacco manufac-  
3                   turing industry; and

4                   “(v) 1 individual as a representative  
5                   of the interests of the tobacco growers.

6                   “(B) NONVOTING MEMBERS.—The mem-  
7                   bers of the committee appointed under clauses  
8                   (iv) and (v) of subparagraph (A) shall serve as  
9                   consultants to those described in clauses (i)  
10                  through (iii) of subparagraph (A) and shall be  
11                  nonvoting representatives.

12                  “(2) LIMITATION.—The Secretary may not ap-  
13                  point to the Advisory Committee any individual who  
14                  is in the regular full-time employ of the Food and  
15                  Drug Administration or any agency responsible for  
16                  the enforcement of this Act. The Secretary may ap-  
17                  point Federal officials as ex officio members.

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

21                  “(c) DUTIES.—The Tobacco Products Scientific Ad-  
22                  visory Committee shall provide advice, information, and  
23                  recommendations to the Secretary—

24                  “(1) as provided in this chapter;

1           “(2) on the effects of the alteration of the nico-  
2           tine yields from tobacco products;

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

6           “(4) on its review of other safety, dependence,  
7           or health issues relating to tobacco products as re-  
8           quested by the Secretary.

9           “(d) COMPENSATION; SUPPORT; FACA.—

10           “(1) COMPENSATION AND TRAVEL.—Members  
11           of the Advisory Committee who are not officers or  
12           employees of the United States, while attending con-  
13           ferences or meetings of the committee or otherwise  
14           engaged in its business, shall be entitled to receive  
15           compensation at rates to be fixed by the Secretary,  
16           which may not exceed the daily equivalent of the  
17           rate in effect for level 4 of the Senior Executive  
18           Schedule under section 5382 of title 5, United  
19           States Code, for each day (including travel time)  
20           they are so engaged; and while so serving away from  
21           their homes or regular places of business each mem-  
22           ber may be allowed travel expenses, including per  
23           diem in lieu of subsistence, as authorized by section  
24           5703 of title 5, United States Code, for persons in  
25           the Government service employed intermittently.



1           “(3) review and consider the evidence for addi-  
2           tional indications for nicotine replacement products,  
3           such as for craving relief or relapse prevention.

4   **“SEC. 920. USER FEE.**

5           “(a) ESTABLISHMENT OF QUARTERLY USER FEE.—  
6   The Secretary shall assess a quarterly user fee with re-  
7   spect to every quarter of each fiscal year commencing fis-  
8   cal year 2005, calculated in accordance with this section,  
9   upon each manufacturer and importer of tobacco products  
10  subject to this chapter.

11          “(b) FUNDING OF FDA REGULATION OF TOBACCO  
12  PRODUCTS.—The Secretary shall make user fees collected  
13  pursuant to this section available to pay, in each fiscal  
14  year, for the costs of the activities of the Food and Drug  
15  Administration related to the regulation of tobacco prod-  
16  ucts under this chapter.

17          “(c) ASSESSMENT OF USER FEE.—

18               “(1) AMOUNT OF ASSESSMENT.—Except as  
19               provided in paragraph (4), the total user fees as-  
20               sessed each year pursuant to this section shall be  
21               sufficient, and shall not exceed what is necessary, to  
22               pay for the costs of the activities described in sub-  
23               section (b) for each fiscal year.

24               “(2) ALLOCATION OF ASSESSMENT BY CLASS  
25               OF TOBACCO PRODUCTS.—

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

8           “(B) APPLICABLE PERCENTAGE.—For  
9           purposes of subparagraph (A) the applicable  
10          percentage for a fiscal year shall be the fol-  
11          lowing:

12                 “(i) 92.07 percent shall be assessed  
13                 on manufacturers and importers of ciga-  
14                 rettes;

15                 “(ii) 0.05 percent shall be assessed on  
16                 manufacturers and importers of little ci-  
17                 gars;

18                 “(iii) 7.15 percent shall be assessed  
19                 on manufacturers and importers of cigars  
20                 other than little cigars;

21                 “(iv) 0.43 percent shall be assessed on  
22                 manufacturers and importers of snuff;

23                 “(v) 0.10 percent shall be assessed on  
24                 manufacturers and importers of chewing  
25                 tobacco;

1           “(vi) 0.06 percent shall be assessed on  
2           manufacturers and importers of pipe to-  
3           bacco; and

4           “(vii) 0.14 percent shall be assessed  
5           on manufacturers and importers of roll-  
6           your-own tobacco.

7           “(3) DISTRIBUTION OF FEE SHARES OF MANU-  
8           FACTURERS AND IMPORTERS EXEMPT FROM USER  
9           FEE.—Where a class of tobacco products is not sub-  
10          ject to a user fee under this section, the portion of  
11          the user fee assigned to such class under subsection  
12          (d)(2) shall be allocated by the Secretary on a pro  
13          rata basis among the classes of tobacco products  
14          that are subject to a user fee under this section.  
15          Such pro rata allocation for each class of tobacco  
16          products that are subject to a user fee under this  
17          section shall be the quotient of—

18                 “(A) the sum of the percentages assigned  
19                 to all classes of tobacco products subject to this  
20                 section; divided by

21                 “(B) the percentage assigned to such class  
22                 under paragraph (2).

23           “(4) ANNUAL LIMIT ON ASSESSMENT.—The  
24          total assessment under this section—

1           “(A) for fiscal year 2005 shall be  
2           \$85,000,000;

3           “(B) for fiscal year 2006 shall be  
4           \$175,000,000;

5           “(C) for fiscal year 2007 shall be  
6           \$300,000,000; and

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

12                 “(i) the total percentage change that  
13                 occurred in the Consumer Price Index for  
14                 all urban consumers (all items; United  
15                 States city average) for the 12-month pe-  
16                 riod ending on June 30 of the preceding  
17                 fiscal year for which fees are being estab-  
18                 lished; or

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

1           5304 of such title for Federal employees  
2           stationed in the District of Columbia.

3           “(5) TIMING OF USER FEE ASSESSMENT.—The  
4           Secretary shall notify each manufacturer and im-  
5           porter of tobacco products subject to this section of  
6           the amount of the quarterly assessment imposed on  
7           such manufacturer or importer under subsection (f)  
8           during each quarter of each fiscal year. Such notifi-  
9           cations shall occur not earlier than 3 months prior  
10          to the end of the quarter for which such assessment  
11          is made, and payments of all assessments shall be  
12          made not later than 60 days after each such notifi-  
13          cation.

14          “(d) DETERMINATION OF USER FEE BY COMPANY  
15 MARKET SHARE.—

16           “(1) IN GENERAL.—The user fee to be paid by  
17           each manufacturer or importer of a given class of to-  
18           bacco products shall be determined in each quarter  
19           by multiplying—

20                   “(A) such manufacturer’s or importer’s  
21                   market share of such class of tobacco products;  
22                   by

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

1           facturers and importers of such class of tobacco  
2           products as determined under subsection (e).

3           “(2) NO FEE IN EXCESS OF MARKET SHARE.—

4           No manufacturer or importer of tobacco products  
5           shall be required to pay a user fee in excess of the  
6           market share of such manufacturer or importer.

7           “(e) DETERMINATION OF VOLUME OF DOMESTIC  
8           SALES.—

9           “(1) IN GENERAL.—The calculation of gross  
10          domestic volume of a class of tobacco product by a  
11          manufacturer or importer, and by all manufacturers  
12          and importers as a group, shall be made by the Sec-  
13          retary using information provided by manufacturers  
14          and importers pursuant to subsection (f), as well as  
15          any other relevant information provided to or ob-  
16          tained by the Secretary.

17          “(2) MEASUREMENT.—For purposes of the cal-  
18          culations under this subsection and the information  
19          provided under subsection (f) by the Secretary, gross  
20          domestic volume shall be measured by—

21                 “(A) in the case of cigarettes, the number  
22                 of cigarettes sold;

23                 “(B) in the case of little cigars, the num-  
24                 ber of little cigars sold;

1           “(C) in the case of large cigars, the num-  
2           ber of cigars weighing more than 3 pounds per  
3           thousand sold; and

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

7           “(f) MEASUREMENT OF GROSS DOMESTIC VOL-  
8           UME.—

9           “(1) IN GENERAL.—Each manufacturer and  
10          importer of tobacco products shall submit to the  
11          Secretary a certified copy of each of the returns or  
12          forms described by this paragraph that are required  
13          to be filed with a Government agency on the same  
14          date that those returns or forms are filed, or re-  
15          quired to be filed, with such agency. The returns  
16          and forms described by this paragraph are those re-  
17          turns and forms related to the release of tobacco  
18          products into domestic commerce, as defined by sec-  
19          tion 5702(k) of the Internal Revenue Code of 1986,  
20          and the repayment of the taxes imposed under chap-  
21          ter 52 of such Code (ATF Form 500.24 and United  
22          States Customs Form 7501 under currently applica-  
23          ble regulations).

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

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

9 “(g) EFFECTIVE DATE.—The user fees prescribed by  
10 this section shall be assessed in fiscal year 2005, based  
11 on domestic sales of tobacco products during fiscal year  
12 2004 and shall be assessed in each fiscal year thereafter.”.

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

14 (a) CIGARETTES AND SMOKELESS TOBACCO.—

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

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

1 the Secretary of Health and Human Services in the  
2 August 28, 1996, issue of the Federal Register (61  
3 Fed. Reg., 44615–44618). Such rule shall—

4 (A) provide for the designation of jurisdic-  
5 tional authority that is in accordance with this  
6 subsection;

7 (B) strike Subpart C—Labeling and sec-  
8 tion 897.32(e); and

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

11 (3) AMENDMENTS TO RULE.—Prior to making  
12 amendments to the rule published under paragraph  
13 (1), the Secretary shall promulgate a proposed rule  
14 in accordance with the Administrative Procedures  
15 Act.

16 (4) RULE OF CONSTRUCTION.—Except as pro-  
17 vided in paragraph (3), nothing in this section shall  
18 be construed to limit the authority of the Secretary  
19 to amend, in accordance with the Administrative  
20 Procedures Act, the regulation promulgated pursu-  
21 ant to this section.

22 (b) LIMITATION ON ADVISORY OPINIONS.—As of the  
23 date of enactment of this Act, the following documents  
24 issued by the Food and Drug Administration shall not  
25 constitute advisory opinions under section 10.85(d)(1) of

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

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

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

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

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

1 tional Determination” (61 Fed. Reg. 44619–45318  
2 (August 28, 1996)).

3 **SEC. 233. CONFORMING AND OTHER AMENDMENTS TO GEN-**  
4 **ERAL PROVISIONS.**

5 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND  
6 COSMETIC ACT.—Except as otherwise expressly provided,  
7 whenever in this section an amendment is expressed in  
8 terms of an amendment to, or repeal of, a section or other  
9 provision, the reference is to a section or other provision  
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 301 et seq.).

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

14 (1) in subsection (a), by inserting “tobacco  
15 product,” after “device,”;

16 (2) in subsection (b), by inserting “tobacco  
17 product,” after “device,”;

18 (3) in subsection (c), by inserting “tobacco  
19 product,” after “device,”;

20 (4) in subsection (e), by striking “515(f), or  
21 519” and inserting “515(f), 519, or 909”;

22 (5) in subsection (g), by inserting “tobacco  
23 product,” after “device,”;

24 (6) in subsection (h), by inserting “tobacco  
25 product,” after “device,”;

1           (7) in subsection (j), by striking “708, or 721”  
2           and inserting “708, 721, 904, 905, 906, 907, 908,  
3           909, or section 921(b)”;

4           (8) in subsection (k), by inserting “tobacco  
5           product,” after “device,”;

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

8           “(p) The failure to register in accordance with section  
9           510 or 905, the failure to provide any information re-  
10          quired by section 510(j), 510(k), 905(i), or 905(j), or the  
11          failure to provide a notice required by section 510(j)(2)  
12          or 905(i)(2).”;

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

15          “(q)(1) The failure or refusal—

16                 “(A) to comply with any requirement prescribed  
17                 under section 518, 520(g), 903(b)(8), or 908, or  
18                 condition           prescribed           under           section  
19                 903(b)(6)(B)(ii)(II);

20                 “(B) to furnish any notification or other mate-  
21                 rial or information required by or under section 519,  
22                 520(g), 904, 909, or section 921; or

23                 “(C) to comply with a requirement under sec-  
24                 tion 522 or 913.”;

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

3           (12) in subsection (r), by inserting “or tobacco  
4           product” after “device” each time that it appears;  
5           and

6           (13) by adding at the end the following:

7           “(aa) The sale of tobacco products in violation  
8           of a no-tobacco-sale order issued under section  
9           303(f).

10          “(bb) The introduction or delivery for introduc-  
11          tion into interstate commerce of a tobacco product  
12          in violation of section 911.

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

20          “(2) Making, selling, disposing of, or keeping in  
21          possession, control, or custody, or concealing any  
22          punch, die, plate, stone, or other item that is de-  
23          signed to print, imprint, or reproduce the trade-  
24          mark, trade name, or other identifying mark, im-  
25          print, or device of another or any likeness of any of

1 the foregoing upon any tobacco product or container  
2 or labeling thereof so as to render such tobacco  
3 product a counterfeit tobacco product.

4 “(3) The doing of any act that causes a tobacco  
5 product to be a counterfeit tobacco product, or the  
6 sale or dispensing, or the holding for sale or dis-  
7 pensing, of a counterfeit tobacco product.

8 “(dd) The charitable distribution of tobacco  
9 products.

10 “(ee) The failure of a manufacturer or dis-  
11 tributor to notify the Attorney General of their  
12 knowledge of tobacco products used in illicit trade.”.

