

107TH CONGRESS
2D SESSION

S. 1976

To provide for a comprehensive Federal effort relating to treatments for,
and the prevention of cancer, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 28, 2002

Mrs. FEINSTEIN (for herself, Mr. SMITH of Oregon, Mr. DASCHLE, Mr. JEFFORDS, Mrs. CLINTON, Mrs. HUTCHISON, Ms. MIKULSKI, Ms. SNOWE, Mrs. BOXER, Ms. COLLINS, Ms. LANDRIEU, Mr. CHAFEE, Mrs. MURRAY, Mrs. LINCOLN, Ms. STABENOW, Ms. CANTWELL, Mrs. CARNAHAN, Mr. SCHUMER, Mr. TORRICELLI, Mr. NELSON of Nebraska, Mr. JOHNSON, Mr. REED, Mr. BREAUX, Mr. CORZINE, Mr. LEAHY, Mr. REID, Mr. KERRY, Mr. NELSON of Florida, Mr. GRAHAM, and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for a comprehensive Federal effort relating to
treatments for, and the prevention of cancer, and for
other purposes.

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 “National Cancer Act of 2002”.

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

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

TITLE I—EXPANSION OF CANCER-RELATED RESEARCH,
 PREVENTION, AND TREATMENT PROGRAMS

- Sec. 101. Expansion of cancer-related research, prevention, and treatment programs.
 Sec. 102. National Institute for Environmental Health Sciences.
 Sec. 103. Amendment to Public Health Service Act.

TITLE II—CANCER-RELATED HEALTH INSURANCE COVERAGE

Subtitle A—Clinical Trials Coverage

- Sec. 201. Coverage for clinical trials under the Public Health Service Act.
 Sec. 202. Coverage for clinical trials under the Employee Retirement Income Security Act of 1974.
 Sec. 203. Coverage for clinical trials under other public health insurance.

Subtitle B—Cancer Screening and Other Coverage

- Sec. 211. Cancer screening coverage.

Subtitle C—Physicians and Quality of Care

- Sec. 221. Managing physicians and quality of care for cancer patients under the Public Health Service Act.
 Sec. 222. Managing physicians and quality of care for cancer patients under the Employee Retirement Income Security Act of 1974.
 Sec. 223. Managing physicians and quality of care for cancer patients under Medicare.
 Sec. 224. Managing physicians and quality of care for cancer patients under Medicaid and SCHIP.

Subtitle D—General Provisions

- Sec. 231. Coverage under other public health insurance.

TITLE III—TOBACCO REGULATION

- Sec. 301. Findings.
 Sec. 302. Purpose.
 Sec. 303. Scope and effect.
 Sec. 304. Relationship to other, related Federal, State, local, and tribal laws.
 Sec. 305. Definitions.
 Sec. 306. FTC jurisdiction not affected.
 Sec. 307. Congressional review provisions.

TITLE IV—REGULATION OF THE TOBACCO INDUSTRY

- Sec. 401. Amendment of Federal Food, Drug, and Cosmetic Act of 1938.
 Sec. 402. Conforming and other amendments to general provisions.
 Sec. 403. FDA rule in effect.

TITLE V—TOBACCO PRODUCT WARNINGS AND SMOKE
CONSTITUENT DISCLOSURE

Subtitle A—Product Warnings, Labeling, and Packaging

- Sec. 501. Cigarette label and advertising warnings.
Sec. 502. Authority to revise cigarette warning label statements.
Sec. 503. Smokeless tobacco labels and advertising warnings.
Sec. 504. Authority to revise smokeless tobacco product warning label statements.
Sec. 505. Tar, nicotine, and other smoke constituent disclosure to the public.

Subtitle B—Testing and Reporting of Tobacco Product Smoke Constituents

- Sec. 511. Regulation requirement.
Sec. 512. FDA amendment.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Each year 1,300,000 Americans are diag-
4 nosed with cancer. Each year 560,000 Americans die
5 from cancer. Approximately 40 percent of all Ameri-
6 cans in the United States will be diagnosed with
7 cancer at some point in their lives.

8 (2) Since 1971, when the National Cancer Act
9 was enacted, and the “War on Cancer” was de-
10 clared, the science of cancer has advanced dramati-
11 cally. The revolution in molecular and cellular biol-
12 ogy has created unprecedented opportunities for un-
13 derstanding cancer and the role of genetics, environ-
14 mental risk factors, and prevention lifestyle factors
15 in relation to cancer.

16 (3) Since 1971, mortality rates for some can-
17 cers have decreased, while such rates for other can-
18 cers have not.

1 (4) Since 1971, the Nation's population has be-
2 come increasingly diverse and cancer affects various
3 minority, socioeconomic, and ethnic groups dis-
4 proportionately.

5 (5) Cancer screening can reduce cancer mor-
6 tality, in some cases by 30 percent or more. While
7 effective screening tools have yet to be developed for
8 the majority of cancers, there are some cancers for
9 which screening tools and procedures do exist.
10 Screening for some cancers, such as breast and cer-
11 vical cancers, has improved dramatically; however,
12 screening rates are still lower than optimal. Cancer
13 screening rates vary by cancer site, population
14 group, and health insurance coverage.

15 (6) Public and private health insurance cov-
16 erage offered in the United States has dramatically
17 changed since 1971. Today, managed care coverage
18 is more typical than the fee-for-service coverage that
19 was more common in the past. This change in the
20 form of coverage has introduced more economic con-
21 siderations into medical decisionmaking, which can
22 affect the quality of all health care provided, includ-
23 ing cancer care.

24 (7) Fewer than 5 percent of cancer patients
25 participate in cancer trials. Only 3 to 4 percent of

1 the elderly, the population most likely to develop
2 cancer, participate in such trials.

3 (8) New translational cancer research centers
4 are needed to provide the preclinical and early clin-
5 ical trials support required to advance scientific dis-
6 coveries into new drugs and technologies to prevent,
7 treat, and diagnose cancer.

8 (9) The quality of cancer care is uneven and
9 often based on pure coincidence of where one lives.
10 Many cancer patients do not receive optimal care.

11 (10) Cancer is a disease of aging and as the
12 American population ages, cancer incidence will
13 grow. It is estimated that the number of cancer di-
14 agnoses in 2010 will increase by 20 percent. The
15 number of cancer deaths is anticipated to increase
16 by 20 percent, at an annual cost of over
17 \$200,000,000,000. With such increases in the inci-
18 dence of cancer, there will be a serious shortage of
19 individuals in the workforce to provide cancer care,
20 particularly in long-term care settings.

21 (11) The number of medical researchers enter-
22 ing medical research is declining, a decrease which
23 will negatively affect the prevention and treatment of
24 cancer.

1 (12) Since 1971, more cancer care, such as the
2 administration of chemotherapy, has moved from in-
3 patient to outpatient settings.

4 (13) Since 1971, the conduct of research has
5 involved more collaboration between the public and
6 private sectors and more multidisciplinary ap-
7 proaches. The biotechnology industry has grown and
8 provided a broad array of new treatment options and
9 scientific opportunities for cancer patients, pro-
10 viders, and researchers.

11 (14) Since 1971, technology and communica-
12 tions have expanded and increased in complexity,
13 transforming research methodologies and making the
14 accessing and transmitting of information more
15 widespread and more readily available.

16 **TITLE I—EXPANSION OF CAN-**
17 **CER-RELATED RESEARCH,**
18 **PREVENTION, AND TREAT-**
19 **MENT PROGRAMS**

20 **SEC. 101. EXPANSION OF CANCER-RELATED RESEARCH,**
21 **PREVENTION, AND TREATMENT PROGRAMS.**

22 Subpart 1 of part C of title IV of the Public Health
23 Service Act (42 U.S.C. 285) is amended—

24 (1) by inserting after the subpart heading the
25 following:

1 **“CHAPTER I—PURPOSE OF INSTITUTE AND**
2 **NATIONAL CANCER PROGRAMS”**; and

3 (2) by adding at the end the following:

4 **“CHAPTER II—PROGRAMS TO PREVENT AND**
5 **TREAT CANCER**

6 **“SEC. 417D. AUTHORIZATION OF APPROPRIATIONS.**

7 “There is authorized to be appropriated to the Na-
8 tional Cancer Institute to carry out this chapter,
9 \$4,800,000,000 for fiscal year 2003, \$5,300,000,000 for
10 fiscal year 2004, \$5,800,000,000 for fiscal year 2005,
11 \$6,400,000,000 for fiscal year 2006, and \$7,100,000,000
12 for fiscal year 2007.