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

15 (1) by striking the subsection heading and in-  
16 serting the following:

17 “(f) CIVIL PENALTIES; NO-TOBACCO-SALE OR-  
18 DERS.—”;

19 (2) in paragraph (1)(A), by inserting “or to-  
20 bacco products” after “devices”;

21 (3) in paragraph (2)(C), by striking “paragraph  
22 (3)(A)” and inserting “paragraph (4)(A)”;

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

1           “(3) If the Secretary finds that a person has  
2 committed repeated violations of restrictions promul-  
3 gated under section 906(d) at a particular retail out-  
4 let then the Secretary may impose a no-tobacco-sale  
5 order on that person prohibiting the sale of tobacco  
6 products in that outlet. A no-tobacco-sale order may  
7 be imposed with a civil penalty under paragraph  
8 (1).”;

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

10           (A) in subparagraph (A)—

11           (i) by striking “assessed” the first  
12 time it appears and inserting “assessed, or  
13 a no-tobacco-sale order may be imposed,”;  
14 and

15           (ii) by striking “penalty” and insert-  
16 ing “penalty, or upon whom a no-tobacco-  
17 order is to be imposed,”;

18           (B) in subparagraph (B)—

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

22           (ii) by adding at the end the fol-  
23 lowing: “A no-tobacco-sale order perma-  
24 nently prohibiting an individual retail out-  
25 let from selling tobacco products shall in-

1           clude provisions that allow the outlet, after  
2           a specified period of time, to request that  
3           the Secretary compromise, modify, or ter-  
4           minate the order.”; and

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

6           “(D) The Secretary may compromise, mod-  
7           ify, or terminate, with or without conditions,  
8           any no-tobacco-sale order.”;

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

10           (A) by striking “(3)(A)” as redesignated,  
11           and inserting “(4)(A)”;

12           (B) by inserting “or the imposition of a  
13           no-tobacco-sale order” after “penalty” the first  
14           2 places it appears; and

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

18           (7) in paragraph (6), as so redesignated, by  
19           striking “paragraph (4)” each place it appears and  
20           inserting “paragraph (5)”.

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

23           (1) in subsection (a)(2)—

24           (A) by striking “and” before “(D)”;

1 (B) by striking “device.” and inserting the  
2 following: “, (E) Any adulterated or misbranded  
3 tobacco product.”;

4 (2) in subsection (d)(1), by inserting “tobacco  
5 product,” after “device,”;

6 (3) in subsection (g)(1), by inserting “or to-  
7 bacco product” after “device” each place it appears;  
8 and

9 (4) in subsection (g)(2)(A), by inserting “or to-  
10 bacco product” after “device” each place it appears.

11 (e) SECTION 702.—Section 702(a) (21 U.S.C.  
12 372(a)) is amended—

13 (1) by inserting “(1)” after “(a)”; and

14 (2) by adding at the end thereof the following:

15 “(2) For a tobacco product, to the extent feasible,  
16 the Secretary shall contract with the States in accordance  
17 with paragraph (1) to carry out inspections of retailers  
18 within that State in connection with the enforcement of  
19 this Act.”.

20 (f) SECTION 703.—Section 703 (21 U.S.C. 373) is  
21 amended—

22 (1) by inserting “tobacco product,” after “de-  
23 vice,” each place it appears; and

24 (2) by inserting “tobacco products,” after “de-  
25 vices,” each place it appears.

1 (g) SECTION 704.—Section 704 (21 U.S.C. 374) is  
2 amended—

3 (1) in subsection (a)(1)(A), by inserting “to-  
4 bacco products,” after “devices,” each place it ap-  
5 pears;

6 (2) in subsection (a)(1)(B), by inserting “or to-  
7 bacco product” after “restricted devices” each place  
8 it appears; and

9 (3) in subsection (b), by inserting “tobacco  
10 product,” after “device,”.

11 (h) SECTION 705.—Section 705(b) (21 U.S.C.  
12 375(b)) is amended by inserting “tobacco products,” after  
13 “devices,”.

14 (i) SECTION 709.—Section 709 (21 U.S.C. 379) is  
15 amended by inserting “or tobacco product” after “device”.

16 (j) SECTION 801.—Section 801 (21 U.S.C. 381) is  
17 amended—

18 (1) in subsection (a)—

19 (A) by inserting “tobacco products,” after  
20 “devices,” the first time it appears;

21 (B) by inserting “or section 905(j)” after  
22 “section 510”; and

23 (C) by striking “drugs or devices” each  
24 time it appears and inserting “drugs, devices,  
25 or tobacco products”;

1           (2) in subsection (e)(1), by inserting “tobacco  
2           product,” after “device,”; and

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

4           “(p)(1) Not later than 2 years after the date of enact-  
5           ment of the Family Smoking Prevention and Tobacco  
6           Control Act, and annually thereafter, the Secretary shall  
7           submit to the Committee on Health, Education, Labor,  
8           and Pensions of the Senate and the Committee on Energy  
9           and Commerce of the House of Representatives, a report  
10          regarding—

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

15           “(B) the public health implications of such ex-  
16          ports, including any evidence of a negative public  
17          health impact; and

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

22          “(2) The Secretary is authorized to establish appro-  
23          priate information disclosure requirements to carry out  
24          this subsection.”.

1 (k) SECTION 1003.—Section 1003(d)(2)(C) (as re-  
2 designated by section 231(a)) is amended—

3 (1) by striking “and” after “cosmetics,”; and

4 (2) inserting a comma and “and tobacco prod-  
5 ucts” after “devices”.

6 (l) GUIDANCE AND EFFECTIVE DATES.—

7 (1) IN GENERAL.—The Secretary of Health and  
8 Human Services shall issue guidance—

9 (A) defining the term “repeated violation”,  
10 as used in section 303(f) of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 333(f)) as  
12 amended by subsection (c), by identifying the  
13 number of violations of particular requirements  
14 over a specified period of time at a particular  
15 retail outlet that constitute a repeated violation;

16 (B) providing for timely and effective no-  
17 tice to the retailer of each alleged violation at  
18 a particular retail outlet;

19 (C) providing for an expedited procedure  
20 for the administrative appeal of an alleged vio-  
21 lation;

22 (D) providing that a person may not be  
23 charged with a violation at a particular retail  
24 outlet unless the Secretary has provided notice

1 to the retailer of all previous violations at that  
2 outlet;

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

8 (F) providing that good faith reliance on  
9 the presentation of a false government issued  
10 photographic identification that contains a date  
11 of birth does not constitute a violation of any  
12 minimum age requirement for the sale of to-  
13 bacco products if the retailer has taken effective  
14 steps to prevent such violations, including—

15 (i) adopting and enforcing a written  
16 policy against sales to minors;

17 (ii) informing its employees of all ap-  
18 plicable laws;

19 (iii) establishing disciplinary sanctions  
20 for employee noncompliance; and

21 (iv) requiring its employees to verify  
22 age by way of photographic identification  
23 or electronic scanning device.

24 (2) GENERAL EFFECTIVE DATE.—The amend-  
25 ments made by subsection (c), other than the

1 amendment made by paragraph (2) of such sub-  
2 section, shall take effect upon the issuance of guid-  
3 ance described in paragraph (1).

4 (3) SPECIAL EFFECTIVE DATE.—The amend-  
5 ments made by paragraph (2) of subsection (c) shall  
6 take effect on the date of enactment of this Act.

7 **PART II—TOBACCO PRODUCT WARNINGS; CON-**  
8 **STITUENT AND SMOKE CONSTITUENT DIS-**  
9 **CLOSURE**

10 **SEC. 235. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

11 Section 4 of the Federal Cigarette Labeling and Ad-  
12 vertising Act (15 U.S.C. 1333) is amended to read as fol-  
13 lows:

14 **“SEC. 4. LABELING.**

15 **“(a) LABEL REQUIREMENTS.—**

16 **“(1) IN GENERAL.—**It shall be unlawful for any  
17 person to manufacture, package, sell, offer to sell,  
18 distribute, or import for sale or distribution within  
19 the United States any cigarettes the package of  
20 which fails to bear, in accordance with the require-  
21 ments of this section, one of the following labels:

22 **“‘WARNING: Cigarettes are addictive’.**

23 **“‘WARNING: Tobacco smoke can harm your**  
24 **children’.**

1           “‘WARNING: Cigarettes cause fatal lung dis-  
2           ease’.

3           “‘WARNING: Cigarettes cause cancer’.

4           “‘WARNING: Cigarettes cause strokes and  
5           heart disease’.

6           “‘WARNING: Smoking during pregnancy can  
7           harm your baby’.

8           “‘WARNING: Smoking can kill you’.

9           “‘WARNING: Tobacco smoke causes fatal lung  
10          disease in non-smokers’.

11          “‘WARNING: Quitting smoking now greatly  
12          reduces serious risks to your health’.

13          “(2) PLACEMENT; TYPOGRAPHY; ETC.—

14                 “(A) IN GENERAL.—Each label statement  
15                 required by paragraph (1) shall be located in  
16                 the upper portion of the front and rear panels  
17                 of the package, directly on the package under-  
18                 neath the cellophane or other clear wrapping.  
19                 Except as provided in subparagraph (B), each  
20                 label statement shall comprise at least the top  
21                 30 percent of the front and rear panels of the  
22                 package. The word ‘WARNING’ shall appear in  
23                 capital letters and all text shall be in con-  
24                 spicuous and legible 17-point type, unless the  
25                 text of the label statement would occupy more

1 than 70 percent of such area, in which case the  
2 text may be in a smaller conspicuous and leg-  
3 ible type size, provided that at least 60 percent  
4 of such area is occupied by required text. The  
5 text shall be black on a white background, or  
6 white on a black background, in a manner that  
7 contrasts, by typography, layout, or color, with  
8 all other printed material on the package, in an  
9 alternating fashion under the plan submitted  
10 under subsection (b)(4).

11 “(B) HINGED LID BOXES.—For any ciga-  
12 rette brand package manufactured or distrib-  
13 uted before January 1, 2000, which employs a  
14 hinged lid style (if such packaging was used for  
15 that brand in commerce prior to June 21,  
16 1997), the label statement required by para-  
17 graph (1) shall be located on the hinged lid  
18 area of the package, even if such area is less  
19 than 25 percent of the area of the front panel.  
20 Except as provided in this paragraph, the provi-  
21 sions of this subsection shall apply to such  
22 packages.

23 “(3) DOES NOT APPLY TO FOREIGN DISTRIBU-  
24 TION.—The provisions of this subsection do not  
25 apply to a tobacco product manufacturer or dis-

1 tributor of cigarettes which does not manufacture,  
2 package, or import cigarettes for sale or distribution  
3 within the United States.

4 “(4) APPLICABILITY TO RETAILERS.—A retailer  
5 of cigarettes shall not be in violation of this sub-  
6 section for packaging that is supplied to the retailer  
7 by a tobacco product manufacturer, importer, or dis-  
8 tributor and is not altered by the retailer in a way  
9 that is material to the requirements of this sub-  
10 section except that this paragraph shall not relieve  
11 a retailer of liability if the retailer sells or distributes  
12 tobacco products that are not labeled in accordance  
13 with this subsection.

14 “(b) ADVERTISING REQUIREMENTS.—

15 “(1) IN GENERAL.—It shall be unlawful for any  
16 tobacco product manufacturer, importer, distributor,  
17 or retailer of cigarettes to advertise or cause to be  
18 advertised within the United States any cigarette  
19 unless its advertising bears, in accordance with the  
20 requirements of this section, one of the labels speci-  
21 fied in subsection (a) of this section.

22 “(2) TYPOGRAPHY, ETC.—Each label statement  
23 required by subsection (a) of this section in cigarette  
24 advertising shall comply with the standards set forth  
25 in this paragraph. For press and poster advertise-

1       ments, each such statement and (where applicable)  
2       any required statement relating to tar, nicotine, or  
3       other constituent (including a smoke constituent)  
4       yield shall comprise at least 20 percent of the area  
5       of the advertisement and shall appear in a con-  
6       spicuous and prominent format and location at the  
7       top of each advertisement within the trim area. The  
8       Secretary may revise the required type sizes in such  
9       area in such manner as the Secretary determines ap-  
10      propriate. The word 'WARNING' shall appear in  
11      capital letters, and each label statement shall appear  
12      in conspicuous and legible type. The text of the label  
13      statement shall be black if the background is white  
14      and white if the background is black, under the plan  
15      submitted under paragraph (4) of this subsection.  
16      The label statements shall be enclosed by a rectan-  
17      gular border that is the same color as the letters of  
18      the statements and that is the width of the first  
19      downstroke of the capital 'W' of the word 'WARN-  
20      ING' in the label statements. The text of such label  
21      statements shall be in a typeface pro rata to the fol-  
22      lowing requirements: 45-point type for a whole-page  
23      broadsheet newspaper advertisement; 39-point type  
24      for a half-page broadsheet newspaper advertisement;  
25      39-point type for a whole-page tabloid newspaper ad-

1 advertisement; 27-point type for a half-page tabloid  
2 newspaper advertisement; 31.5-point type for a dou-  
3 ble page spread magazine or whole-page magazine  
4 advertisement; 22.5-point type for a 28 centimeter  
5 by 3 column advertisement; and 15-point type for a  
6 20 centimeter by 2 column advertisement. The label  
7 statements shall be in English, except that in the  
8 case of—

9 “(A) an advertisement that appears in a  
10 newspaper, magazine, periodical, or other publi-  
11 cation that is not in English, the statements  
12 shall appear in the predominant language of the  
13 publication; and

14 “(B) in the case of any other advertise-  
15 ment that is not in English, the statements  
16 shall appear in the same language as that prin-  
17 cipally used in the advertisement.

18 “(3) MATCHBOOKS.—Notwithstanding para-  
19 graph (2), for matchbooks (defined as containing not  
20 more than 20 matches) customarily given away with  
21 the purchase of tobacco products, each label state-  
22 ment required by subsection (a) may be printed on  
23 the inside cover of the matchbook.

24 “(4) ADJUSTMENT BY SECRETARY.—The Sec-  
25 retary may, through a rulemaking under section 553

1 of title 5, United States Code, adjust the format and  
2 type sizes for the label statements required by this  
3 section or the text, format, and type sizes of any re-  
4 quired tar, nicotine yield, or other constituent (in-  
5 cluding smoke constituent) disclosures, or to estab-  
6 lish the text, format, and type sizes for any other  
7 disclosures required under the Federal Food, Drug,  
8 and Cosmetic Act (21 U.S.C. 301 et. seq.). The text  
9 of any such label statements or disclosures shall be  
10 required to appear only within the 20 percent area  
11 of cigarette advertisements provided by paragraph  
12 (2) of this subsection. The Secretary shall promul-  
13 gate regulations which provide for adjustments in  
14 the format and type sizes of any text required to ap-  
15 pear in such area to ensure that the total text re-  
16 quired to appear by law will fit within such area.