13 **“SEC. 417D-1. STUDY AND STRATEGIC PLANS.**

14 “(a) IN GENERAL.—Not later than July 1, 2004, the
15 Institute shall prepare 1 or more a strategic plans to iden-
16 tify unmet needs and the level of funding in the areas of
17 prevention, treatment, early detection, and quality of life,
18 and to expand and intensify cancer research and cancer-
19 related research by July 1, 2005 for—

20 “(1) behavioral research associated with caus-
21 ing and preventing cancer;

22 “(2) research regarding prevention of cancer
23 other than behavioral interventions;

24 “(3) research to reduce disparities among racial
25 and ethnic minorities and other disparity popu-
26 lations;

1 “(4) research regarding palliative care, pain
2 management;

3 “(5) research regarding preserving and restor-
4 ing quality-of-life for cancer patients;

5 “(6) research regarding environmental risk fac-
6 tors for cancer and gene-environment interactions;

7 “(7) research regarding management of symp-
8 toms;

9 “(8) research regarding tools for early detec-
10 tion, especially for which there currently is no ade-
11 quate screening technologies; and

12 “(9) cancer survivorship.

13 “(b) PRIORITIES.—The National Cancer Institute
14 shall determine priorities based on scientific opportunities,
15 in consultation with medical, scientific, patient, and pro-
16 vider representatives, and prepare 1 or more strategic
17 plans by July 1, 2004.

18 **“SEC. 417D-2. GRANTS FOR TRANSLATIONAL CANCER RE-**

19 **SEARCH.**

20 “(a) IN GENERAL.—The Director of the Institute
21 shall carry out a program to establish translational cancer
22 research centers.

23 “(b) DUTIES OF DIRECTOR.—In carrying out the
24 program, the Director shall—

1 “(1) award grants to public or nonprofit private
2 entities to plan and operate a national network of at
3 least 20 existing or new translational cancer re-
4 search centers to conduct translational, multidisci-
5 plinary cancer research;

6 “(2) establish networks and partnerships link-
7 ing the translational cancer research centers de-
8 scribed in paragraph (1) to community cancer pro-
9 viders (hospitals, clinics, providers’ practices, par-
10 ticularly in underserved areas) and expand opportu-
11 nities for all cancer patients to participate in clinical
12 trials of new agents developed by these centers;

13 “(3) facilitate the process to award grants, con-
14 tracts, and cooperative agreements to private entities
15 to conduct translational cancer research in the fol-
16 lowing areas—

17 “(A) cancer drugs, biologics, and devices;
18 and

19 “(B) cancer diagnostic tests, techniques
20 and technology; and

21 “(4) develop and implement a strategic plan by
22 July 1, 2004, in collaboration with translational cen-
23 ters as authorized in paragraph (7) for intensifying,
24 expanding, and disseminating results of translational
25 research to providers of cancer care.

1 “(c) GRANTS.—

2 “(1) IN GENERAL.—The Director shall award
3 grants to public or nonprofit private entities to es-
4 tablish translational cancer research centers to con-
5 duct translational, multidisciplinary cancer research.
6 Funds shall not be used for construction of new fa-
7 cilities.

8 “(2) EQUITY.—The Director shall award grants
9 under subsection (b)(1) to provide, to the greatest
10 extent practicable, a broad distribution of such
11 grants among geographic regions of the United
12 States.

13 “(3) DUTIES.—A public or nonprofit entity that
14 receives a grant under subsection (b)(1) shall use
15 funds received through such grant to establish and
16 operate a translational cancer research center.

17 “(4) APPLICATION.—A public or nonprofit enti-
18 ty desiring a grant under this subsection shall sub-
19 mit an application to the Director at such time, in
20 such manner, and containing such information as
21 the Director may reasonably require.

22 “(d) DUTIES OF TRANSLATIONAL RESEARCH CEN-
23 TERS.—The translational research centers shall—

24 “(1) perform research for discovery and pre-
25 clinical evaluation of drugs, biologics, devices, tech-

1 nologies, and strategies with potential to improve the
2 prevention, diagnosis, and treatment of cancer and
3 to improve pain and symptom management and
4 quality of life of cancer patients;

5 “(2) perform clinical research studies on prom-
6 ising cancer treatments or strategies, in appropriate
7 human populations;

8 “(3) evaluate promising cancer diagnostic tests,
9 techniques, or technologies in individuals being eval-
10 uated for the presence of cancer;

11 “(4) perform all phases of clinical trials of new
12 drugs, devices, biologics, or other strategies for
13 treating patients with cancer, in collaboration with
14 the existing NCI Cooperative Groups;

15 “(5) develop and implement a plan to ensure
16 the availability of adequate sources of patients for
17 each type of clinical research study;

18 “(6) create systems and external relationships,
19 which do not duplicate capabilities available in the
20 private sector, to accelerate the findings from
21 translational research to a stage that private compa-
22 nies can assume development and commercialization;
23 and

24 “(7) develop and implement a plan expanding
25 and disseminating the efficacious products of

1 translational research to providers of cancer care, in-
2 cluding products approved by the Food and Drug
3 Administration.

4 “(e) DEFINITIONS.—In this section:

5 “(1) CLINICAL TRIAL.—The term ‘clinical trial’
6 means a scientifically-designed clinical investigation
7 in which a patient participates in examining the ef-
8 fects of a drug, biologic medical treatment, or med-
9 ical device for the prevention, diagnosis, or treat-
10 ment of cancer or the potential side effects of treat-
11 ment.

12 “(2) TRANSLATIONAL CANCER RESEARCH.—
13 The term ‘translational cancer research’ means sci-
14 entific laboratory and clinical research and testing
15 needed to transform scientific discoveries into new
16 approaches and products that can prevent, control,
17 diagnose, and treat cancer, optimize quality of life,
18 and ultimately, cure cancer.

19 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
20 is authorized to be appropriated to carry out this section,
21 \$100,000,000 in fiscal year 2003, and \$100,000,000 for
22 each of the fiscal years 2004, 2005, 2006, and 2007.

1 **“SEC. 417D-3. CLINICAL TRIALS.**

2 “(a) IN GENERAL.—The Director of the Institute
3 shall carry out a program to increase patient and provider
4 participation in clinical trials.

5 “(b) PROGRAM.—The program described in sub-
6 section (a) shall include—

7 “(1) an outreach program;

8 “(2) a diversity assurance program;

9 “(3) an assistance program, including recom-
10 mending sources of funding for patients support
11 costs; and

12 “(4) culturally appropriate materials.

13 “(c) OUTREACH PROGRAM.—In carrying out the out-
14 reach program described in subsection (a), the Director
15 shall regularly provide information to cancer care pro-
16 viders, professional and patient organizations, including
17 community-based organizations, and patients to increase
18 provider participation and patient enrollment in clinical
19 trials.

20 “(d) DIVERSITY ASSURANCE PROGRAM.—In carrying
21 out the diversity assurance program described in sub-
22 section (a), the Director shall require that all research
23 grant applications include assurances that the applicant
24 will actively recruit a diverse patient population, including
25 disparity populations, to participate in trials, when such
26 recruitment is medically appropriate.

1 **“SEC. 417D-4. CANCER CARE WORKFORCE.**

2 “(a) IN GENERAL.—The Secretary shall establish a
3 program to address current and future cancer care work-
4 force needs.

5 “(b) PROGRAM.—The program described in sub-
6 section (a) shall—

7 “(1) set annual and long-term training goals to
8 assure an adequate cancer care workforce;

9 “(2) prepare and implement a plan to provide
10 assistance to individuals based on cancer health pro-
11 fessions with the most severe shortages;

12 “(3) award grants, scholarships, fellowships,
13 and loans to eligible individuals to increase the can-
14 cer care workforce;

15 “(4) make awards to eligible individuals to in-
16 crease cancer care workforce training for all individ-
17 uals to become cancer care providers, especially but
18 not limited to, such individuals who make a commit-
19 ment to serve in underserved communities or areas
20 with disproportionately high cancer incidence or
21 mortality and for health professions for which there
22 are anticipated shortages, including providers, phar-
23 macists, nurses for all settings, allied health profes-
24 sionals, physicians, specialists, and public health
25 professionals; and

1 “(5) be coordinated with existing programs to
2 prevent duplication.

3 “(c) ELIGIBILITY.—To be eligible to receive a schol-
4 arship, loan, or fellowship under this section, an individual
5 shall submit an application to the Secretary at such time,
6 in such manner, and containing such information as the
7 Secretary reasonably requires. In such application, such
8 individual shall demonstrate the intent to seek training to
9 get a certificate, license, or postsecondary degree in health
10 care, or in the case of licensed health care professionals,
11 the intent to seek professional development to upgrade
12 skills and knowledge or to obtain specialized knowledge ac-
13 cording to criteria developed by the Secretary.

14 “(d) USE OF FUNDS.—A recipient of a grant, schol-
15 arship, loan, or fellowship under this section may use
16 funds from such grant, scholarship, loan, or fellowship to
17 pay the costs of tuition and fees for training in—

18 “(1) care and treatment of cancer patients and
19 survivors;

20 “(2) quality of life and symptom management;

21 “(3) cancer screening and early detection;

22 “(4) cancer prevention;

23 “(5) genetic testing and counseling;

24 “(6) language and cultural competency in can-
25 cer care; and

1 “(7) palliative and end-of-life care.

2 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
3 is authorized to be appropriated to carry out this section,
4 \$100,000,000 in fiscal year 2003 and such sums as may
5 be necessary in each year for fiscal years 2004, 2005,
6 2006, and 2007.

7 **“SEC. 417D-5. INSTITUTE OF MEDICINE STUDY ON CANCER.**

8 “(a) INSTITUTE OF MEDICINE STUDY.—The Sec-
9 retary shall request the Institute of Medicine of the Na-
10 tional Academies of Sciences to initiate a study by Janu-
11 ary 1, 2003, of the feasibility and costs of providing medi-
12 care coverage under title XVIII of the Social Security Act
13 to individuals who are diagnosed with cancer and cancer
14 survivors through 5 years of remission of cancer at any
15 age and who have no other means of purchasing health
16 care or health insurance, as determined under criteria es-
17 tablished by the Secretary.

18 “(b) CONTENT.—

19 “(1) IN GENERAL.—The study under subsection
20 (a) shall be conducted in 2 parts.

21 “(2) FIRST PART.—The first part shall—

22 “(A) examine options for providing medi-
23 care coverage to such individuals;

1 “(B) estimate the cost to the medicare pro-
2 gram and to current and future beneficiaries;
3 and

4 “(C) identify advantages associated with
5 medicare coverage in terms of access to cancer
6 care, improved quality of care and patient out-
7 comes and assess the feasibility of providing
8 medicare coverage to uninsured cancer patients
9 through 5 years of remission and make a rec-
10 ommendation to Congress about whether Medi-
11 care should be expanded to this population
12 group.

13 “(3) SECOND PART.—The second part shall—

14 “(A) identify changes in medicare benefits
15 to facilitate the provision of care consistent with
16 quality cancer care standards, including pre-
17 scription drug benefits and benefits to improve
18 home care, symptom management, psychosocial
19 services, and palliative and hospice care;

20 “(B) estimate the cost to the medicare pro-
21 gram and to beneficiaries; and

22 “(C) assess the medical advantages and
23 disadvantages associated with expanding bene-
24 fits.

1 “(4) DEADLINES.—The first part shall be com-
2 pleted by June 30, 2004, and the second part shall
3 be completed by December 31, 2004.

4 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
5 are authorized to be appropriated to carry out this section
6 \$1,000,000 in fiscal year 2003 and \$1,200,000 in fiscal
7 year 2004.

8 **“SEC. 417D-6. CANCER CARE GUIDELINES.**

9 “The Agency for Healthcare Research and Quality
10 shall regularly convene cancer experts, providers, patients,
11 representatives of disparity populations, and other rel-
12 evant experts, including representatives of the National
13 Cancer Institute, the Health Resources Administration,
14 and the Centers for Disease Control and Prevention, to
15 coordinate the development and regularly update—

16 “(1) consensus protocols and practice guidelines
17 for optimal cancer treatments, including prevention,
18 palliation, symptom management, and end-of-life
19 care;

20 “(2) quality of care measures to assist providers
21 and patients in making and evaluating treatment de-
22 cisions; and

23 “(3) guidelines for providing patients with
24 multi-disciplinary consultation before treatment is
25 initiated and with one physician, preferably a spe-

1 cialist when feasible, to provide overall coordination
2 and management of cancer care among all providers
3 of the patient’s treatment and services.

4 **“SEC. 417D-7. RESEARCH AND OTHER ACTIVITIES OF THE**
5 **AGENCY FOR HEALTHCARE RESEARCH AND**
6 **QUALITY TO IMPROVE THE QUALITY AND**
7 **OUTCOMES OF CANCER CARE.**

8 “(a) IN GENERAL.—

9 “(1) RESEARCH.—The Director for Healthcare
10 Research and Quality shall conduct and support re-
11 search and other activities to build an evidence base
12 regarding effective clinical and organizational inter-
13 vention strategies to improve the quality and out-
14 comes of cancer care, and access to such care, at all
15 stages of the health care continuum and to facilitate
16 the prompt use of that information to improve prac-
17 tice.

18 “(2) FACTORS.—In carrying out paragraph (1),
19 the Director shall take into account the breadth of
20 the continuum of cancer care, from prevention and
21 early detection, through diagnosis and treatment, to
22 rehabilitation, long term survivorship and remission,
23 through psychosocial, palliative, and end-of-life care.

24 “(b) SPECIFIC REQUIREMENTS.—The Agency for
25 Healthcare Research and Quality shall—

1 “(1) conduct and support research to develop
2 new scientific knowledge regarding the effectiveness
3 and cost effectiveness of interventions that improve
4 the quality and outcomes of cancer care, and access
5 to such care;

6 “(2) regularly assess and synthesize existing
7 scientific evidence on the effectiveness of such inter-
8 ventions;

9 “(3) ensure the targeted dissemination of the
10 most current scientific evidence in appropriate for-
11 mats for use by professional societies and organiza-
12 tions representing clinicians and other caregivers, or-
13 ganizations through which health care and support
14 services are delivered, and organizations rep-
15 resenting cancer patients and their families;

16 “(4) facilitate, as appropriate, the prompt use
17 of existing scientific information by the professional
18 societies and organization listed in paragraph (3) to
19 develop guidance, best practices, quality improve-
20 ment strategies or other initiatives to improve prac-
21 tice;

22 “(5) develop quality of care measures to assist
23 clinicians and other caregivers, providers and health
24 plans, patients and their families, and purchasers;

1 “(6) collect information, as appropriate, and
2 conduct and support research on trends in medical
3 care practice patterns and the relationship of such
4 trends to the quality and outcomes of cancer care;
5 and

6 “(7) assess effective strategies by which an in-
7 dividual physician can provide overall coordination
8 and management of cancer care.

9 “(c) COORDINATION OF FEDERAL QUALITY IM-
10 PROVEMENT ACTIVITIES AND REPORTING OF DATA.—In
11 carrying out subsection (b)—

12 “(1) the Director for Healthcare Research and
13 Quality, working through the Quality Interagency
14 Coordination (QUIC) Task Force, and in collabora-
15 tion with the Director, National Cancer Institute,
16 shall facilitate coordination of Federal research and
17 implementation initiatives to improve the quality and
18 outcomes of cancer care;

19 “(2) the Agency for Healthcare Research and
20 Quality shall serve as a resource for other Federal
21 agencies in the measurement of the quality of cancer
22 care;

23 “(3) the Director for Healthcare Research and
24 Quality and the Director, National Cancer Institute
25 shall work cooperatively to develop data in order to

1 set benchmarks for, and subsequently measure
2 changes in the quality of cancer care for inclusion,
3 as soon as practicable, in the annual report required
4 by section 913(b)(2); and

5 “(4) the Director for Healthcare Research and
6 Quality shall ensure coordination of these activities,
7 as appropriate, with his responsibilities for research
8 on health disparities under section 903.

9 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
10 is authorized to be appropriated to carry out this section,
11 \$8,000,000 for each of the fiscal years 2003 through
12 2007.

13 **“SEC. 417D-8. CENTERS FOR DISEASE CONTROL AND PRE-**
14 **VENTION.**

15 “(a) PROGRAM.—The Director of the Centers for
16 Disease Control and Prevention shall—

17 “(1) expand and update the National Program
18 of Comprehensive Cancer Control Plans;

19 “(2) prepare a model State cancer control and
20 prevention program, including partnerships between
21 nonprofit, private, and public entities;

22 “(3) assist States, territories, tribal organiza-
23 tions, and the District of Columbia in developing
24 and implementing a cancer prevention and control
25 program so that every State will have an active plan

1 in place and so that States, territories, tribal organi-
2 zations, and the District of Columbia will use treat-
3 ments to prevent and control cancer and so that dis-
4 parities in specific populations will be addressed;

5 “(4) coordinate with the National Cancer Insti-
6 tute;

7 “(5) prepare model programs to prevent and
8 control cancer and improve access to and the quality
9 of cancer care among racial and ethnic minority and
10 medically underserved populations with dispropor-
11 tionate incidence of or death from cancer;

12 “(6) promote cancer education, prevention, and
13 early detection of cancer; and

14 “(7) award grants to public and nonprofit orga-
15 nizations for cancer control and prevention.

16 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
17 is authorized to be appropriated to carry out this section,
18 \$65,000,000 for fiscal year 2003 and such sums as may
19 be necessary for fiscal years 2004, 2005, 2006, and 2007.

20 **“SEC. 417D-9. CANCER CARE RESEARCHERS.**

21 “(a) SUPPLY OF CANCER RESEARCHERS.—In order
22 to ensure a sufficient number of researchers trained in the
23 prevention, diagnosis, cure, and treatment of cancer in fu-
24 ture fiscal years, the Director of the National Cancer In-

1 stitute, in coordination with the Secretary of Veterans Af-
2 fairs, shall carry out activities to—

3 “(1) increase the number and amount of insti-
4 tutional training grants to institutions supporting
5 cancer research; and

6 “(2) increase the number of career development
7 awards for health professionals, particularly minori-
8 ties, who intend to have, or who expand, careers in
9 basic, clinical, and translational cancer research, in-
10 cluding cancer prevention, cancer information tech-
11 nology, bioinformatics, behavioral research, and re-
12 search on palliative, psychosocial, and end-of-life
13 care.