17 “(c) MARKETING REQUIREMENTS.—

18 “(1) RANDOM DISPLAY.—The label statements  
19 specified in subsection (a)(1) shall be randomly dis-  
20 played in each 12-month period, in as equal a num-  
21 ber of times as is possible on each brand of the  
22 product and be randomly distributed in all areas of  
23 the United States in which the product is marketed  
24 in accordance with a plan submitted by the tobacco

1 product manufacturer, importer, distributor, or re-  
2 tailer and approved by the Secretary.

3 “(2) ROTATION.—The label statements speci-  
4 fied in subsection (a)(1) shall be rotated quarterly in  
5 alternating sequence in advertisements for each  
6 brand of cigarettes in accordance with a plan sub-  
7 mitted by the tobacco product manufacturer, im-  
8 porter, distributor, or retailer to, and approved by,  
9 the Secretary.

10 “(3) REVIEW.—The Secretary shall review each  
11 plan submitted under paragraph (2) and approve it  
12 if the plan—

13 “(A) will provide for the equal distribution  
14 and display on packaging and the rotation re-  
15 quired in advertising under this subsection; and

16 “(B) assures that all of the labels required  
17 under this section will be displayed by the to-  
18 bacco product manufacturer, importer, dis-  
19 tributor, or retailer at the same time.

20 “(4) APPLICABILITY TO RETAILERS.—This sub-  
21 section and subsection (b) apply to a retailer only if  
22 that retailer is responsible for or directs the label  
23 statements required under this section except that  
24 this paragraph shall not relieve a retailer of liability  
25 if the retailer displays, in a location open to the pub-

1       lic, an advertisement that is not labeled in accord-  
2       ance with the requirements of this subsection and  
3       subsection (b).”.

4       **SEC. 236. AUTHORITY TO REVISE CIGARETTE WARNING**  
5                                   **LABEL STATEMENTS.**

6       Section 4 of the Federal Cigarette Labeling and Ad-  
7       vertising Act (15 U.S.C. 1333), as amended by section  
8       235, is further amended by adding at the end the fol-  
9       lowing:

10       “(d) CHANGE IN REQUIRED STATEMENTS.—The  
11       Secretary may, by a rulemaking conducted under section  
12       553 of title 5, United States Code, adjust the format, type  
13       size, and text of any of the label requirements, require  
14       color graphics to accompany the text, increase the re-  
15       quired label area from 30 percent up to 50 percent of the  
16       front and rear panels of the package, or establish the for-  
17       mat, type size, and text of any other disclosures required  
18       under the Federal Food, Drug, and Cosmetic Act (21  
19       U.S.C. 301 et seq.), if the Secretary finds that such a  
20       change would promote greater public understanding of the  
21       risks associated with the use of tobacco products.”.

1 **SEC. 237. STATE REGULATION OF CIGARETTE ADVER-**  
2 **TISING AND PROMOTION.**

3 Section 5 of the Federal Cigarette Labeling and Ad-  
4 vertising Act (15 U.S.C. 1334) is amended by adding at  
5 the end the following:

6 “(c) EXCEPTION.—Notwithstanding subsection (b), a  
7 State or locality may enact statutes and promulgate regu-  
8 lations, based on smoking and health, that take effect  
9 after the effective date of the Family Smoking Prevention  
10 and Tobacco Control Act, imposing specific bans or re-  
11 strictions on the time, place, and manner, but not content,  
12 of the advertising or promotion of any cigarettes.”.

13 **SEC. 238. SMOKELESS TOBACCO LABELS AND ADVERTISING**  
14 **WARNINGS.**

15 Section 3 of the Comprehensive Smokeless Tobacco  
16 Health Education Act of 1986 (15 U.S.C. 4402) is amend-  
17 ed to read as follows:

18 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

19 “(a) GENERAL RULE.—

20 “(1) It shall be unlawful for any person to man-  
21 ufacture, package, sell, offer to sell, distribute, or  
22 import for sale or distribution within the United  
23 States any smokeless tobacco product unless the  
24 product package bears, in accordance with the re-  
25 quirements of this Act, one of the following labels:

1           “‘WARNING: This product can cause mouth  
2 cancer’.

3           “‘WARNING: This product can cause gum dis-  
4 ease and tooth loss’.

5           “‘WARNING: This product is not a safe alter-  
6 native to cigarettes’.

7           “‘WARNING: Smokeless tobacco is addictive’.

8           “(2) Each label statement required by para-  
9 graph (1) shall be—

10                   “(A) located on the 2 principal display  
11 panels of the package, and each label statement  
12 shall comprise at least 30 percent of each such  
13 display panel; and

14                   “(B) in 17-point conspicuous and legible  
15 type and in black text on a white background,  
16 or white text on a black background, in a man-  
17 ner that contrasts by typography, layout, or  
18 color, with all other printed material on the  
19 package, in an alternating fashion under the  
20 plan submitted under subsection (b)(3), except  
21 that if the text of a label statement would oc-  
22 cupy more than 70 percent of the area specified  
23 by subparagraph (A), such text may appear in  
24 a smaller type size, so long as at least 60 per-

1 cent of such warning area is occupied by the  
2 label statement.

3 “(3) The label statements required by para-  
4 graph (1) shall be introduced by each tobacco prod-  
5 uct manufacturer, packager, importer, distributor, or  
6 retailer of smokeless tobacco products concurrently  
7 into the distribution chain of such products.

8 “(4) The provisions of this subsection do not  
9 apply to a tobacco product manufacturer or dis-  
10 tributor of any smokeless tobacco product that does  
11 not manufacture, package, or import smokeless to-  
12 bacco products for sale or distribution within the  
13 United States.

14 “(5) A retailer of smokeless tobacco products  
15 shall not be in violation of this subsection for pack-  
16 aging that is supplied to the retailer by a tobacco  
17 products manufacturer, importer, or distributor and  
18 that is not altered by the retailer unless the retailer  
19 offers for sale, sells, or distributes a smokeless to-  
20 bacco product that is not labeled in accordance with  
21 this subsection.

22 “(b) REQUIRED LABELS.—

23 “(1) It shall be unlawful for any tobacco prod-  
24 uct manufacturer, packager, importer, distributor, or  
25 retailer of smokeless tobacco products to advertise or

1 cause to be advertised within the United States any  
2 smokeless tobacco product unless its advertising  
3 bears, in accordance with the requirements of this  
4 section, one of the labels specified in subsection (a).

5 “(2) Each label statement required by sub-  
6 section (a) in smokeless tobacco advertising shall  
7 comply with the standards set forth in this para-  
8 graph. For press and poster advertisements, each  
9 such statement and (where applicable) any required  
10 statement relating to tar, nicotine, or other con-  
11 stituent yield shall—

12 “(A) comprise at least 20 percent of the  
13 area of the advertisement, and the warning area  
14 shall be delineated by a dividing line of con-  
15 trasting color from the advertisement; and

16 “(B) the word ‘WARNING’ shall appear in  
17 capital letters and each label statement shall  
18 appear in conspicuous and legible type. The text  
19 of the label statement shall be black on a white  
20 background, or white on a black background, in  
21 an alternating fashion under the plan submitted  
22 under paragraph (3).

23 “(3)(A) The label statements specified in sub-  
24 section (a)(1) shall be randomly displayed in each  
25 12-month period, in as equal a number of times as

1 is possible on each brand of the product and be ran-  
2 domly distributed in all areas of the United States  
3 in which the product is marketed in accordance with  
4 a plan submitted by the tobacco product manufac-  
5 turer, importer, distributor, or retailer and approved  
6 by the Secretary.

7 “(B) The label statements specified in sub-  
8 section (a)(1) shall be rotated quarterly in alter-  
9 nating sequence in advertisements for each brand of  
10 smokeless tobacco product in accordance with a plan  
11 submitted by the tobacco product manufacturer, im-  
12 porter, distributor, or retailer to, and approved by,  
13 the Secretary.

14 “(C) The Secretary shall review each plan sub-  
15 mitted under subparagraph (B) and approve it if the  
16 plan—

17 “(i) will provide for the equal distribution  
18 and display on packaging and the rotation re-  
19 quired in advertising under this subsection; and

20 “(ii) assures that all of the labels required  
21 under this section will be displayed by the to-  
22 bacco product manufacturer, importer, dis-  
23 tributor, or retailer at the same time.

24 “(D) This paragraph applies to a retailer only  
25 if that retailer is responsible for or directs the label

1 statements under this section, unless the retailer dis-  
2 plays in a location open to the public, an advertise-  
3 ment that is not labeled in accordance with the re-  
4 quirements of this subsection.

5 “(c) TELEVISION AND RADIO ADVERTISING.—It is  
6 unlawful to advertise smokeless tobacco on any medium  
7 of electronic communications subject to the jurisdiction of  
8 the Federal Communications Commission.”.

9 **SEC. 239. AUTHORITY TO REVISE SMOKELESS TOBACCO**  
10 **PRODUCT WARNING LABEL STATEMENTS.**

11 Section 3 of the Comprehensive Smokeless Tobacco  
12 Health Education Act of 1986 (15 U.S.C. 4402), as  
13 amended by section 237, is further amended by adding  
14 at the end the following:

15 “(d) AUTHORITY TO REVISE WARNING LABEL  
16 STATEMENTS.—The Secretary may, by a rulemaking con-  
17 ducted under section 553 of title 5, United States Code,  
18 adjust the format, type size, and text of any of the label  
19 requirements, require color graphics to accompany the  
20 text, increase the required label area from 30 percent up  
21 to 50 percent of the front and rear panels of the package,  
22 or establish the format, type size, and text of any other  
23 disclosures required under the Federal Food, Drug, and  
24 Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary  
25 finds that such a change would promote greater public un-

1 derstanding of the risks associated with the use of smoke-  
2 less tobacco products.”.

3 **SEC. 240. TAR, NICOTINE, AND OTHER SMOKE CON-**  
4 **STITUENT DISCLOSURE TO THE PUBLIC.**

5 Section 4(a) of the Federal Cigarette Labeling and  
6 Advertising Act (15 U.S.C. 1333 (a)), as amended by sec-  
7 tion 235, is further amended by adding at the end the  
8 following:

9 “(4)(A) The Secretary shall, by a rulemaking  
10 conducted under section 553 of title 5, United  
11 States Code, determine (in the Secretary’s sole dis-  
12 cretion) whether cigarette and other tobacco product  
13 manufacturers shall be required to include in the  
14 area of each cigarette advertisement specified by  
15 subsection (b) of this section, or on the package  
16 label, or both, the tar and nicotine yields of the ad-  
17 vertised or packaged brand. Any such disclosure  
18 shall be in accordance with the methodology estab-  
19 lished under such regulations, shall conform to the  
20 type size requirements of subsection (b) of this sec-  
21 tion, and shall appear within the area specified in  
22 subsection (b) of this section.

23 “(B) Any differences between the requirements  
24 established by the Secretary under subparagraph (A)  
25 and tar and nicotine yield reporting requirements es-

1        established by the Federal Trade Commission shall be  
2        resolved by a memorandum of understanding be-  
3        tween the Secretary and the Federal Trade Commis-  
4        sion.

5            “(C) In addition to the disclosures required by  
6        subparagraph (A) of this paragraph, the Secretary  
7        may, under a rulemaking conducted under section  
8        553 of title 5, United States Code, prescribe disclo-  
9        sure requirements regarding the level of any ciga-  
10       rette or other tobacco product constituent including  
11       any smoke constituent. Any such disclosure may be  
12       required if the Secretary determines that disclosure  
13       would be of benefit to the public health, or otherwise  
14       would increase consumer awareness of the health  
15       consequences of the use of tobacco products, except  
16       that no such prescribed disclosure shall be required  
17       on the face of any cigarette package or advertise-  
18       ment. Nothing in this section shall prohibit the Sec-  
19       retary from requiring such prescribed disclosure  
20       through a cigarette or other tobacco product pack-  
21       age or advertisement insert, or by any other means  
22       under the Federal Food, Drug, and Cosmetic Act  
23       (21 U.S.C. 301 et seq.).

24            “(D) This paragraph applies to a retailer only  
25        if that retailer is responsible for or directs the label

1 statements required under this section, except that  
2 this paragraph shall not relieve a retailer of liability  
3 if the retailer sells or distributes tobacco products  
4 that are not labeled in accordance with the require-  
5 ments of this subsection.”.

6 **PART III—PREVENTION OF ILLICIT TRADE IN**  
7 **TOBACCO PRODUCTS**

8 **SEC. 241. LABELING, RECORDKEEPING, RECORDS INSPEC-**  
9 **TION.**

10 Chapter IX of the Federal Food, Drug, and Cosmetic  
11 Act, as added by section 231, is further amended by add-  
12 ing at the end the following:

13 **“SEC. 921. LABELING, RECORDKEEPING, RECORDS INSPEC-**  
14 **TION.**

15 “(a) ORIGIN LABELING.—The label, packaging, and  
16 shipping containers of tobacco products for introduction  
17 or delivery for introduction into interstate commerce in the  
18 United States shall bear the statement ‘sale only allowed  
19 in the United States.’

20 “(b) REGULATIONS CONCERNING RECORDKEEPING  
21 FOR TRACKING AND TRACING.—

22 “(1) IN GENERAL.—Not later than 9 months  
23 after the date of enactment of the Family Smoking  
24 Prevention and Tobacco Control Act, the Secretary  
25 shall promulgate regulations regarding the establish-

1       ment and maintenance of records by any person who  
2       manufactures, processes, transports, distributes, re-  
3       ceives, packages, holds, exports, or imports tobacco  
4       products.

5           “(2) INSPECTION.—In promulgating the regula-  
6       tions described in paragraph (1), the Secretary shall  
7       consider which records are needed for inspection to  
8       monitor the movement of tobacco products from the  
9       point of manufacture through distribution to retail  
10      outlets to assist in investigating potential illicit  
11      trade, smuggling or counterfeiting of tobacco prod-  
12      ucts.