14 “(b) LOAN REPAYMENT.—

15 “(1) ESTABLISHMENT.—The Director, in con-
16 sultation with the Director of the National Institutes
17 of Health, shall establish a cancer research loan re-
18 payment program.

19 “(2) CONTRACTS.—Under the program estab-
20 lished under paragraph (1), the Director shall enter
21 into contracts with qualified health professionals
22 under which such professionals will agree to conduct
23 cancer research, in consideration of the Federal Gov-
24 ernment agreeing to repay, for each year of such
25 services, not more than \$35,000 of the principal and

1 interest of the educational loans of such profes-
2 sionals obtained to support training for degrees or li-
3 censes, as determined appropriate by the Director.

4 “(c) POSTDOCTORAL STIPENDS.—

5 “(1) IN GENERAL.—The Director of the Na-
6 tional Cancer Institute, shall develop and implement,
7 for postdoctoral trainees and fellows, a stipend
8 schedule that by October 1, 2003, begins for entry-
9 level positions and individuals with no or limited ex-
10 perience comparable to grade 11 of the Federal gen-
11 eral schedule under title 5, United States Code (civil
12 service salary schedule) and that adequately reflects
13 training, education, experience, and comparable sala-
14 ries or stipends for comparable work in non-Federal
15 settings, and provides for annual cost-of-living ad-
16 justments.

17 “(2) AUTHORIZATION OF APPROPRIATIONS.—

18 There is authorized to be appropriated to carry out
19 this subsection, \$79,000,000 for fiscal year 2003,
20 and \$86,000,000 for fiscal year 2004, \$95,000,000
21 for fiscal year 2005, \$105,000,000 for fiscal year
22 2006, and \$115,000,000 for fiscal year 2007.

23 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
24 is authorized to be appropriated to carry out this section,

1 \$10,500,000 for fiscal year 2003, and \$10,500,000 for
2 each of fiscal years 2004 through 2007.”.

3 **SEC. 102. NATIONAL INSTITUTE FOR ENVIRONMENTAL**
4 **HEALTH SCIENCES.**

5 (a) IN GENERAL.—Not later than October 1, 2002,
6 the Director of the National Institute for Environmental
7 Health Sciences shall, in coordination with the National
8 Cancer Institute, prepare and submit to the Secretary of
9 Health and Human Services a strategic plan that identi-
10 fies the unmet needs regarding research on environmental
11 risk factors for cancer and gene-environment interactions
12 and describes how to increase the amount of such research
13 and resources for such research.

14 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
15 authorized to be appropriated to carry out this section
16 such sums as may be necessary.

17 **SEC. 103. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
18 **ACT.**

19 (a) PROGRAMS.—Title XV of the Public Health Serv-
20 ice Act (42 U.S.C. 300k et seq.) is amended by adding
21 at the end the following:

1 **“SEC. 1511. DEMONSTRATION PROGRAM FOR COLORECTAL**
2 **CANCER SCREENING.**

3 “(a) IN GENERAL.—The Director of the Centers for
4 Disease Control and Prevention may award grants to
5 States to screen women for colorectal cancer.

6 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
7 is authorized to be appropriated to carry out this section,
8 \$50,000,000 for fiscal year 2003, and such sums as may
9 be necessary for fiscal years 2004 through 2007.”.

10 (b) SUPPLEMENTAL GRANTS.—Section 1509(d)(1) of
11 title XV of the Public Health Service Act (42 U.S.C.
12 300n–4a(d)(1)) is amended by striking “\$3,000,000” and
13 all that follows through the period, and inserting
14 “\$250,000,000 for fiscal year 2003, and such sums as
15 may be necessary for fiscal years 2004 through 2007.”.

16 (c) FUNDING.—Section 1510(a) of title XV of the
17 Public Health Service Act (42 U.S.C. 300n–5(a)) is
18 amended by striking “\$50,000,000” and all that follows
19 through the period, and inserting “such sums for each of
20 the fiscal years 2003 through 2007.”.

1 **TITLE II—CANCER-RELATED**
 2 **HEALTH INSURANCE COVERAGE**
 3 **Subtitle A—Clinical Trials**
 4 **Coverage**

5 **SEC. 201. COVERAGE FOR CLINICAL TRIALS UNDER THE**
 6 **PUBLIC HEALTH SERVICE ACT.**

7 (a) GROUP.—Subpart 2 of part A of title XXVII of
 8 the Public Health Service Act (42 U.S.C. 300gg–4 et seq.)
 9 is amended by adding at the end the following:

10 **“SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING**
 11 **IN CLINICAL TRIALS.**

12 “(a) COVERAGE.—

13 “(1) IN GENERAL.—If a group health plan, or
 14 health insurance issuer that is providing health in-
 15 surance coverage, provides coverage to a qualified in-
 16 dividual (as defined in subsection (b)), the plan or
 17 issuer—

18 “(A) may not deny the individual partici-
 19 pation in the clinical trial referred to in sub-
 20 section (b)(2);

21 “(B) subject to subsection (c), may not
 22 deny (or limit or impose additional conditions
 23 on) the coverage of routine patient costs for
 24 items and services furnished in connection with
 25 participation in the trial; and

1 “(C) may not discriminate against the in-
2 dividual on the basis of the enrollee’s partici-
3 pation in such trial.

4 “(2) EXCLUSION OF CERTAIN COSTS.—For pur-
5 poses of paragraph (1)(B), routine patient costs do
6 not include the cost of the tests or measurements
7 conducted primarily for the purpose of the clinical
8 trial involved.

9 “(3) USE OF IN-NETWORK PROVIDERS.—If one
10 or more participating providers is participating in a
11 clinical trial, nothing in paragraph (1) shall be con-
12 strued as preventing a plan or issuer from requiring
13 that a qualified individual participate in the trial
14 through such a participating provider if the provider
15 will accept the individual as a participant in the
16 trial. Nothing in this section should prevent a quali-
17 fied individual from participating in a trial even if
18 the plan or issuer does not have an in-network pro-
19 vider participating.

20 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
21 poses of subsection (a), the term ‘qualified individual’
22 means an individual who is a participant or beneficiary
23 in a group health plan, or who is an enrollee under health
24 insurance coverage, and who is referred by the treating
25 physician and meets the following conditions:

1 “(1) The individual is eligible to participate in
2 an approved clinical trial according to the trial pro-
3 tocol with respect to treatment of such illness.

4 “(2) The treatment for the individual is being
5 provided with therapeutic or palliative intent.

6 “(3) The individual has been diagnosed by a
7 qualified provider to have cancer.

8 “(4) Either the referring physician is a partici-
9 pating health care professional and has concluded
10 that the individual’s participation in such trial would
11 be appropriate based upon the individual meeting
12 the conditions described above in paragraphs (1)
13 through (3), or the participant, beneficiary, or en-
14 rollee provides medical and scientific information es-
15 tablishing that the individual’s participation in such
16 trial would be appropriate based upon the individual
17 meeting the criteria described above in such para-
18 graphs.

19 “(c) PAYMENT.—

20 “(1) IN GENERAL.—Under this section a group
21 health plan or health insurance issuer shall provide
22 for payment for routine patient costs described in
23 subsection (a)(2) but is not required to pay for costs
24 of items and services (as determined by the appro-

1 piate Secretary) to be paid for by the sponsors of
2 an approved clinical trial.

3 “(2) PAYMENT RATE.—In the case of covered
4 items and services provided by—

5 “(A) a participating provider, the payment
6 rate shall be at the agreed upon rate; or

7 “(B) a nonparticipating provider, the pay-
8 ment rate shall be at the rate the plan or issuer
9 would normally pay for comparable services
10 under subparagraph (A).

11 “(d) APPROVED CLINICAL TRIAL DEFINED.—In this
12 section, the term ‘approved clinical trial’ means a clinical
13 research study or clinical investigation—

14 “(1) approved and funded (which may include
15 funding through in-kind contributions) by—

16 “(A) the National Institutes of Health;

17 “(B) a cooperative group or center of the
18 National Institutes of Health;

19 “(C) the Department of Veterans Affairs;

20 “(D) the Department of Defense;

21 “(E) the Centers for Disease Control and
22 Prevention; or

23 “(F) the Agency for Healthcare Research
24 and Quality;

1 “(2) approved by the Food and Drug Adminis-
2 tration; or

3 “(3) a qualified non-governmental research en-
4 tity that specifies compliance with the guidelines set
5 forth in section 46 of title 45, Code of Federal Reg-
6 ulations and whose research is reviewed and ap-
7 proved through an institutional review board that—

8 “(A) has been registered with the Depart-
9 ment of Health and Human Services; and

10 “(B) is an institutional review board of an
11 institution that has received an appropriate
12 Federal assurance from the Department of
13 Health and Human Services assuring compli-
14 ance with such section of such Code.

15 “(e) CONDITIONS FOR DEPARTMENTS.—The condi-
16 tions described in the paragraph for a study or investiga-
17 tion conducted by a department, are that the study or in-
18 vestigation has been reviewed and approved through a sys-
19 tem of peer review that the appropriate Secretary
20 determines—

21 “(1) to be comparable to the system of peer re-
22 view of studies and investigations used by the Na-
23 tional Institutes of Health; and

1 “(2) assures unbiased review of the highest eth-
2 ical standards by qualified individuals who have no
3 interest in the outcome of the review.

4 “(f) CONSTRUCTION.—Nothing in this section shall
5 be construed to limit a plan’s or issuer’s coverage with
6 respect to clinical trials. Nothing in this section shall be
7 construed to result in a reduction, diminishment, or
8 change in coverage resulting in less coverage.”.

9 (b) INDIVIDUAL.—Part B of title XXVII of the Pub-
10 lic Health Service Act is amended by inserting after sec-
11 tion 2752 (42 U.S.C. 300gg–52) the following:

12 **“SEC. 2753. PATIENT PROTECTION STANDARDS.**

13 “The provisions of section 2707 shall apply to health
14 insurance coverage offered by a health insurance issuer
15 in the individual market in the same manner as such pro-
16 visions apply to health insurance coverage offered by a
17 health insurance issuer in connection with a group health
18 plan.”.

19 **SEC. 202. COVERAGE FOR CLINICAL TRIALS UNDER THE**
20 **EMPLOYEE RETIREMENT INCOME SECURITY**
21 **ACT OF 1974.**

22 (a) IN GENERAL.—Subpart B of part 7 of subtitle
23 B of title I of the Employee Retirement Income Security
24 Act of 1974 (29 U.S.C. 1185 et seq.) is amended by add-
25 ing at the end the following:

1 **“SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
2 **CLINICAL TRIALS.**

3 “(a) COVERAGE.—

4 “(1) IN GENERAL.—If a group health plan, or
5 health insurance issuer offering group health insur-
6 ance coverage, provides coverage to a qualified indi-
7 vidual (as defined in subsection (b)), the plan or
8 issuer—

9 “(A) may not deny the individual partici-
10 pation in the clinical trial referred to in sub-
11 section (b)(2);

12 “(B) subject to subsection (c), may not
13 deny (or limit or impose additional conditions
14 on) the coverage of routine patient costs for
15 items and services furnished in connection with
16 participation in the trial; and

17 “(C) may not discriminate against the in-
18 dividual on the basis of the enrollee’s participa-
19 tion in such trial.

20 “(2) EXCLUSION OF CERTAIN COSTS.—For pur-
21 poses of paragraph (1)(B), routine patient costs do
22 not include the cost of the tests or measurements
23 conducted primarily for the purpose of the clinical
24 trial involved.

25 “(3) USE OF IN-NETWORK PROVIDERS.—If one
26 or more participating providers is participating in a

1 clinical trial, nothing in paragraph (1) shall be con-
2 strued as preventing a plan or issuer from requiring
3 that a qualified individual participate in the trial
4 through such a participating provider if the provider
5 will accept the individual as a participant in the
6 trial. Nothing in this section should prevent a quali-
7 fied individual from participating in a trial even if
8 the plan or issuer does not have an in-network pro-
9 vider participating.

10 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
11 poses of subsection (a), the term ‘qualified individual’
12 means an individual who is a participant or beneficiary
13 in a group health plan, or who is an enrollee under health
14 insurance coverage, and who is referred by the treating
15 physician and meets the following conditions:

16 “(1) The individual is eligible to participate in
17 an approved clinical trial according to the trial pro-
18 tocol with respect to treatment of such illness.

19 “(2) The treatment for the individual is being
20 provided with therapeutic or palliative intent.

21 “(3) The individual has been diagnosed by a
22 qualified provider to have cancer.

23 “(4) Either the referring physician is a partici-
24 pating health care professional and has concluded
25 that the individual’s participation in such trial would

1 be appropriate based upon the individual meeting
2 the conditions described above in paragraphs (1)
3 through (3) or the participant, beneficiary, or en-
4 rollee provides medical and scientific information es-
5 tablishing that the individual's participation in such
6 trial would be appropriate based upon the individual
7 meeting the criteria described above in such para-
8 graphs.

9 “(c) PAYMENT.—

10 “(1) IN GENERAL.—Under this section a group
11 health plan or health insurance issuer shall provide
12 for payment for routine patient costs described in
13 subsection (a)(2) but is not required to pay for costs
14 of items and services (as determined by the appro-
15 priate Secretary) to be paid for by the sponsors of
16 an approved clinical trial.

17 “(2) PAYMENT RATE.—In the case of covered
18 items and services provided by—

19 “(A) a participating provider, the payment
20 rate shall be at the agreed upon rate; or

21 “(B) a nonparticipating provider, the pay-
22 ment rate shall be at the rate the plan or issuer
23 would normally pay for comparable services
24 under subparagraph (A).

1 “(d) APPROVED CLINICAL TRIAL DEFINED.—In this
2 section, the term ‘approved clinical trial’ means a clinical
3 research study or clinical investigation—

4 “(1) approved and funded (which may include
5 funding through in-kind contributions) by—

6 “(A) the National Institutes of Health;

7 “(B) a cooperative group or center of the
8 National Institutes of Health;

9 “(C) the Department of Veterans Affairs;

10 “(D) the Department of Defense;

11 “(E) the Centers for Disease Control and
12 Prevention; or

13 “(F) the Agency for Healthcare Research
14 and Quality;

15 “(2) approved by the Food and Drug Adminis-
16 tration; or

17 “(3) a qualified non-governmental research en-
18 tity that specifies compliance with the guidelines set
19 forth in section 46 of title 45, Code of Federal Reg-
20 ulations, and whose research is reviewed and ap-
21 proved through an institutional review board that—

22 “(A) has been registered with the Depart-
23 ment of Health and Human Services; and

24 “(B) is an institutional review board of an
25 institution that has received an appropriate fed-

1 eral assurance from the Department of Health
2 and Human Services assuring compliance with
3 such section of such Code.

4 “(e) CONDITIONS FOR DEPARTMENTS.—The condi-
5 tions described in the paragraph for a study or investiga-
6 tion conducted by a department, are that the study or in-
7 vestigation has been reviewed and approved through a sys-
8 tem of peer review that the appropriate Secretary
9 determines—

10 “(1) to be comparable to the system of peer re-
11 view of studies and investigations used by the Na-
12 tional Institutes of Health; and

13 “(2) assures unbiased review of the highest eth-
14 ical standards by qualified individuals who have no
15 interest in the outcome of the review.

16 “(f) CONSTRUCTION.—Nothing in this section shall
17 be construed to limit a plan’s or issuer’s coverage with
18 respect to clinical trials. Nothing in this section shall be
19 construed to result in a reduction, diminishment, or
20 change in coverage resulting in less coverage.”.

21 (b) CONFORMING AMENDMENT.—The table of con-
22 tents in section 1 of the Employee Retirement Income Se-
23 curity Act of 1974 is amended by inserting after the item
24 relating to section 713 the following new item:

“Sec. 714. Coverage for individuals participating in clinical trials.”.

1 **SEC. 203. COVERAGE FOR CLINICAL TRIALS UNDER OTHER**
 2 **PUBLIC HEALTH INSURANCE.**

3 Coverage for individuals participating in clinical
 4 trials, as described in section 2707 and 2753 of the Public
 5 Health Service Act (as added under section 201), shall be
 6 provided for any individual, participant, or beneficiary who
 7 have coverage under—

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

10 (2) the medicare program under title XVIII of
 11 the Social Security Act (42 U.S.C. 1395 et seq.);

12 (3) the State Children’s Health Insurance Pro-
 13 gram under title XXI of the Social Security Act (42
 14 U.S.C. 1398 et seq.);

15 (4) a health plan offered under chapter 89 of
 16 title 5, United States Code;

17 (5) programs offered by the Department of De-
 18 fense;

19 (6) a medical care program of the Indian
 20 Health Service or of a tribal organization; and

21 (7) a health benefit plan under section 5(e) of
 22 the Peace Corps Act (22 U.S.C. 2504(e)).