13          “(3) CODES.—The Secretary may require codes  
14      on the labels of tobacco products or other designs or  
15      devices for the purpose of tracking or tracing the to-  
16      bacco product through the distribution system.

17          “(4) SIZE OF BUSINESS.—The Secretary shall  
18      take into account the size of a business in promul-  
19      gating regulations under this section.

20          “(5) RECORDKEEPING BY RETAILERS.—The  
21      Secretary shall not require any retailer to maintain  
22      records relating to individual purchasers of tobacco  
23      products for personal consumption.

24          “(c) RECORDS INSPECTION.—If the Secretary has a  
25      reasonable belief that a tobacco product is part of an illicit

1 trade or smuggling or is a counterfeit product, each person  
2 who manufactures, processes, transports, distributes, re-  
3 ceives, holds, packages, exports, or imports tobacco prod-  
4 ucts shall, at the request of an officer or employee duly  
5 designated by the Secretary, permit such officer or em-  
6 ployee, at reasonable times and within reasonable limits  
7 and in a reasonable manner, upon the presentation of ap-  
8 propriate credentials and a written notice to such person,  
9 to have access to and copy all records (including financial  
10 records) relating to such article that are needed to assist  
11 the Secretary in investigating potential illicit trade, smug-  
12 gling or counterfeiting of tobacco products.

13 “(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

14 “(1) IN GENERAL.—If the manufacturer or dis-  
15 tributor of a tobacco product has knowledge which  
16 reasonably supports the conclusion that a tobacco  
17 product manufactured or distributed by such manu-  
18 facturer or distributor that has left the control of  
19 such person may be or has been—

20 “(A) imported, exported, distributed or of-  
21 fered for sale in interstate commerce by a per-  
22 son without paying duties or taxes required by  
23 law; or

24 “(B) imported, exported, distributed or di-  
25 verted for possible illicit marketing, the manu-

1           factorer or distributor shall promptly notify the  
2           Attorney General of such knowledge.

3           “(2) KNOWLEDGE DEFINED.—For purposes of  
4           this subsection, the term ‘knowledge’ as applied to  
5           a manufacturer or distributor means—

6                   “(A) the actual knowledge that the manu-  
7                   facturer or distributor had; or

8                   “(B) the knowledge which a reasonable  
9                   person would have had under like circumstances  
10                  or which would have been obtained upon the ex-  
11                  ercise of due care.”.

12 **SEC. 242. STUDY AND REPORT.**

13           (a) STUDY.—The Comptroller General of the United  
14           States shall conduct a study of cross-border trade in to-  
15           bacco products to—

16                   (1) collect data on cross-border trade in tobacco  
17                   products, including illicit trade and trade of counter-  
18                   feit tobacco products and make recommendations on  
19                   the monitoring of such trade;

20                   (2) collect data on cross-border advertising (any  
21                   advertising intended to be broadcast, transmitted, or  
22                   distributed from the United States to another coun-  
23                   try) of tobacco products and make recommendations  
24                   on how to prevent or eliminate, and what tech-

1 nologies could help facilitate the elimination of,  
2 cross-border advertising.

3 (b) REPORT.—Not later than 18 months after the  
4 date of enactment of this Act, the Comptroller General  
5 of the United States shall submit to the Committee on  
6 Health, Education, Labor, and Pensions of the Senate and  
7 the Committee on Energy and Commerce of the House  
8 of Representatives a report on the study described in sub-  
9 section (a).

10 **TITLE III—RESPONSIBLE MAR-**  
11 **KETING AND CONSUMER**  
12 **AWARENESS**

13 **Subtitle A—General Provisions**

14 **SEC. 301. NUTRITION LABELING OF RESTAURANT FOODS.**

15 Section 403(q)(5) of the Federal Food, Drug, and  
16 Cosmetic Act (21 U.S.C. 343(q)(5)(A)(i)) is amended—

17 (1) in clause (A)—

18 (A) in subclause (i), by inserting “except  
19 as provided in clauses (H) and (I),” before  
20 “which” the first place it appears; and

21 (B) in subclause (ii), by inserting “except  
22 as provided in clauses (H) and (I),” before  
23 “which” the first place it appears; and

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

1       “(H) RESTAURANTS AND RETAIL FOOD ESTABLISH-  
2 MENTS.—

3           “(i) IN GENERAL.—Except for food described in  
4 subclause (iii), in the case of food that is served,  
5 processed, or prepared in a restaurant or similar re-  
6 tail food establishment that is part of a chain with  
7 20 or more locations doing business under the same  
8 trade name (regardless of the type of ownership of  
9 the locations), the restaurant or establishment shall  
10 disclose the information described in subclause (ii).

11           “(ii) INFORMATION REQUIRED TO BE DIS-  
12 CLOSED.—Except as provided in subclause (iii), the  
13 establishment shall disclose—

14           “(I)(aa) in a statement adjacent to the  
15 name of the food on any menu listing the food  
16 for sale, or by any other means deemed equiva-  
17 lent by the Secretary, the number of calories,  
18 grams of saturated fat plus trans fat, and milli-  
19 grams of sodium contained in a standard serv-  
20 ing of the food, as usually offered for sale, in  
21 a clear and conspicuous manner; and

22           “(bb) information, specified by the Sec-  
23 retary by regulation, designed to enable the  
24 public to understand, in the context of a total

1 daily diet, the significance of the nutrition in-  
2 formation that is provided; and

3 “(II) in a statement adjacent to the name  
4 of the food on any menu board or other sign  
5 listing the food for sale, or by any other means  
6 deemed equivalent by the Secretary—

7 “(aa) the number of calories con-  
8 tained in a serving of the food, as usually  
9 offered for sale, in a clear and conspicuous  
10 manner; and

11 “(bb) notification that the information  
12 required by subitems (aa) and (bb) of item  
13 (I) shall be provided in writing at the re-  
14 quest of a prospective purchaser.

15 “(iii) NONAPPLICABILITY TO CERTAIN FOOD.—

16 This clause does not apply to—

17 “(I) items that are not listed on a menu or  
18 menu board (such as condiments and other  
19 items placed on the table or counter for general  
20 use); or

21 “(II) daily specials, temporary menu items,  
22 or other irregular menu items, as specified by  
23 the Secretary by regulation.

24 “(iv) SELF-SERVICE FACILITIES.—In the case  
25 of food sold at a salad bar, buffet line, cafeteria line,

1 or similar self-service facility, a restaurant or other  
 2 establishment shall place a sign that lists calories  
 3 per standard serving adjacent to each food offered.

4 “(v) VOLUNTARY PROVISION OF NUTRITION IN-  
 5 FORMATION; STATE REGULATION OF NUTRITION IN-  
 6 FORMATION FOR RESTAURANT FOOD.—

7 “(I) RETAIL FOOD ESTABLISHMENTS.—  
 8 Nothing in this clause precludes a restaurant or  
 9 similar retail food establishment from providing  
 10 additional nutrition information, voluntarily, if  
 11 the information complies with the nutrition la-  
 12 beling requirements contained in this subpara-  
 13 graph.

14 “(II) STATE OR LOCAL REQUIREMENTS.—  
 15 Nothing in this clause precludes a State or po-  
 16 litical subdivision of a State from requiring that  
 17 a restaurant or similar food establishment pro-  
 18 vide nutrition information in addition to that  
 19 required under this clause.

20 “(vi) REGULATIONS.—

21 “(I) PROPOSED REGULATION.—Not later  
 22 than 1 year after the date of enactment of this  
 23 clause, the Secretary shall promulgate proposed  
 24 regulations to carry out this clause.

1           “(II) CONTENTS.—The regulations shall  
2 allow for the variations in serving sizes and in  
3 food preparation that can reasonably be ex-  
4 pected to result from inadvertent human error,  
5 training of food service workers, and other fac-  
6 tors.

7           “(III) FINAL REGULATIONS.—Not later  
8 than 2 years after the date of enactment of this  
9 clause, the Secretary shall promulgate final reg-  
10 ulations to implement this clause.

11           “(IV) FAILURE TO PROMULGATE FINAL  
12 REGULATIONS BY REQUIRED DATE.—If the Sec-  
13 retary does not promulgate final regulations  
14 under item (III) by the date that is 2 years  
15 after the date of enactment of this clause—

16           “(aa) the proposed regulations issued  
17 in accordance with item (I) shall become  
18 effective as the final regulations on the day  
19 after that date; and

20           “(bb) the Secretary shall publish in  
21 the Federal Register notice of the final  
22 regulations.

23           “(I) VENDING MACHINES.—

24           “(i) IN GENERAL.—In the case of an article of  
25 food sold from a vending machine that—

1           “(I) does not permit a prospective pur-  
2           chaser to examine the article so as to be able  
3           to read a statement affixed to the article before  
4           purchasing the article; and

5           “(II) is operated by a person that is en-  
6           gaged in the business of owning and operating  
7           20 or more vending machines;

8           the vending machine operator shall provide a con-  
9           spicuous sign in close proximity to the article that  
10          includes a statement disclosing the number of cal-  
11          ories contained in the article.

12          “(ii) VOLUNTARY PROVISION OF NUTRITION IN-  
13          FORMATION; STATE REGULATION OF NUTRITION IN-  
14          FORMATION FOR VENDING MACHINES.—

15          “(I) VENDING MACHINE OPERATORS.—

16          Nothing in this clause precludes a vending ma-  
17          chine operator from providing additional nutri-  
18          tion information, voluntarily, if the information  
19          complies with the nutrition labeling require-  
20          ments contained in this subparagraph.

21          “(II) STATE OR LOCAL REQUIREMENTS.—

22          Nothing in this title precludes a State or polit-  
23          ical subdivision of a State from requiring that  
24          a vending machine operator provide nutrition

1 information in addition to that required under  
2 this clause.

3 “(iii) REGULATIONS.—

4 “(I) PROPOSED REGULATIONS.—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) FINAL REGULATIONS.—Not later  
9 than 2 years after the date of enactment of this  
10 clause, the Secretary shall promulgate final reg-  
11 ulations to implement this clause.

12 “(III) FAILURE TO PROMULGATE FINAL  
13 REGULATIONS BY REQUIRED DATE.—If the Sec-  
14 retary does not promulgate final regulations  
15 under item (II) by the date that is 2 years after  
16 the date of enactment of this clause—

17 “(aa) the proposed regulations issued  
18 in accordance with item (I) shall become  
19 effective as the final regulations on the day  
20 after that date; and

21 “(bb) the Secretary shall publish in  
22 the Federal Register notice of the final  
23 regulations.”.

1 **SEC. 302. RULEMAKING AUTHORITY FOR ADVERTISING TO**  
2 **CHILDREN.**

3 (a) PURPOSE.—The purpose of this section is to re-  
4 store the authority of the Federal Trade Commission to  
5 issue regulations that restrict the marketing or advertising  
6 of foods and beverages to children under the age of 18  
7 years if the Federal Trade Commission determines that  
8 there is evidence that consumption of certain foods and  
9 beverages is detrimental to the health of children.

10 (b) AUTHORITY.—Section 18 of the Federal Trade  
11 Commission Act (15 U.S.C. 57a) is amended by striking  
12 subsection (h).

13 **SEC. 303. LABEL AND DISCLOSURE REQUIREMENTS FOR IN-**  
14 **FANT FORMULAS.**

15 Section 412 of the Federal Food, Drug, and Cosmetic  
16 Act (21 U.S.C. 350a) is amended by adding at the end  
17 the following:

18 “(j) LABEL AND DISCLOSURE REQUIREMENTS.—

19 “(1) PACKAGING LABEL REQUIREMENTS.—

20 “(A) IN GENERAL.—An infant formula  
21 shall be deemed misbranded unless the label of  
22 such infant formula contains the following  
23 statement: ‘The United States Department of  
24 Health and Human Services has determined  
25 that: (1) breast-feeding is the ideal method of  
26 feeding and nurturing infants; (2) breast milk

1 is the most complete form of nutrition for in-  
2 fants; and (3) breast milk is more beneficial to  
3 infants than infant formula.’.

4 “(B) SPECIFICATIONS OF LABEL.—The  
5 label statement required under subparagraph  
6 (A) shall be—

7 “(i) in conspicuous and legible type  
8 that is not smaller than 12-point font;

9 “(ii) in black font on a white back-  
10 ground, or white font on a black back-  
11 ground;

12 “(iii) with respect to typography and  
13 layout, in contrast with the other printed  
14 material on the package; and

15 “(iv) enclosed by a border that is the  
16 same color as the letters of the statement.

17 “(2) ADVERTISING REGULATIONS.—

18 “(A) IN GENERAL.—The Secretary shall  
19 promulgate regulations establishing labeling  
20 and disclosure requirements for advertisements  
21 of infant formula.

22 “(B) SPECIFICATIONS OF ADVERTISE-  
23 MENTS.—The regulations promulgated under  
24 subparagraph (A) shall—

1           “(i) establish labeling and disclosure  
2 requirements for all forms of media by  
3 which infant formula is advertised, includ-  
4 ing print, television, radio, and Internet  
5 marketing; and

6           “(ii) be at least as stringent as the  
7 packaging label requirements under para-  
8 graph (1).”.

9 **SEC. 304. FOOD ADVERTISING IN SCHOOLS.**

10       Section 10 of the Child Nutrition Act of 1966 (42  
11 U.S.C. 1779) is amended by adding at the end the fol-  
12 lowing:

13       “(d) **FOOD ADVERTISING.**—The Secretary may pro-  
14 hibit the advertising of food in participating schools if the  
15 Secretary determines that consumption of the advertised  
16 food has a detrimental effect on the diets or health of chil-  
17 dren.”.

18 **SEC. 305. DISALLOWANCE OF DEDUCTIONS FOR ADVER-**  
19 **TISING AND MARKETING EXPENSES RELAT-**  
20 **ING TO TOBACCO PRODUCT USE.**

21       (a) **IN GENERAL.**—Part IX of subchapter B of chap-  
22 ter 1 of subtitle A of the Internal Revenue Code of 1986  
23 (relating to items not deductible) is amended by adding  
24 at the end the following new section:

1 **“SEC. 280I. DISALLOWANCE OF DEDUCTION FOR TOBACCO**  
 2 **ADVERTISING AND MARKETING EXPENSES.**

3 “No deduction shall be allowed under this chapter for  
 4 expenses relating to advertising or marketing cigars, ciga-  
 5 rettes, smokeless tobacco, pipe tobacco, or any similar to-  
 6 bacco product. For purposes of this section, any term used  
 7 in this section which is also used in section 5702 shall  
 8 have the same meaning given such term by section 5702.”.

9 (b) CONFORMING AMENDMENT.—The table of sec-  
 10 tions for such part IX is amended by adding after the  
 11 item relating to section 280H the following new item:

“Sec. 280I. Disallowance of deduction for tobacco advertising  
 and marketing expenses.”.

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

15 **SEC. 306. FEDERAL-STATE TOBACCO COUNTER-ADVER-**  
 16 **TISING PROGRAMS.**

17 Part P of title III of the Public Health Service Act  
 18 (42 U.S.C. 280g et seq.), as amended in section 212, is  
 19 further amended by adding at the end the following:

20 **“SEC. 399S. FEDERAL-STATE TOBACCO COUNTER-ADVER-**  
 21 **TISING PROGRAMS.**

22 “(a) IN GENERAL.—The Secretary, acting through  
 23 the Director of the Centers for Disease Control and Pre-  
 24 vention, shall award grants to and enter into contracts

1 with eligible entities for the implementation of national  
2 and local media (such as counter-advertising) and non-  
3 media campaigns designed to reduce the use of tobacco  
4 products.

5 “(b) ELIGIBILITY.—To be eligible to receive a grant  
6 under subsection (a), an entity shall be—

7 “(1) a public entity, including a State public  
8 health department; or

9 “(2) a private, nonprofit entity that—

10 “(A) is not affiliated with a manufacturer  
11 or importer of a tobacco product;

12 “(B) has demonstrated a record of con-  
13 ducting a national antitobacco public education  
14 campaign to effectively reduce the use of to-  
15 bacco products;

16 “(C) has expertise in conducting a multi-  
17 media communications campaign; and

18 “(D) has expertise in developing strategies  
19 that affect behavior changes in children and  
20 other targeted populations.

21 “(c) APPLICATION.—An eligible entity shall submit  
22 an application to the Secretary for a grant under this sec-  
23 tion at such time, in such manner, and accompanied by  
24 such information as the Secretary may require.

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

3               “(1) design and implement multimedia public  
4 education and social marketing campaigns that—

5                       “(A) discourage the use of tobacco prod-  
6 ucts;

7                       “(B) encourage the use of products de-  
8 signed to enable tobacco use cessation; and

9                       “(C) educate the public about the hazards  
10 of environmental tobacco smoke exposure; or

11               “(2) conduct research related to the effective-  
12 ness of the campaigns described in paragraph (1).

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

15               “(1) 50 percent of such amounts to eligible  
16 public entities; and

17               “(2) 50 percent of such amounts to eligible pri-  
18 vate, nonprofit entities.

19       “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
20 are authorized to be appropriated \$200,000,000 to carry  
21 out this section.”.

## 22       **Subtitle B—Penalties for Failure to** 23               **Reduce Teen Smoking**

### 24       **SEC. 311. CHILD CIGARETTE USE SURVEYS.**

25       (a) ANNUAL PERFORMANCE SURVEY.—

1           (1) IN GENERAL.—Not later than August 31,  
2           2006, and annually thereafter, the Secretary of  
3           Health and Human Services (referred to in this sec-  
4           tion as the “Secretary”) shall publish the results of  
5           an annual cigarette survey, to be carried out after  
6           the date of enactment of this Act and completed  
7           prior to August 21, 2006, and prior to August 21  
8           of each year thereafter, to determine—

9                   (A) the percentage of all young individuals  
10                   who used a type of cigarette within the 30-day  
11                   period prior to the conduct of the survey in-  
12                   volved; and

13                   (B) the percentage of young individuals  
14                   who identify each brand of each type of ciga-  
15                   rette as the usual brand smoked within such  
16                   30-day period.

17           (2) YOUNG INDIVIDUALS.—For the purposes of  
18           this subtitle, the term “young individuals” means in-  
19           dividuals who are under 18 years of age.

20           (b) SIZE AND METHODOLOGY.—

21                   (1) IN GENERAL.—The survey referred to in  
22                   subsection (a) shall be comparable in size and meth-  
23                   odology to the Monitoring the Future survey that  
24                   was completed in 1999 to measure the use of ciga-  
25                   rettes (by brand) by youths under 18 years of age

1 within the 30-day period prior to the conduct of the  
2 study.

3 (2) CONCLUSIVE ACCURATENESS.—A survey  
4 using the methodology described in paragraph (1)  
5 shall be deemed conclusively proper, correct, and ac-  
6 curate for purposes of this section.

7 (3) DEFINITION.—In this subtitle, the term  
8 “Monitoring the Future survey” means the com-  
9 bined survey of 8th, 10th, and 12th grade students  
10 that was conducted at the Institute for Social Re-  
11 search at the University of Michigan.

12 (c) REDUCTION.—The Secretary, based on a com-  
13 parison of the results of the first annual cigarette survey  
14 referred to in subsection (a) and the Monitoring the Fu-  
15 ture survey referred to in subsection (b)(1), shall deter-  
16 mine the percentage reduction (if any) in youth cigarette  
17 use for each manufacturer of cigarettes.

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

23 (e) NONAPPLICABILITY.—Chapter 35 of title 44,  
24 United States Code, shall not apply to information re-  
25 quired for the purposes of carrying out this section.

1 (f) DEFINITION.—In this subtitle the term “ciga-  
2 rette” has the meaning given such term in section 3(1)  
3 of the Federal Cigarette Labeling and Advertising Act (15  
4 U.S.C. 1332(1)).

5 **SEC. 312. CIGARETTE USE REDUCTION GOAL AND NON-**  
6 **COMPLIANCE.**

7 (a) GOAL.—It shall be the cigarette use reduction  
8 goal that each manufacturer reduce youth cigarette use  
9 by at least 15 percent during the period between the Moni-  
10 toring the Future survey referred to in section 311(b)(1)  
11 and the completion of the first annual cigarette survey  
12 (and such subsequent surveys as compared to the previous  
13 year’s survey) referred to in section 311(a).

14 (b) NONCOMPLIANCE.—

15 (1) INDUSTRY-WIDE PENALTY.—If the Sec-  
16 retary determines that the cigarette use reduction  
17 goal under subsection (a) has not been achieved, the  
18 Secretary shall, not later than September 10, 2006,  
19 and September 10 of each year thereafter, impose  
20 an industry-wide penalty on the manufacturers of  
21 cigarettes in an amount that is in the aggregate  
22 equal to—

23 (A) if youth cigarette use has been reduced  
24 by 5 percent or less, \$6,000,000,000;

1 (B) if youth cigarette use has been reduced  
2 by at least 6 percent but less than 10 percent,  
3 \$4,000,000,000; and

4 (C) if youth cigarette use has been reduced  
5 by at least 11 percent but less than 15 percent,  
6 \$2,000,000,000.

7 (2) PAYMENT.—The industry-wide penalty im-  
8 posed under this subsection shall be paid by each  
9 manufacturer based on the percentage of cigarettes  
10 of each such manufacturer that are used by youth  
11 (as determined under the Monitoring the Future  
12 survey and compared to the cigarettes manufactured  
13 by all manufacturers) as such percentage relates to  
14 the total amount to be paid by all manufacturers.

15 (3) FINAL DETERMINATION.—The determina-  
16 tion of the Secretary as to the amount and allocation  
17 of a surcharge under this subtitle shall be final and  
18 the manufacturer shall pay such surcharge within 10  
19 days of the date on which the manufacturer is as-  
20 sessed. Such payment shall be retained by the Sec-  
21 retary pending final judicial review of what, if any,  
22 change in the surcharge is appropriate.

23 (4) COMPLIANCE BY CERTAIN MANUFACTUR-  
24 ERS.—A manufacturer that individually complies  
25 with the goal under subsection (a) shall not be liable

1 for the payment of any portion of the penalty under  
2 this subsection.

3 (5) LIMITATION.—With respect to cigarettes, a  
4 manufacturer with a market share of 1 percent or  
5 less of youth cigarette use shall not be liable for the  
6 payment of a surcharge under this section.

7 (c) PENALTIES NONDEDUCTIBLE.—The payment of  
8 penalties under this subtitle shall not be considered to be  
9 an ordinary and necessary expense in carrying on a trade  
10 or business for purposes of the Internal Revenue Code of  
11 1986 and shall not be deductible.

12 (d) JUDICIAL REVIEW.—

13 (1) AFTER PAYMENT.—A manufacturer of ciga-  
14 rettes may seek judicial review of any action under  
15 this subtitle only after the assessment involved has  
16 been paid by the manufacturer to the Department of  
17 the Treasury and only in the United States District  
18 Court for the District of Columbia.

19 (2) REVIEW BY ATTORNEY GENERAL.—Prior to  
20 the filing of an action by a manufacturer seeking ju-  
21 dicial review of an action under this subtitle, the  
22 manufacturer shall notify the Attorney General of  
23 such intent to file and the Attorney General shall  
24 have 30 days in which to respond to the action.

1           (3) REVIEW.—The amount of any surcharge  
2           paid under this subtitle shall be subject to judicial  
3           review by the United States Court of Appeals for the  
4           District of Columbia Circuit, based on the arbitrary  
5           and capricious standard of section 706 of title 5,  
6           United States Code. Notwithstanding any other pro-  
7           vision of law, no court shall have the authority to  
8           stay any surcharge payment due to the Secretary  
9           under this subtitle pending judicial review until the  
10          Secretary has made or failed to make a compliance  
11          determination, as described under this subtitle, that  
12          has adversely affected the person seeking the review.

13 **SEC. 313. ENFORCEMENT.**

14          (a) INITIAL PENALTY.—There is hereby imposed an  
15          initial penalty on the failure of any manufacturer to make  
16          any payment required under this subtitle within 10 days  
17          after the date on which such payment is due.

18          (b) AMOUNT OF PENALTY.—The amount of the pen-  
19          alty imposed by subsection (a) on any failure with respect  
20          to a manufacturer shall be an amount equal to 2 percent  
21          of the penalty owed under section 312 for each day during  
22          the noncompliance period.

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

1 spect to any failure to make the surcharge payment re-  
 2 quired under this subtitle, the period—

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

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

7 (d) LIMITATIONS.—No penalty shall be imposed by  
 8 subsection (a) on—

9 (1) any failure to make a surcharge payment  
 10 under this subtitle during any period for which it is  
 11 established to the satisfaction of the Secretary that  
 12 none of the persons responsible for such failure  
 13 knew or, exercising reasonable diligence, would have  
 14 known, that such failure existed; or

15 (2) any manufacturer that produces less than 1  
 16 percent of cigarettes used by youth in that year (as  
 17 determined by the annual survey).

18 **TITLE IV—REIMBURSEMENT**  
 19 **AND COVERAGE OF PREVEN-**  
 20 **TIVE SERVICES**

21 **SEC. 401. COVERAGE OF SUBSTANCE USE (OTHER THAN TO-**  
 22 **BACCO), DIET, EXERCISE, INJURY PREVEN-**  
 23 **TION, AND DENTAL HEALTH COUNSELING.**

24 (a) COVERAGE.—

1           (1) IN GENERAL.—Section 1861(s)(2) of the  
2           Social Security Act (42 U.S.C. 1395x(s)(2)), as  
3           amended by section 642(a) of the Medicare Prescrip-  
4           tion Drug, Improvement, and Modernization Act of  
5           2003 (Public Law 108–173; 117 Stat. 2322), is  
6           amended—

7                   (A) in subparagraph (Y), by striking  
8                   “and” after the semicolon at the end;

9                   (B) in subparagraph (Z), by adding “and”  
10                  after the semicolon at the end; and

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

13                  “(AA) substance use (other than tobacco), diet,  
14                  exercise, injury prevention, and dental health coun-  
15                  seling (as defined in subsection (bbb)(1));”.

16           (2) CONFORMING AMENDMENTS.—(A) Section  
17           1862(a)(12) of the Social Security Act (42 U.S.C.  
18           1395y(a)(12)) is amended by inserting “(except as  
19           otherwise allowed under subsection  
20           1861(s)(2)(AA))” after “directly supporting teeth”.

21           (B) Clauses (i) and (ii) of section  
22           1861(s)(2)(K) of the Social Security Act (42 U.S.C.  
23           1395x(s)(2)(K)), as amended by section 611(d)(2) of  
24           the Medicare Prescription Drug, Improvement, and  
25           Modernization Act of 2003 (Public Law 108–173;

1 117 Stat. 2304), are each amended by striking  
2 “subsection (ww)(1)” and inserting “subsections  
3 (ww)(1) and (bbb)”.

4 (b) SERVICES DESCRIBED.—Section 1861 of the So-  
5 cial Security Act (42 U.S.C. 1395x), as amended by sec-  
6 tion 706(b) of the Medicare Prescription Drug, Improve-  
7 ment, and Modernization Act of 2003 (Public Law 108-  
8 173; 117 Stat. 2339), is amended by adding at the end  
9 the following new subsection:

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

12 “(bbb) The term ‘substance use (other than tobacco),  
13 diet, exercise, injury prevention, and dental health coun-  
14 seling’ means therapy and counseling relating to substance  
15 use (other than tobacco), diet, exercise, injury prevention,  
16 and dental health counseling that is furnished—

17 “(1) by or under the supervision of a physician;  
18 or

19 “(2) by any other health care professional  
20 who—

21 “(A) is legally authorized to furnish such  
22 services under State law (or the State regu-  
23 latory mechanism provided by State law) of the  
24 State in which the services are furnished; and

1           “(B) is authorized to receive payment for  
2           other services under this title or is designated  
3           by the Secretary for this purpose.”.