23 **Subtitle B—Cancer Screening and**
 24 **Other Coverage**

25 **SEC. 211. CANCER SCREENING COVERAGE.**

26 (a) GROUP HEALTH PLANS.—

1 (1) PUBLIC HEALTH SERVICE ACT AMEND-
2 MENTS.—

3 (A) IN GENERAL.—Subpart 2 of part A of
4 title XXVII of the Public Health Service Act
5 (42 U.S.C. 300gg–4 et seq.), as amended by
6 section 201(a), is further amended by adding at
7 the end the following:

8 **“SEC. 2708. COVERAGE OF CANCER SCREENING.**

9 “(a) REQUIREMENT.—A group health plan, and a
10 health insurance issuer offering group health insurance
11 coverage, shall provide coverage and payment under the
12 plan or coverage for the following items and services under
13 terms and conditions that are no less favorable than the
14 terms and conditions applicable to other screening benefits
15 otherwise provided under the plan or coverage:

16 “(1) MAMMOGRAMS.—In the case of a female
17 participant or beneficiary who is 40 years of age or
18 older, or is under 40 years of age but is at high risk
19 (as defined in subsection (e)) of developing breast
20 cancer, an annual mammography (as defined in sec-
21 tion 1861(jj) of the Social Security Act) conducted
22 by a facility that has a certificate (or provisional cer-
23 tificate) issued under section 354.

24 “(2) CLINICAL BREAST EXAMINATIONS.—In the
25 case of a female participant or beneficiary who—

1 “(A)(i) is 40 years of age or older or (ii)
2 is at least 20 (but less than 40) years of age
3 and is at high risk of developing breast cancer,
4 an annual clinical breast examination; or

5 “(B) is at least 20, but less than 40, years
6 of age and who is not at high risk of developing
7 breast cancer, a clinical breast examination
8 each 3 years.

9 “(3) PAP TESTS AND PELVIC EXAMINATIONS.—
10 In the case of a female participant or beneficiary
11 who is 18 years of age or older, or who is under 18
12 years of age and is or has been sexually active—

13 “(A) an annual diagnostic laboratory test
14 (popularly known as a ‘pap smear’) consisting
15 of a routine exfoliative cytology test (Papani-
16 colaou test) provided to a woman for the pur-
17 pose of early detection of cervical or vaginal
18 cancer and including an interpretation by a
19 qualified health professional of the results of
20 the test; and

21 “(B) an annual pelvic examination.

22 “(4) COLORECTAL CANCER SCREENING PROCE-
23 DURES.—In the case of a participant or beneficiary
24 who is 50 years of age or older, or who is under 50
25 years of age and is at risk of developing colorectal

1 cancer, the procedures described in section
2 1861(pp)(1) of the Social Security Act (42 U.S.C.
3 1395x(pp)(1)) or section 4104(a)(2) of the Balanced
4 Budget Act of 1997 (111 Stat. 362), shall be fur-
5 nished to the individual for the purpose of early de-
6 tection of colorectal cancer. The group health plan
7 or health insurance issuer shall provide coverage for
8 the method and frequency of colorectal cancer
9 screening determined to be appropriate by a health
10 care provider treating such participant or bene-
11 ficiary, in consultation with the participant or bene-
12 ficiary.

13 “(5) PROSTATE CANCER SCREENING.—In the
14 case of a male participant or beneficiary who is 50
15 years of age or older, or who is younger than 50
16 years of age and is at high risk for prostate cancer
17 (including African American men or a male who has
18 a history of prostate cancer in a first degree family
19 member), the procedures described in section
20 1861(oo)(2) of Social Security Act (42 U.S.C.
21 1395x(oo)(2)) shall be furnished to the individual
22 for the early detection of prostate cancer. The group
23 health plan or health insurance issuer shall provide
24 coverage for the method and frequency of prostate
25 cancer screening determined to be appropriate by a

1 health care provider treating such participant or
2 beneficiary, in consultation with the participant or
3 beneficiary.

4 “(6) TOBACCO THERAPY AND COUNSELING.—

5 “(A) IN GENERAL.—Therapy and coun-
6 seling for cessation of tobacco use for individ-
7 uals who use tobacco products or who are being
8 treated for tobacco use that is furnished—

9 “(i) by or under the supervision of a
10 physician; or

11 “(ii) by any other health care
12 professional—

13 “(I) who is legally authorized to
14 furnish such services under State law
15 (or the State regulatory mechanism
16 provided by State law) of the State in
17 which the services are furnished; and

18 “(II) who, for medicare bene-
19 ficiaries, is authorized to receive pay-
20 ment for other services under this title
21 or is designated by the Secretary for
22 this purpose.

23 “(B) LIMITATION.—Subject to subpara-
24 graph (C), such therapy and counseling are lim-
25 ited to—

1 “(i) therapy and counseling services
2 recommended in ‘Treating Tobacco Use
3 and Dependence: A Clinical Practice
4 Guideline’, published by the Public Health
5 Service in June 2000, or any subsequent
6 modification of such Guideline; and

7 “(ii) such other therapy and coun-
8 seling services that the Secretary recog-
9 nizes to be effective.

10 “(C) EXCLUSION.—Such therapy and
11 counseling shall not include coverage for drugs
12 or biologicals that are not otherwise covered
13 under the plan or coverage.

14 “(7) MEDICAL NUTRITION THERAPY SERV-
15 ICES.—Medical nutrition therapy services, as defined
16 in section 1861(vv) of the Social Security Act (42
17 U.S.C. 1395x(vv)) for the purpose of improving the
18 health of cancer patients and preventing cancer in
19 other beneficiaries.

20 “(8) GENETIC TESTS AND GENETIC SERV-
21 ICES.—

22 “(A) IN GENERAL.—Genetic tests and ge-
23 netic services provided by a licensed health care
24 professional to obtain predictive genetic infor-
25 mation about an individual at risk of cancer for

1 purposes of a health assessment, cancer man-
2 agement, cancer prevention, other diagnostic or
3 therapeutic purposes, or genetic education and
4 counseling.

5 “(B) DEFINITIONS.—In this paragraph:

6 “(i) FAMILY MEMBER.—The term
7 ‘family member’ means with respect to an
8 individual—

9 “(I) the spouse of the individual;

10 “(II) a dependent child of the in-
11 dividual, including a child who is born
12 to or placed for adoption with the in-
13 dividual; and

14 “(III) all other individuals re-
15 lated by blood to the individual or the
16 spouse or child described in subclause
17 (I) or (II).

18 “(ii) GENETIC INFORMATION.—The
19 term ‘genetic information’ means informa-
20 tion about genes, gene products, or inher-
21 ited characteristics that may derive from
22 an individual or a family member of such
23 individual (including information about a
24 request for or the receipt of genetic serv-

1 ices by such individual or family member
2 of such individual).

3 “(iii) GENETIC SERVICES.—The term
4 ‘genetic services’ means health services, in-
5 cluding genetic tests, provided to obtain,
6 assess, or interpret genetic information for
7 diagnostic and therapeutic purposes, and
8 for genetic education and counseling.

9 “(iv) GENETIC TEST.—The term ‘ge-
10 netic test’ means the analysis of human
11 DNA, RNA, chromosomes, proteins, and
12 certain metabolites in order to detect
13 genotypes, mutations, or chromosomal
14 changes.

15 “(v) PREDICTIVE GENETIC INFORMA-
16 TION.—

17 “(I) IN GENERAL.—The term
18 ‘predictive genetic information’
19 means—

20 “(aa) information about an
21 individual’s genetic tests;

22 “(bb) information about ge-
23 netic tests of family members of
24 the individual; or

1 “(cc) information about the
2 occurrence of a disease or dis-
3 order in family members.

4 “(II) LIMITATIONS.—The term
5 ‘predictive genetic information’ shall
6 not include—

7 “(aa) information about the
8 sex or age of the individual;

9 “(bb) information about
10 chemical, blood, or urine analyses
11 of the individual, unless these
12 analyses are genetic tests; or

13 “(cc) information about
14 physical exams of the individual,
15 and other information relevant to
16 determining the current health
17 status of the individual.

18 “(9) OTHER TESTS AND PROCEDURES.—Such
19 other tests or procedures for the detection of cancer,
20 and modifications to the tests and procedures, with
21 such frequency, as the Secretary determines to be
22 appropriate, in consultation with appropriate organi-
23 zations and agencies, for the diagnosis or detection
24 of cancer.

1 “(b) PROHIBITIONS.—A group health plan, and a
2 health insurance issuer offering group health insurance
3 coverage in connection with a group health plan, shall
4 not—

5 “(1) deny to an individual eligibility, or contin-
6 ued eligibility, to enroll or to renew coverage under
7 the terms of the plan, solely for the purpose of
8 avoiding the requirements of this section;

9 “(2) provide monetary payments or rebates to
10 individuals to encourage such individuals to accept
11 less than the minimum protections available under
12 this section;

13 “(3) penalize or otherwise reduce or limit the
14 reimbursement of a provider because such provider
15 provided care to an individual participant or bene-
16 ficiary in accordance with this section; or

17 “(4) provide incentives (monetary or otherwise)
18 to a provider to induce such provider to provide care
19 to an individual participant or beneficiary in a man-
20 ner inconsistent with this section.

21 “(c) RULES OF CONSTRUCTION.—

22 “(1) Nothing in this section shall be construed
23 to require an individual who is a participant or bene-
24 ficiary to undergo a procedure, examination, or test
25 described in subsection (a).