4           (c) PAYMENT AND ELIMINATION OF COST-SHAR-  
5     ING.—

6           (1) PAYMENT AND ELIMINATION OF COINSUR-  
7     ANCE.—Section 1833(a)(1) of the Social Security  
8     Act (42 U.S.C. 1395l(a)(1)), as amended by section  
9     302(b)(2) of the Medicare Prescription Drug, Im-  
10    provement, and Modernization Act of 2003 (Public  
11    Law 108–173; 117 Stat. 2229), is amended—

12           (A) in subparagraph (N), by inserting “or  
13           substance use (other than tobacco), diet, exer-  
14           cise, injury prevention, and dental health coun-  
15           seling (as defined in section 1861(bbb))” after  
16           “(as defined in section 1848(j)(3))”;

17           (B) by striking “and” before “(V)”;

18           (C) by inserting before the semicolon at  
19           the end the following: “and (W) with respect to  
20           substance use (other than tobacco), diet, exer-  
21           cise, injury prevention, and dental health coun-  
22           seling (as defined in section 1861(bbb)) the  
23           amount paid shall be the lesser of the actual  
24           charge for the services or the amount deter-

1           mined under the payment basis determined  
2           under section 1848”.

3           (2) PAYMENT UNDER PHYSICIAN FEE SCHED-  
4           ULE.—Section 1848(j)(3) of the Social Security Act  
5           (42 U.S.C. 1395w-4(j)(3)), as amended by section  
6           611(c) of the Medicare Prescription Drug, Improve-  
7           ment, and Modernization Act of 2003 (Public Law  
8           108-173; 117 Stat. 2304), is amended by inserting  
9           “(2)(AA),” after “(2)(W),”.

10          (3) ELIMINATION OF COINSURANCE IN OUT-  
11          PATIENT HOSPITAL SETTINGS.—

12                 (A) EXCLUSION FROM OPD FEE SCHED-  
13                 ULE.—Section 1833(t)(1)(B)(iv) of the Social  
14                 Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)), as  
15                 amended by section 614(a) of the Medicare  
16                 Prescription Drug, Improvement, and Mod-  
17                 ernization Act of 2003 (Public Law 108-173;  
18                 117 Stat. 2306), is amended by striking “and  
19                 diagnostic mammography” and inserting “, di-  
20                 agnostic mammography, or substance use  
21                 (other than tobacco), diet, exercise, injury pre-  
22                 vention, and dental health counseling (as de-  
23                 fined in section 1861(bbb))”.

1 (B) CONFORMING AMENDMENTS.—Section  
2 1833(a)(2) of the Social Security Act (42  
3 U.S.C. 1395l(a)(2)) is amended—

4 (i) in subparagraph (F), by striking  
5 “and” after the semicolon at the end;

6 (ii) in subparagraph (G)(ii), by strik-  
7 ing the comma at the end and inserting  
8 “; and”; and

9 (iii) by inserting after subparagraph  
10 (G)(ii) the following new subparagraph:

11 “(H) with respect to substance use (other  
12 than tobacco), diet, exercise, injury prevention,  
13 and dental health counseling (as defined in sec-  
14 tion 1861(bbb)) furnished by an outpatient de-  
15 partment of a hospital, the amount determined  
16 under paragraph (1)(W),”.

17 (4) ELIMINATION OF DEDUCTIBLE.—The first  
18 sentence of section 1833(b) of the Social Security  
19 Act (42 U.S.C. 1395l(b)) is amended—

20 (A) by striking “and” before “(6)”; and

21 (B) by inserting before the period at the  
22 end the following: “, and (7) such deductible  
23 shall not apply with respect to substance use  
24 (other than tobacco), diet, exercise, injury pre-

1           vention, and dental health counseling (as de-  
2           fined in section 1861(bbb))”.

3           (d) APPLICATION OF LIMITS ON BILLING.—Section  
4 1842(b)(18)(C) of the Social Security Act (42 U.S.C.  
5 1395u(b)(18)(C)) is amended by adding at the end the  
6 following new clause:

7           “(vii) Any health care professional designated  
8           under section 1861(bbb)(2)(B) to perform substance  
9           use (other than tobacco), diet, exercise, injury pre-  
10          vention, and dental health counseling that is not oth-  
11          erwise described in this subparagraph.”.

12          (e) EFFECTIVE DATE.—The amendments made by  
13 this section shall take effect as if included in the enact-  
14 ment of the Medicare Prescription Drug, Improvement,  
15 and Modernization Act of 2003 (Public Law 108–173; 117  
16 Stat. 2066) and shall apply to services furnished on and  
17 after January 1, 2006.

18 **SEC. 402. PREVENTIVE MENTAL HEALTH SCREENINGS.**

19          (a) COVERAGE.—

20               (1) IN GENERAL.—Section 1861(s)(2) of the  
21          Social Security Act (42 U.S.C. 1395x(s)(2)), as  
22          amended by section 401(a)(1), is amended—

23                       (A) in subparagraph (Z), by striking  
24                       “and” after the semicolon at the end;

1 (B) in subparagraph (AA), by adding  
2 “and” after the semicolon at the end; and

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

5 “(BB) screenings for clinical depression, anx-  
6 iety, and impaired cognitive functioning (as defined  
7 in subsection (ccc)(1));”.

8 (2) CONFORMING AMENDMENTS.—Clauses (i)  
9 and (ii) of section 1861(s)(2)(K) of the Social Secu-  
10 rity Act (42 U.S.C. 1395x(s)(2)(K)), as amended by  
11 section 401(a)(2)(B), are each amended by striking  
12 “and (bbb)” and inserting “(bbb), and (ccc)”.

13 (b) SERVICES DESCRIBED.—Section 1861 of the So-  
14 cial Security Act (42 U.S.C. 1395x), as amended by sec-  
15 tion 401(b), is amended by adding at the end the following  
16 new subsection:

17 “Screenings for Clinical Depression, Anxiety, and  
18 Impaired Cognitive Functioning

19 “(ccc)(1) The term ‘screening for clinical depression,  
20 anxiety, and impaired cognitive functioning’ means a con-  
21 sultation for the purpose of detecting clinical depression,  
22 anxiety, and impaired cognitive functioning during which  
23 a qualified health professional (as defined in paragraph  
24 (2))—

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

3           “(B) assesses the individual’s risk of clinical de-  
4 pression, anxiety, and impaired cognitive func-  
5 tioning; and

6           “(C) if the qualified health professional deter-  
7 mines that the individual is at high risk for clinical  
8 depression, anxiety, or impaired cognitive func-  
9 tioning, refers the individual for a full diagnostic  
10 evaluation and such additional treatment as may be  
11 required.

12 Nothing in subparagraph (C) shall be construed as prohib-  
13 iting a qualified health professional performing the screen-  
14 ing for clinical depression, anxiety, and impaired cognitive  
15 functioning with respect to an individual from directly pro-  
16 viding the diagnostic evaluation and additional treatment  
17 described in such clause to such individual if such profes-  
18 sional is legally authorized to provide such an evaluation  
19 and additional treatment under State law (or the State  
20 regulatory mechanism provided by State law) of the State  
21 in which the screening is performed.

22           “(2) For purposes of this subsection, the term ‘quali-  
23 fied health professional’ means an individual who—

24           “(A) is—

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

3           “(ii) a nurse practitioner (as defined in  
4           subsection (aa)(5)); or

5           “(iii) a mental health care professional (in-  
6           cluding clinical psychologists (as defined by the  
7           Secretary for purposes of section 1861(ii)) and  
8           clinical social workers (as defined in subsection  
9           1861(hh))) that is licensed or certified to per-  
10          form mental health services by the State in  
11          which the screenings are performed; and

12          “(B) has an agreement in effect with the Sec-  
13          retary to accept—

14               “(i) the amount determined under section  
15               1833(a)(1)(W) as full payment for screenings  
16               for clinical depression, anxiety, and impaired  
17               cognitive functioning; and

18               “(ii) an assignment described in section  
19               1842(b)(3)(B)(ii) with respect to payment for  
20               each screening furnished by the professional to  
21               an individual enrolled under part B.

22          “(3) The Secretary shall, in consultation with mental  
23          health professionals and other stakeholders with experi-  
24          ence in screening for clinical depression, anxiety, and im-  
25          paired cognitive functioning, shall establish or identify a

1 list of approved screenings to be used under this para-  
2 graph. The Secretary, in consultation with such profes-  
3 sionals and stakeholders, shall review and update such list  
4 not less frequently than once every 5 years.”.

5 (c) PAYMENT AND ELIMINATION OF COST-SHAR-  
6 ING.—

7 (1) PAYMENT AND ELIMINATION OF COINSUR-  
8 ANCE.—Section 1833(a)(1) of the Social Security  
9 Act (42 U.S.C. 1395l(a)(1)), as amended by section  
10 401(c)(1), is amended—

11 (A) in subparagraph (N), by striking “or  
12 substance use (other than tobacco), diet, exer-  
13 cise, injury prevention, and dental health coun-  
14 seling (as defined in section 1861(bbb))” and  
15 inserting “substance use (other than tobacco),  
16 diet, exercise, injury prevention, and dental  
17 health counseling (as defined in section  
18 1861(bbb)), or screenings for clinical depres-  
19 sion, anxiety, and impaired cognitive func-  
20 tioning (as defined in section 1861(ccc))”; and

21 (B) in subparagraph (W), by inserting  
22 “and screenings for clinical depression, anxiety,  
23 and impaired cognitive functioning (as defined  
24 in section 1861(ccc))” after “(as defined in sec-  
25 tion 1861(bbb))”.

1           (2) PAYMENT UNDER PHYSICIAN FEE SCHED-  
2           ULE.—Section 1848(j)(3) of the Social Security Act  
3           (42 U.S.C. 1395w-4(j)(3)), as amended by section  
4           401(c)(2), is amended by inserting “(2)(BB),” after  
5           “(2)(AA),”.

6           (3) ELIMINATION OF COINSURANCE IN OUT-  
7           PATIENT HOSPITAL SETTINGS.—

8           (A) EXCLUSION FROM OPD FEE SCHED-  
9           ULE.—Section 1833(t)(1)(B)(iv) of the Social  
10          Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)), as  
11          amended by section 401(c)(3)(A), is amended  
12          by striking “or substance use (other than to-  
13          bacco), diet, exercise, injury prevention, and  
14          dental health counseling (as defined in section  
15          1861(bbb))” and inserting “substance use  
16          (other than tobacco), diet, exercise, injury pre-  
17          vention, and dental health counseling (as de-  
18          fined in section 1861(bbb)), or screenings for  
19          clinical depression, anxiety, and impaired cog-  
20          nitive functioning (as defined in section  
21          1861(ccc))”.

22          (B) CONFORMING AMENDMENT.—Section  
23          1833(a)(2)(H) of the Social Security Act (42  
24          U.S.C. 1395l(a)(2)(H)), as added by section  
25          401(c)(3)(B)(iii), is amended by inserting “and

1           screenings for clinical depression, anxiety, and  
2           impaired cognitive functioning (as defined in  
3           section 1861(ccc))” after “(as defined in section  
4           1861(bbb))”.

5           (4) ELIMINATION OF DEDUCTIBLE.—Section  
6           1833(b)(7) of the Social Security Act (42 U.S.C.  
7           1395l(b)(7)), as amended by section 401(c)(4), is  
8           amended by inserting “or screenings for clinical de-  
9           pression, anxiety, and impaired cognitive functioning  
10          (as defined in section 1861(ccc))” before the period  
11          at the end.

12          (d) APPLICATION OF LIMITS ON BILLING.—Section  
13          1842(b)(18)(C) of the Social Security Act (42 U.S.C.  
14          1395u(b)(18)(C)), as amended by section 401(d), is  
15          amended by adding at the end the following new clause:

16                 “(viii) A mental health care professional de-  
17                 scribed in section 1861(ccc)(2) that is authorized to  
18                 perform screenings for clinical depression, anxiety,  
19                 and impaired cognitive functioning (as defined in  
20                 section 1861(ccc)(1)) that is not otherwise described  
21                 in this subparagraph.”.

22          (e) FREQUENCY.—Section 1862(a)(1) of the Social  
23          Security Act (42 U.S.C. 1395y(a)(1)), as amended by sec-  
24          tion 613(c) of the Medicare Prescription Drug, Improve-

1 ment, and Modernization Act of 2003 (Public Law 108–  
2 173; 117 Stat. 2306), is amended—

3 (1) in subparagraph (L), by striking “and”  
4 after the comma at the end;

5 (2) in subparagraph (M), by striking the semi-  
6 colon at the end and inserting “, and”; and

7 (3) by adding at the end the following new sub-  
8 paragraph:

9 “(N) in the case of screenings for clinical de-  
10 pression, anxiety, and impaired cognitive functioning  
11 (as defined in section 1861(ccc)(1)), which is per-  
12 formed more frequently than is covered under such  
13 section;”.

14 (f) EFFECTIVE DATE.—The amendments made by  
15 this section shall take effect as if included in the enact-  
16 ment of the Medicare Prescription Drug, Improvement,  
17 and Modernization Act of 2003 (Public Law 108–173; 117  
18 Stat. 2066) and shall apply to services furnished on and  
19 after January 1, 2006.

20 **SEC. 403. ENCOURAGEMENT OF CESSATION OF TOBACCO**  
21 **USE.**

22 (a) MEDICARE COVERAGE OF COUNSELING AND  
23 PHARMACOTHERAPY FOR CESSATION OF TOBACCO  
24 USE.—

25 (1) COVERAGE.—

1 (A) IN GENERAL.—Section 1861(s)(2) of  
2 the Social Security Act (42 U.S.C.  
3 1395x(s)(2)), as amended by section 402(a)(1),  
4 is amended—

5 (i) in subparagraph (AA), by striking  
6 “and” after the semicolon at the end;

7 (ii) in subparagraph (BB), by adding  
8 “and” after the semicolon at the end; and

9 (iii) by adding at the end the fol-  
10 lowing new subparagraph:

11 “(CC) counseling and pharmacotherapy for ces-  
12 sation of tobacco use (as defined in subsection  
13 (ddd)(1));”.

14 (B) CONFORMING AMENDMENTS.—Clauses  
15 (i) and (ii) of section 1861(s)(2)(K) of the So-  
16 cial Security Act (42 U.S.C. 1395x(s)(2)(K)),  
17 as amended by section 402(a)(2), are each  
18 amended by striking “and (ccc)” and inserting  
19 “(ccc), and (ddd)”.

20 (2) SERVICES DESCRIBED.—Section 1861 of  
21 the Social Security Act (42 U.S.C. 1395x), as  
22 amended by section 402(b), is amended by adding at  
23 the end the following new subsection:

1 “Counseling and Pharmacotherapy for Cessation of  
2 Tobacco Use

3 “(ddd)(1) Subject to paragraphs (2) and (3), the  
4 term ‘counseling and pharmacotherapy for cessation of to-  
5 bacco use’ means diagnostic, therapy, and counseling serv-  
6 ices and pharmacotherapy (including the coverage of pre-  
7 scription and nonprescription tobacco cessation agents ap-  
8 proved by the Food and Drug Administration) for ces-  
9 sation of tobacco use for individuals who use tobacco prod-  
10 ucts or who are being treated for tobacco use which are  
11 furnished—

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

13 or

14 “(B) by any other health care professional  
15 who—

16 “(i) is legally authorized to furnish such  
17 services under State law (or the State regu-  
18 latory mechanism provided by State law) of the  
19 State in which the services are furnished; and

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

23 “(2) Such term is limited to—

24 “(A) services recommended in ‘Treating To-  
25 bacco Use and Dependence: A Clinical Practice

1 Guideline’, published by the Public Health Service in  
2 June 2000, or any subsequent modification of such  
3 Guideline; and

4 “(B) such other services that the Secretary rec-  
5 ognizes to be effective.

6 “(3) Each individual who is described in paragraph  
7 (1) and enrolled under part B shall be eligible for the serv-  
8 ices described in this subsection for up to 3 attempts to  
9 cease the use of tobacco.”.

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

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

16 (i) in subparagraph (N) by striking  
17 “or screenings for clinical depression, anx-  
18 iety, and impaired cognitive functioning (as  
19 defined in section 1861(ccc))” and insert-  
20 ing “, screenings for clinical depression,  
21 anxiety, and impaired cognitive functioning  
22 (as defined in section 1861(ccc)), or coun-  
23 seling and pharmacotherapy for cessation  
24 of tobacco use (as defined in section  
25 1861(ddd))”; and

1 (ii) in subparagraph (W), by striking  
2 “and screenings for clinical depression,  
3 anxiety, and impaired cognitive functioning  
4 (as defined in section 1861(ccc))” and in-  
5 serting “screenings for clinical depression,  
6 anxiety, and impaired cognitive functioning  
7 (as defined in section 1861(ccc)), and  
8 counseling and pharmacotherapy for ces-  
9 sation of tobacco use (as defined in section  
10 1861(ddd))”.

11 (B) PAYMENT UNDER PHYSICIAN FEE  
12 SCHEDULE.—Section 1848(j)(3) of the Social  
13 Security Act (42 U.S.C. 1395w-4(j)(3)), as  
14 amended by section 402(c)(2), is amended by  
15 inserting “(2)(CC) (with separate payment  
16 amounts for pharmacotherapy, including pre-  
17 scription and nonprescription tobacco cessation  
18 agents approved by the Food and Drug Admin-  
19 istration),” after “(2)(BB),”.

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

22 (i) EXCLUSION FROM OPD FEE  
23 SCHEDULE.—Section 1833(t)(1)(B)(iv) of  
24 the Social Security Act (42 U.S.C.  
25 1395l(t)(1)(B)(iv)), as amended by section

1 402(c)(3)(A), is amended by striking “or  
2 screenings for clinical depression, anxiety,  
3 and impaired cognitive functioning (as de-  
4 fined in section 1861(ccc))” and inserting  
5 “screenings for clinical depression, anxiety,  
6 and impaired cognitive functioning (as de-  
7 fined in section 1861(ccc)), or counseling  
8 and pharmacotherapy for cessation of to-  
9 bacco use (as defined in section  
10 1861(ddd))”.

11 (ii) CONFORMING AMENDMENT.—Sec-  
12 tion 1833(a)(2)(H) of the Social Security  
13 Act (42 U.S.C. 1395l(a)(2)(H)), as added  
14 by section 402(c)(3)(B), is amended by  
15 striking “and screenings for clinical de-  
16 pression, anxiety, and impaired cognitive  
17 functioning (as defined in section  
18 1861(ccc))” and inserting “screenings for  
19 clinical depression, anxiety, and impaired  
20 cognitive functioning (as defined in section  
21 1861(ccc)), and counseling and  
22 pharmacotherapy for cessation of tobacco  
23 use (as defined in section 1861(ddd))”.

24 (D) ELIMINATION OF DEDUCTIBLE.—Sec-  
25 tion 1833(b)(7) of the Social Security Act (42

1 U.S.C. 1395l(b)(7)), as added by section  
2 402(c)(4), is amended by striking “or  
3 screenings for clinical depression, anxiety, and  
4 impaired cognitive functioning (as defined in  
5 section 1861(ccc))” and inserting “screenings  
6 for clinical depression, anxiety, and impaired  
7 cognitive functioning (as defined in section  
8 1861(ccc)), or counseling and pharmacotherapy  
9 for cessation of tobacco use (as defined in sec-  
10 tion 1861(ddd))”.

11 (4) APPLICATION OF LIMITS ON BILLING.—Sec-  
12 tion 1842(b)(18)(C) of the Social Security Act (42  
13 U.S.C. 1395u(b)(18)(C)), as amended by section  
14 402(d), is amended by adding at the end the fol-  
15 lowing new clause:

16 “(ix) Any individual designated by the Sec-  
17 retary under section 1861(ddd)(1)(B)(ii).”.

18 (5) FREQUENCY.—Section 1862(a)(1) of the  
19 Social Security Act (42 U.S.C. 1395y(a)(1)), as  
20 amended by section 402(e), is amended—

21 (A) in subparagraph (M), by striking  
22 “and” after the comma at the end;

23 (B) in subparagraph (N), by striking the  
24 semicolon at the end and inserting “, and”; and

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

3 “(O) in the case of counseling and  
4 pharmacotherapy for cessation of tobacco use (as de-  
5 fined in section 1861(ddd)), which is performed with  
6 respect to more attempts to cease tobacco use than  
7 is covered under such section;”.

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

10 (1) DROPPING EXCEPTION FROM MEDICAID  
11 PRESCRIPTION DRUG COVERAGE FOR TOBACCO CES-  
12 SATION MEDICATIONS.—Section 1927(d)(2) of the  
13 Social Security Act (42 U.S.C. 1396r–8(d)(2)) is  
14 amended—

15 (A) by striking subparagraph (E);

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

19 (C) in subparagraph (F) (as redesignated  
20 by paragraph (2)), by inserting before the pe-  
21 riod at the end the following: “, except agents  
22 approved by the Food and Drug Administration  
23 for purposes of promoting, and when used to  
24 promote, tobacco cessation”.

1           (2) REQUIRING COVERAGE OF TOBACCO CES-  
2           SATION COUNSELING AND PHARMACOTHERAPY  
3           SERVICES FOR PREGNANT WOMEN.—Section  
4           1905(a)(4) of the Social Security Act (42 U.S.C.  
5           1396d(a)(4)) is amended—

6                   (A) by striking “and” before “(C)”; and

7                   (B) by inserting before the semicolon at  
8           the end the following: “; and (D) counseling  
9           and pharmacotherapy for cessation of tobacco  
10          use (as defined in section 1861(ddd)) for preg-  
11          nant women”.

12          (3) REMOVAL OF COST-SHARING FOR TOBACCO  
13          CESSATION COUNSELING AND PHARMACOTHERAPY  
14          SERVICES FOR PREGNANT WOMEN.—Section 1916 of  
15          the Social Security Act (42 U.S.C. 1396o) is amend-  
16          ed in each of subsections (a)(2)(B) and (b)(2)(B),  
17          by inserting “, and counseling for cessation of to-  
18          bacco use (as defined in section 1861(ddd))” after  
19          “complicate the pregnancy”.

20          (c) COVERAGE UNDER FEHBP.—The last sentence  
21          of section 8904(a) of title 5, United States Code, is  
22          amended by striking “both for costs associated with care  
23          in a general hospital and for other health services of a  
24          catastrophic nature” and inserting “for costs associated  
25          with care in a general hospital, for other health services

1 of a catastrophic nature, and for counseling and  
 2 pharmacotherapy for cessation of tobacco use (as defined  
 3 in section 1861(ddd)(1) of the Social Security Act)”.

4 (d) EFFECTIVE DATE.—The amendments made by  
 5 this section shall take effect as if included in the enact-  
 6 ment of the Medicare Prescription Drug, Improvement,  
 7 and Modernization Act of 2003 (Public Law 108–173; 117  
 8 Stat. 2066) and shall apply to services furnished on and  
 9 after January 1, 2006.

10 **SEC. 404. RECOGNITION OF SCHOOL-BASED HEALTH CEN-**  
 11 **TERS AS MODEL FOR DELIVERY OF PRIMARY**  
 12 **CARE FOR CHILDREN UNDER THE MEDICAID**  
 13 **AND STATE CHILDREN’S HEALTH INSURANCE**  
 14 **PROGRAMS.**

15 (a) IN GENERAL.—Title XIX of the Social Security  
 16 Act (42 U.S.C. 1396 et seq.) is amended by inserting after  
 17 section 1911 the following:

18 “SCHOOL-BASED HEALTH CENTERS  
 19 “SEC. 1911A. Not later than 12 months after the  
 20 date of enactment of this section, the Secretary shall es-  
 21 tablish procedures to encourage a State program estab-  
 22 lished under this title, title XXI, or both, to recognize  
 23 school-based health centers as a model of delivery for pri-  
 24 mary care for children who are eligible for medical assist-  
 25 ance under this title or child health assistance under title  
 26 XXI. Such procedures shall include the following:

1           “(1) RECOGNITION OF, AND REIMBURSEMENT  
2           FOR, SERVICES PROVIDED THROUGH SCHOOL-BASED  
3           HEALTH CENTERS.—Procedures that encourage a  
4           State to recognize as primary care providers under  
5           this title and title XXI, providers who furnish phys-  
6           ical or mental health services that are available as  
7           medical assistance under this title or child health as-  
8           sistance under title XXI to children who are eligible  
9           for such assistance through school-based health cen-  
10          ters, and to reimburse such providers or centers (as  
11          appropriate) for furnishing such services to such  
12          children.

13           “(2) EXCEPTIONS TO THE ‘FREE CARE’  
14          RULE.—Procedures that allow a State the option to  
15          permit school-based health centers to bill the State  
16          for physical or mental health services that are avail-  
17          able as medical assistance under this title or child  
18          health assistance under title XXI and that are fur-  
19          nished to children who are eligible for such assist-  
20          ance through such centers without billing all chil-  
21          dren who are provided such services.

22           “(3) EXCEPTIONS TO THE ‘THIRD PARTY LI-  
23          ABILITY’ COST AVOIDANCE POLICY.—Procedures  
24          that encourage a State to include physical or mental  
25          health services that are available as medical assist-

1       ance under this title and that are provided through  
2       school-based health centers in the list of diagnosis  
3       billing codes for preventive pediatric care services  
4       that the State will pay for under this title and then  
5       seek reimbursement from any liable third party in  
6       accordance with the requirements of section  
7       1902(a)(25).

8               “(4) ASSURANCE OF PAYMENT FOR SERVICES  
9       COVERED BY A CONTRACT WITH A MANAGED CARE  
10      ENTITY.—Procedures that encourage a State to in-  
11      clude in any contract entered into with a managed  
12      care entity (as defined in section 1932(a)(1)(B))  
13      under this title or title XXI provisions which ensure  
14      that the entity will make prompt payment to a  
15      school-based health center for furnishing physical or  
16      mental health services to a child who is eligible for  
17      medical assistance under this title or child health as-  
18      sistance under title XXI that are within the scope of  
19      items and services for which benefits are available  
20      with respect to the child under the contract between  
21      the entity and the State (or to a provider who fur-  
22      nishes such services to such a child through a  
23      school-based health center), regardless of whether  
24      the center (or provider) is a participating provider  
25      with respect to such entity, at a rate established by

1 the entity for such services that is not less than the  
2 level and amount of payment which the entity would  
3 make for the services if the services were furnished  
4 by a participating provider.”.

5 (b) REPORT TO CONGRESS.—Not later than 36  
6 months after the date of enactment of this section, the  
7 Secretary of Health and Human Services shall submit a  
8 report to Congress on the effectiveness of the procedures  
9 established in accordance with section 1911A of the Social  
10 Security Act (as added by subsection (a)) in encouraging  
11 the use of school-based health centers for the delivery of  
12 primary care physical and mental health services to chil-  
13 dren who are eligible for medical assistance under title  
14 XIX of the Social Security Act (42 U.S.C. 1396 et seq.)  
15 or child health assistance under title XXI of such Act (42  
16 U.S.C. 1397aa et seq.), together with such recommenda-  
17 tions for administrative or legislative action as the Sec-  
18 retary determines to be appropriate.

19 **SEC. 405. PREVENTIVE HEALTH CARE DEMONSTRATION**  
20 **PROGRAM.**

21 (a) ESTABLISHMENT.—

22 (1) IN GENERAL.—Not later than 18 months  
23 after the date of enactment of this Act, the Sec-  
24 retary of Health and Human Services (in this sec-  
25 tion referred to as the “Secretary”) shall conduct a

1 5-year demonstration program under part B of title  
2 XVIII of the Social Security Act under which the  
3 Secretary establishes demonstration projects to con-  
4 tract with appropriate entities to provide preventive  
5 health care to eligible beneficiaries through the de-  
6 velopment and implementation of a disease preven-  
7 tion plan (as described in subsection (b)).

8 (2) SITES.—The Secretary shall designate at  
9 least 2 sites at which to conduct the demonstration  
10 program under this section, of which—

11 (A) 1 shall be in an urban area; and

12 (B) 1 shall be in a rural area.

13 (3) NUMBER OF ELIGIBLE BENEFICIARIES.—  
14 Each demonstration project site under this section  
15 shall consist of at least 1,000 eligible beneficiaries  
16 representative of the population of individuals enti-  
17 tled to benefits under part A of title XVIII of the  
18 Social Security Act, and enrolled under part B of  
19 such title. The Secretary may expand the population  
20 as needed to measure statistical significance.