1 “(2) Nothing in this section shall be construed
2 as preventing a group health plan or issuer from im-
3 posing deductibles, coinsurance, or other cost-shar-
4 ing in relation to benefits described in subsection (a)
5 consistent with such subsection, except that such co-
6 insurance or other cost-sharing shall not discrimi-
7 nate on any basis related to the coverage required
8 under this section.

9 “(3) Nothing in this section shall be construed
10 to result in a reduction, diminishment, or change in
11 coverage resulting in less coverage.

12 “(d) NOTICE.—A group health plan under this part
13 shall comply with the notice requirement under section
14 714(d) of the Employee Retirement Income Security Act
15 of 1974 with respect to the requirements of this section
16 as if such section applied to such plan.

17 “(e) RISK DEFINED.—For purposes of this section,
18 an individual is considered to be at ‘risk’ of developing
19 a particular type of cancer if, under guidelines developed
20 or recognized by the Secretary based upon scientific evi-
21 dence, the individual—

22 “(1) has 1 or more first degree family members
23 who have developed that type of cancer;

24 “(2) has previously had that type of cancer;

1 “(3) has the presence of an appropriate recog-
2 nized gene marker that is identified as putting the
3 individual at a higher risk of developing that type of
4 cancer; or

5 “(4) has other predisposing or environmental
6 risk factors that significantly increases the risk of
7 the individual contracting that type of cancer.

8 For purposes of this subsection, the term ‘type of cancer’
9 includes other types of cancer that the Secretary recog-
10 nizes as closely related for purposes of establishing risk.

11 **“SEC. 2709. PATIENT ACCESS TO INFORMATION.**

12 “(a) DISCLOSURE REQUIREMENT.—A group health
13 plan, and health insurance issuer offering group health in-
14 surance coverage shall—

15 “(1) provide to participants and beneficiaries at
16 the time of initial coverage under the plan (or the
17 effective date of this section, in the case of individ-
18 uals who are participants or beneficiaries as of such
19 date), and at least annually thereafter, the informa-
20 tion described in subsection (b) in printed form;

21 “(2) provide to participants and beneficiaries,
22 within a reasonable period (as specified by the ap-
23 propriate Secretary) before or after the date of sig-
24 nificant changes in the information described in sub-

1 section (b), information in printed form regarding
2 such significant changes; and

3 “(3) upon request, make available to partici-
4 pants and beneficiaries, the applicable authority, and
5 prospective participants and beneficiaries, the infor-
6 mation described in subsection (b) in printed form.

7 “(b) INFORMATION PROVIDED.—The information de-
8 scribed in subsection (a) that shall be disclosed includes
9 the following, as such relates to cancer screening required
10 under section 2708(a):

11 “(1) BENEFITS.—Benefits offered under the
12 plan or coverage, including—

13 “(A) covered benefits, including benefit
14 limits and coverage exclusions;

15 “(B) cost sharing, such as deductibles, co-
16 insurance, and copayment amounts, including
17 any liability for balance billing, any maximum
18 limitations on out of pocket expenses, and the
19 maximum out of pocket costs for services that
20 are provided by nonparticipating providers or
21 that are furnished without meeting the applica-
22 ble utilization review requirements;

23 “(C) the extent to which benefits may be
24 obtained from nonparticipating providers; and

1 “(D) the extent to which a participant,
2 beneficiary, or enrollee may select from among
3 participating providers and the types of pro-
4 viders participating in the plan or issuer net-
5 work.

6 “(2) ACCESS.—A description of the following:

7 “(A) The number, mix, and distribution of
8 providers under the plan or coverage.

9 “(B) Out-of-network coverage (if any) pro-
10 vided by the plan or coverage.

11 “(C) Any point-of-service option (including
12 any supplemental premium or cost-sharing for
13 such option).

14 “(D) The procedures for participants,
15 beneficiaries, and enrollees to select, access, and
16 change participating primary and specialty pro-
17 viders.

18 “(E) The rights and procedures for obtain-
19 ing referrals (including standing referrals) to
20 participating and nonparticipating providers.

21 “(F) The name, address, and telephone
22 number of participating health care providers
23 and an indication of whether each such provider
24 is available to accept new patients.

1 “(G) How the plan or issuer addresses the
 2 needs of participants, beneficiaries, and enroll-
 3 ees and others who do not speak English or
 4 who have other special communications needs in
 5 accessing providers under the plan or coverage,
 6 including the provision of information under
 7 this subsection.”.

8 (B) TECHNICAL AMENDMENT.—Section
 9 2723(c) of the Public Health Service Act (42
 10 U.S.C. 300gg–23(c)) is amended by striking
 11 “section 2704” and inserting “sections 2704
 12 and 2708”.

13 (2) ERISA AMENDMENTS.—

14 (A) IN GENERAL.—Subpart B of part 7 of
 15 subtitle B of title I of the Employee Retirement
 16 Income Security Act of 1974 (29 U.S.C. 1185
 17 et seq.), as amended by section 202, is further
 18 amended by adding at the end the following
 19 new section:

20 **“SEC. 715. COVERAGE OF CANCER SCREENING.**

21 “(a) REQUIREMENT.—A group health plan, and a
 22 health insurance issuer offering group health insurance
 23 coverage, shall provide coverage and payment under the
 24 plan or coverage for the following items and services under
 25 terms and conditions that are no less favorable than the

1 terms and conditions applicable to other screening benefits
2 otherwise provided under the plan or coverage:

3 “(1) MAMMOGRAMS.—In the case of a female
4 participant or beneficiary who is 40 years of age or
5 older, or is under 40 years of age but is at high risk
6 (as defined in subsection (e)) of developing breast
7 cancer, an annual mammography (as defined in sec-
8 tion 1861(jj) of the Social Security Act) conducted
9 by a facility that has a certificate (or provisional cer-
10 tificate) issued under section 354 of the Public
11 Health Service Act.

12 “(2) CLINICAL BREAST EXAMINATIONS.—In the
13 case of a female participant or beneficiary who—

14 “(A)(i) is 40 years of age or older or (ii)
15 is at least 20 (but less than 40) years of age
16 and is at high risk of developing breast cancer,
17 an annual clinical breast examination; or

18 “(B) is at least 20, but less than 40, years
19 of age and who is not at high risk of developing
20 breast cancer, a clinical breast examination
21 each 3 years.

22 “(3) PAP TESTS AND PELVIC EXAMINATIONS.—
23 In the case of a female participant or beneficiary
24 who is 18 years of age or older, or who is under 18
25 years of age and is or has been sexually active—

1 “(A) an annual diagnostic laboratory test
2 (popularly known as a ‘pap smear’) consisting
3 of a routine exfoliative cytology test (Papani-
4 colaou test) provided to a woman for the pur-
5 pose of early detection of cervical or vaginal
6 cancer and including an interpretation by a
7 qualified health professional of the results of
8 the test; and

9 “(B) an annual pelvic examination.

10 “(4) COLORECTAL CANCER SCREENING PROCE-
11 DURES.—In the case of a participant or beneficiary
12 who is 50 years of age or older, or who is under 50
13 years of age and is at risk of developing colorectal
14 cancer, the procedures described in section
15 1861(pp)(1) of the Social Security Act (42 U.S.C.
16 1395x(pp)(1)) or section 4104(a)(2) of the Balanced
17 Budget Act of 1997 (111 Stat. 362), shall be fur-
18 nished to the individual for the purpose of early de-
19 tection of colorectal cancer. The group health plan
20 or health insurance issuer shall provided coverage
21 for the method and frequency of colorectal cancer
22 screening determined to be appropriate by a health
23 care provider treating such participant or bene-
24 ficiary, in consultation with the participant or bene-
25 ficiary.

1 “(5) PROSTATE CANCER SCREENING.—In the
2 case of a male participant or beneficiary who is 50
3 years of age or older, or who is younger than 50
4 years of age and is at high risk for prostate cancer
5 (including African American men or a male who has
6 a history of prostate cancer in a first degree family
7 member), the procedures described in section
8 1861(oo)(2) of Social Security Act (42 U.S.C.
9 1395x(oo)(2)) shall be furnished to the individual
10 for the early detection of prostate cancer. The group
11 health plan or health insurance issuer shall provide
12 coverage for the method and frequency of prostate
13 cancer screening determined to be appropriate by a
14 health care provider treating such participant or
15 beneficiary, in consultation with the participant or
16 beneficiary.

17 “(6) TOBACCO THERAPY AND COUNSELING.—

18 “(A) IN GENERAL.—Therapy and coun-
19 seling for cessation of tobacco use for individ-
20 uals who use tobacco products or who are being
21 treated for tobacco use that is furnished—

22 “(i) by or under the supervision of a
23 physician; or

24 “(ii) by any other health care profes-
25 sional who—

1 “(I) is legally authorized to fur-
2 nish such services under State law (or
3 the State regulatory mechanism pro-
4 vided by State law) of the State in
5 which the services are furnished; and

6 “(II) for medicare beneficiaries,
7 is authorized to receive payment for
8 other services under this title or is
9 designated by the Secretary for this
10 purpose.