21 (4) IDENTIFYING ELIGIBLE BENEFICIARIES.—  
22 The Secretary shall develop a method for identifying  
23 eligible beneficiaries who may benefit from the dem-  
24 onstration program and communicate with them re-  
25 garding their eligibility.

1           (5) VOLUNTARY PARTICIPATION.—Participation  
2 of health care providers, and individual beneficiaries,  
3 in the demonstration program shall be voluntary.

4           (b) DISEASE PREVENTION PLAN.—

5           (1) IN GENERAL.—The disease prevention plan  
6 described in this subsection is a plan, developed in  
7 consultation with an eligible beneficiary participating  
8 in the demonstration program, to mitigate the risk  
9 factors associated with a particular disease.

10          (2) PLAN CONTENTS.—The disease prevention  
11 plan should include the following:

12           (A) POINT OF CONTACT.—The disease pre-  
13 vention plan shall provide for a point of contact  
14 responsible for communicating with the partici-  
15 pating beneficiary and with other health care  
16 providers on behalf of such beneficiary.

17           (B) PERSONAL HEALTH CARE.—The dis-  
18 ease prevention plan shall provide for instruc-  
19 tion on personal health care.

20           (C) PHYSICIAN AND HEALTH CARE PRO-  
21 VIDER TRAINING.—The disease prevention plan  
22 shall provide for the training of physicians or  
23 other health care providers in the communica-  
24 tion of relevant clinical information.

1           (D) MONITORING TECHNOLOGY.—The dis-  
2           ease prevention plan may provide for necessary  
3           monitoring technology to facilitate the exchange  
4           of information, including information such as  
5           vital signs, symptoms, and health self assess-  
6           ments.

7           (c) PROGRAM STANDARDS AND CRITERIA.—The Sec-  
8           retary shall establish performance standards for the dem-  
9           onstration program under this section, including best  
10          practices for the prevention of chronic diseases. Such prac-  
11          tices shall be standardized to the greatest extent possible.  
12          The eligibility of entities or individuals to enter into a con-  
13          tract to provide preventive health care under the dem-  
14          onstration program shall be conditioned, at a minimum,  
15          on performance that meets or exceeds such standards.

16          (d) PAYMENT.—The Secretary shall develop a meth-  
17          od and level of payment for entities that participate in  
18          the program under this section based on best practices,  
19          as determined by the Secretary.

20          (e) WAIVER AUTHORITY.—The Secretary may waive  
21          such requirements of titles XI and XVIII of the Social  
22          Security Act as may be necessary to carry out the pur-  
23          poses of the demonstration program under this section.

24          (f) EVALUATION AND REPORT.—

1           (1) EVALUATION.—The Secretary shall conduct  
2 evaluations of—

3           (A) the benefits due to a reduction, if any,  
4 in disease incidence for participants in the dem-  
5 onstration projects compared to the medicare  
6 population as a whole, as determined by the use  
7 of appropriate statistical techniques;

8           (B) the long term cost effectiveness of the  
9 demonstration projects to the medicare program  
10 in terms of acute care costs avoided due to dis-  
11 ease prevention; and

12           (C) patient satisfaction under the dem-  
13 onstration projects.

14           (2) REPORT.—Not later than 6 months after  
15 the date on which the demonstration program under  
16 this section ends, the Secretary shall prepare and  
17 submit to Congress a report on the demonstration  
18 program together with—

19           (A) recommendations on whether the dem-  
20 onstration program should be expanded in  
21 terms of its success in disease prevention and  
22 the cost effectiveness of the demonstration pro-  
23 gram; and

1           (B) such recommendations for legislation  
2           or administrative action as the Secretary deter-  
3           mines appropriate.

4           (g) FUNDING.—The Secretary shall provide for the  
5 transfer from the Federal Supplementary Medical Insur-  
6 ance Trust Fund under section 1841 of the Social Secu-  
7 rity Act (42 U.S.C. 1395t) of such funds, not to exceed  
8 \$50,000,000, as are necessary for the costs of carrying  
9 out the demonstration program under this Act.

10          (h) DEFINITIONS.—In this section:

11           (1) APPROPRIATE ENTITY.—The term “appro-  
12           priate entity” means—

13               (A) a chronic care improvement program;

14               (B) a hospital; and

15               (C) any other entity that the Secretary de-  
16           termines appropriate based on clinical, finan-  
17           cial, or other requirements appropriate to carry  
18           out the purposes of the demonstration program  
19           under this section.

20           (2) ELIGIBLE BENEFICIARY.—The term “eligi-  
21           ble beneficiary” means an individual who—

22               (A) is entitled to benefits under part A of  
23           title XVIII of the Social Security Act or en-  
24           rolled under part B of such title; and

- 1 (B) has 2 or more risk factors associated  
2 with—
- 3 (i) chronic obstructive pulmonary dis-  
4 ease;
  - 5 (ii) diabetes; or
  - 6 (iii) any other chronic condition that  
7 the Secretary determines would be appro-  
8 priate for the purpose of providing signifi-  
9 cant potential cost benefits to the medicare  
10 program through the prevention of such  
11 condition.

12 **SEC. 406. PREVENTIVE HEALTH SERVICES FOR WOMEN.**

13 Section 1509 of the Public Health Service Act (42  
14 U.S.C. 300n-4a) is amended to read as follows:

15 **“SEC. 1509. ESTABLISHMENT OF PROGRAM FOR ADDI-  
16 TIONAL PREVENTIVE HEALTH SERVICES.**

17 “(a) IN GENERAL.—The Secretary, acting through  
18 the Director of the Centers for Disease Control and Pre-  
19 vention, may, through a competitive review process, award  
20 grants to States that have received grants under section  
21 1501 for a fiscal year, to enable such State to carry out  
22 programs—

23 “(1) to provide preventive health services, in ad-  
24 dition to the services authorized in such section

1 1501, for diseases such as cardiovascular diseases,  
2 osteoporosis, and obesity;

3 “(2) to provide screenings, such as screening  
4 for blood pressure, cholesterol, and osteoporosis, and  
5 other services that the Secretary, acting through the  
6 Director of the Centers for Disease Control and Pre-  
7 vention, determines to be appropriate and feasible;

8 “(3) for health education, counseling, and inter-  
9 ventions for behavioral risk factors, such as physical  
10 inactivity and poor nutrition, and diseases referred  
11 to in paragraph (1);

12 “(4) to provide appropriate referrals for medical  
13 treatment of women receiving services pursuant to  
14 paragraph (1) through (3), and ensuring, to the ex-  
15 tent practicable, the provision of appropriate follow-  
16 up services; and

17 “(5) to evaluate the activities conducted under  
18 paragraphs (1) through (4) through appropriate sur-  
19 veillance, research, or program monitoring activities.

20 “(b) STATUS AS PARTICIPANT IN PROGRAM REGARD-  
21 ING BREAST AND CERVICAL CANCER.—The Secretary  
22 may not make a grant to a State under subsection (a)  
23 unless the State involved agrees that services under the  
24 grant will be provided in conjunction with entities that are

1 screening women for breast or cervical cancer pursuant  
2 to a grant under section 1501.

3 “(c) APPLICABILITY OF PROVISIONS.—The provi-  
4 sions of this title shall apply to a grant under subsection  
5 (a) to the same extent and in the same manner as such  
6 provisions apply to a grant under section 1501.

7 “(d) FUNDING.—

8 “(1) IN GENERAL.—There is authorized to be  
9 appropriated such sums as may be necessary to  
10 carry out this section for fiscal year 2005 and for  
11 each subsequent fiscal year.

12 “(2) LIMITATION REGARDING FUNDING WITH  
13 RESPECT TO BREAST AND CERVICAL CANCER.—No  
14 additional resources shall be appropriated for a fis-  
15 cal year under paragraph (1) unless the amount ap-  
16 propriated under section 1510(a) for such fiscal year  
17 is at least \$173,920,000.”.

18 **TITLE V—HELP (HEALTHY LIFE-**  
19 **STYLES AND PREVENTION)**  
20 **AMERICA TRUST FUND**

21 **SEC. 501. HELP (HEALTHY LIFESTYLES AND PREVENTION)**

22 **AMERICA TRUST FUND.**

23 (a) CREATION OF TRUST FUND.—There is estab-  
24 lished in the Treasury of the United States a trust fund  
25 to be known as the ‘HeLP (Healthy Lifestyles and Preven-

1 tion) America Trust Fund' (referred to in this section as  
2 the 'Trust Fund'), consisting of such amounts as may be  
3 appropriated or credited to the Trust Fund as provided  
4 in this section.

5 (b) TRANSFERS TO TRUST FUND.—There is hereby  
6 appropriated to the Trust Fund an amount equivalent  
7 to—

8 (1) the increase in revenues received in the  
9 Treasury as the result of the amendment made by  
10 section 305 of this Act,

11 (2) the increase in revenues received in the  
12 Treasury as the result of the amendments made by  
13 title II of this Act, and

14 (3) the receipts paid by tobacco companies  
15 under subtitle B of title III of this Act.

16 (c) DISTRIBUTION OF AMOUNTS IN TRUST FUND.—

17 (1) MANDATORY EXPENDITURES.—On a fiscal  
18 year basis (beginning with fiscal year 2006) and  
19 without further appropriation the Secretary of the  
20 Treasury shall distribute from amounts in the Trust  
21 Fund such amounts as are necessary to provide for  
22 the Federal expenditures attributable to the fol-  
23 lowing:

1 (A) The amendments made to the Fruit  
2 and Vegetable Program by section 101 of this  
3 Act.

4 (B) Smoking cessation drugs under title  
5 XIX of the Social Security Act as identified by  
6 the Secretary of Health and Human Services.

7 (C) Coverage of smoking cessation under  
8 the Federal Employee Health Benefits Program  
9 under chapter 89 of title 5, United States Code  
10 (as amended by section 403).

11 (D) The amendments made to the medi-  
12 care program under title XVIII of the Social  
13 Security Act by sections 401 and 402 of this  
14 Act.

15 (E) The preventive health care demonstra-  
16 tion program carried out under section 405 of  
17 this 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 \$2,050,000,000  
22 shall be available, as provided in appropriation Acts,  
23 for each fiscal year (beginning with fiscal year 2006)  
24 only for purposes of making expenditures to carry  
25 out the following:

1 (A) School nutrition environment enhance-  
2 ment grants under section 18(l) of the Richard  
3 B. Russell National School Lunch Act (as  
4 added by section 103).

5 (B) Mental health services in schools under  
6 paragraphs (7) and (8) of section 5541(c) of  
7 the Elementary and Secondary Education Act  
8 of 1965 (as added by section 104).

9 (C) The Baby-Friendly Hospital Initiative  
10 carried out under section 105 of this Act.

11 (D) The grant program to strengthen fam-  
12 ilies and build children's resilience carried out  
13 under section 520K of the Public Health Serv-  
14 ice Act (as added by section 106).

15 (E) The reservation for early Head Start  
16 programs under section 640(a)(6)(A) of the  
17 Head Start Act (as amended by section 107).

18 (F) Community grants to prevent and re-  
19 duce the incidence of chronic disease under sec-  
20 tion 399P of the Public Health Service Act (as  
21 added by section 213).

22 (G) Living well with a disability and work-  
23 ing well with a disability programs under sec-  
24 tions 399Q and 399R of the Public Health  
25 Service Act (as added by section 212).

1           (H) The amendments made to title 23,  
2           United States Code, by section 213 of this Act  
3           and the nonmotorized transportation pilot pro-  
4           gram carried out under section 213(d).

5           (I) The national assessment of mental  
6           health needs program carried out under section  
7           506C of the Public Health Service Act (as  
8           added by section 214).

9           (J) The preventive medicine and public  
10          health training grant program carried out  
11          under section 747A of the Public Health Serv-  
12          ice Act (as added by section 215).

13          (K) Federal-State tobacco counter-adver-  
14          tising programs under section 399S of the Pub-  
15          lic Health Service Act (as added by section  
16          306).

17          (L) Preventive health services for women,  
18          including well-integrated screening and evalua-  
19          tion for women across the Nation, under section  
20          1509 of the Public Health Service Act (as  
21          added by section 406).

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

1 (N) Research regarding obesity under sec-  
2 tion 601 of this Act.

3 (O) Expanded Food and Nutrition Edu-  
4 cation Program under section 3175 of title 23,  
5 United States Code.

6 (P) The following programs under the au-  
7 thority of the Secretary of Health and Human  
8 Services through the Centers for Disease Con-  
9 trol and Prevention:

10 (i) Nutrition and physical activity  
11 grants.

12 (ii) Division of Adolescent and School  
13 Health.

14 (iii) Verb Campaign.

15 (iv) Prevention research centers.

16 (v) 5-a-day programs.

17 (vi) Steps to a healthier United  
18 States.

19 (Q) Access to local foods and school gar-  
20 dens, as authorized by section 122 of the Child  
21 Nutrition and WIC Reauthorization Act of  
22 2004 (Public Law 108–265).

23 (d) APPLICATION OF CERTAIN RULES.—For pur-  
24 poses of this section, rules similar to the rules of sections

1 9601 and 9602 of the Internal Revenue Code of 1986 shall  
2 apply.

3 **TITLE VI—RESEARCH**

4 **SEC. 601. EXPANSION OF RESEARCH REGARDING OBESITY.**

5 The Secretary of Health and Human Services shall,  
6 based on the conclusions of the United States Preventive  
7 Services Task Force on Obesity, conduct research on obe-  
8 sity prevention, treatment, and control with regard to the  
9 following:

10 (1) The effectiveness of physical activity and di-  
11 etary counseling with children and adolescents in the  
12 primary care setting to prevent, treat, and control  
13 obesity.

14 (2) The cost-effectiveness of intensive dietary  
15 and physical activity counseling to prevent, treat,  
16 and control obesity in a variety of populations.

17 (3) The effectiveness of dietary and physical ac-  
18 tivity counseling among children and adolescents,  
19 low income populations, and minority groups in the  
20 primary care setting to prevent, treat, and control  
21 obesity.

22 (4) The effectiveness of the assessment of obe-  
23 sity by a primary care physician and subsequent re-

- 1 referral for obesity counseling to a nonaffiliated obe-
- 2 sity expert or specialist.

○