11 “(B) LIMITATION.—Subject to subpara-
12 graph (C), such therapy and counseling are lim-
13 ited to—

14 “(i) therapy and counseling services
15 recommended in ‘Treating Tobacco Use
16 and Dependence: A Clinical Practice
17 Guideline’, published by the Public Health
18 Service in June 2000, or any subsequent
19 modification of such Guideline; and

20 “(ii) such other therapy and coun-
21 seling services that the Secretary recog-
22 nizes to be effective.

23 “(C) EXCLUSION.—Such therapy and
24 counseling shall not include coverage for drugs

1 or biologicals that are not otherwise covered
2 under the plan or coverage.

3 “(7) MEDICAL NUTRITION THERAPY SERV-
4 ICES.—Medical nutrition therapy services, as defined
5 in section 1861(vv) of the Social Security Act (42
6 U.S.C. 1395x(vv)) for the purpose of improving the
7 health of cancer patients and preventing cancer in
8 other beneficiaries.

9 “(8) GENETIC TESTS AND GENETIC SERV-
10 ICES.—

11 “(A) IN GENERAL.—Genetic tests and ge-
12 netic services provided by a licensed health care
13 professional to obtain predictive genetic infor-
14 mation about an individual at risk of cancer for
15 purposes of a health assessment, cancer man-
16 agement, cancer prevention, other diagnostic or
17 therapeutic purposes, or genetic education and
18 counseling.

19 “(B) DEFINITIONS.—In this paragraph:

20 “(i) FAMILY MEMBER.—The term
21 ‘family member’ means with respect to an
22 individual—

23 “(I) the spouse of the individual;

24 “(II) a dependent child of the in-
25 dividual, including a child who is born

1 to or placed for adoption with the in-
2 dividual; and

3 “(III) all other individuals re-
4 lated by blood to the individual or the
5 spouse or child described in subclause
6 (I) or (II).

7 “(ii) GENETIC INFORMATION.—The
8 term ‘genetic information’ means informa-
9 tion about genes, gene products, or inher-
10 ited characteristics that may derive from
11 an individual or a family member of such
12 individual (including information about a
13 request for or the receipt of genetic serv-
14 ices by such individual or family member
15 of such individual).

16 “(iii) GENETIC SERVICES.—The term
17 ‘genetic services’ means health services, in-
18 cluding genetic tests, provided to obtain,
19 assess, or interpret genetic information for
20 diagnostic and therapeutic purposes, and
21 for genetic education and counseling.

22 “(iv) GENETIC TEST.—The term ‘ge-
23 netic test’ means the analysis of human
24 DNA, RNA, chromosomes, proteins, and
25 certain metabolites in order to detect

1 genotypes, mutations, or chromosomal
2 changes.

3 “(v) PREDICTIVE GENETIC INFORMA-
4 TION.—

5 “(I) IN GENERAL.—The term
6 ‘predictive genetic information’
7 means—

8 “(aa) information about an
9 individual’s genetic tests;

10 “(bb) information about ge-
11 netic tests of family members of
12 the individual; or

13 “(cc) information about the
14 occurrence of a disease or dis-
15 order in family members.

16 “(II) LIMITATIONS.—The term
17 ‘predictive genetic information’ shall
18 not include—

19 “(aa) information about the
20 sex or age of the individual;

21 “(bb) information about
22 chemical, blood, or urine analyses
23 of the individual, unless these
24 analyses are genetic tests; or

1 “(cc) information about
2 physical exams of the individual,
3 and other information relevant to
4 determining the current health
5 status of the individual.

6 “(9) OTHER TESTS AND PROCEDURES.—Such
7 other tests or procedures for the detection of cancer,
8 and modifications to the tests and procedures, with
9 such frequency, as the Secretary determines to be
10 appropriate, in consultation with appropriate organi-
11 zations and agencies, for the diagnosis or detection
12 of cancer.

13 “(b) PROHIBITIONS.—A group health plan, and a
14 health insurance issuer offering group health insurance
15 coverage in connection with a group health plan, may
16 not—

17 “(1) deny to an individual eligibility, or contin-
18 ued eligibility, to enroll or to renew coverage under
19 the terms of the plan, solely for the purpose of
20 avoiding the requirements of this section;

21 “(2) provide monetary payments or rebates to
22 individuals to encourage such individuals to accept
23 less than the minimum protections available under
24 this section;

1 “(3) penalize or otherwise reduce or limit the
2 reimbursement of a provider because such provider
3 provided care to an individual participant or bene-
4 ficiary in accordance with this section; or

5 “(4) provide incentives (monetary or otherwise)
6 to a provider to induce such provider to provide care
7 to an individual participant or beneficiary in a man-
8 ner inconsistent with this section.

9 “(c) RULES OF CONSTRUCTION.—

10 “(1) Nothing in this section shall be construed
11 to require an individual who is a participant or bene-
12 ficiary to undergo a procedure, examination, or test
13 described in subsection (a).

14 “(2) Nothing in this section shall be construed
15 as preventing a group health plan or issuer from im-
16 posing deductibles, coinsurance, or other cost-shar-
17 ing in relation to benefits described in subsection (a)
18 consistent with such subsection, except that such co-
19 insurance or other cost-sharing shall not discrimi-
20 nate on any basis related to the coverage required
21 under this section.

22 “(3) Nothing in this section shall be construed
23 to result in a reduction, diminishment, or change in
24 coverage resulting in less coverage.

1 “(d) NOTICE UNDER GROUP HEALTH PLAN.—The
2 imposition of the requirement of this section shall be treat-
3 ed as a material modification in the terms of the plan de-
4 scribed in section 102(a), for purposes of assuring notice
5 of such requirements under the plan; except that the sum-
6 mary description required to be provided under the last
7 sentence of section 104(b)(1) with respect to such modi-
8 fication shall be provided by not later than 60 days after
9 the first day of the first plan year in which such require-
10 ment apply.

11 “(e) RISK DEFINED.—For purposes of this section,
12 an individual is considered to be at ‘risk’ of developing
13 a particular type of cancer if, under guidelines developed
14 or recognized by the Secretary based upon scientific evi-
15 dence, the individual—

16 “(1) has 1 or more first degree family members
17 who have developed that type of cancer;

18 “(2) has previously had that type of cancer;

19 “(3) has the presence of an appropriate recog-
20 nized gene marker that is identified as putting the
21 individual at a higher risk of developing that type of
22 cancer; or

23 “(4) has other predisposing or environmental
24 risk factors that significantly increases the risk of
25 the individual contracting that type of cancer.

1 For purposes of this subsection, the term ‘type of cancer’
2 includes other types of cancer that the Secretary recog-
3 nizes as closely related for purposes of establishing risk.

4 **“SEC. 716. PATIENT ACCESS TO INFORMATION.**

5 “(a) DISCLOSURE REQUIREMENT.—A group health
6 plan, and health insurance issuer offering group health in-
7 surance coverage shall—

8 “(1) provide to participants and beneficiaries at
9 the time of initial coverage under the plan (or the
10 effective date of this section, in the case of individ-
11 uals who are participants or beneficiaries as of such
12 date), and at least annually thereafter, the informa-
13 tion described in subsection (b) in printed form;

14 “(2) provide to participants and beneficiaries,
15 within a reasonable period (as specified by the ap-
16 propriate Secretary) before or after the date of sig-
17 nificant changes in the information described in sub-
18 section (b), information in printed form regarding
19 such significant changes; and

20 “(3) upon request, make available to partici-
21 pants and beneficiaries, the applicable authority, and
22 prospective participants and beneficiaries, the infor-
23 mation described in subsection (b) in printed form.

24 “(b) INFORMATION PROVIDED.—The information de-
25 scribed in subsection (a) that shall be disclosed includes

1 the following, as such relates to cancer screening required
2 under section 715(a):

3 “(1) BENEFITS.—Benefits offered under the
4 plan or coverage, including—

5 “(A) covered benefits, including benefit
6 limits and coverage exclusions;

7 “(B) cost sharing, such as deductibles, co-
8 insurance, and copayment amounts, including
9 any liability for balance billing, any maximum
10 limitations on out of pocket expenses, and the
11 maximum out of pocket costs for services that
12 are provided by nonparticipating providers or
13 that are furnished without meeting the applica-
14 ble utilization review requirements;

15 “(C) the extent to which benefits may be
16 obtained from nonparticipating providers; and

17 “(D) the extent to which a participant,
18 beneficiary, or enrollee may select from among
19 participating providers and the types of pro-
20 viders participating in the plan or issuer net-
21 work.

22 “(2) ACCESS.—A description of the following:

23 “(A) The number, mix, and distribution of
24 providers under the plan or coverage.

1 “(B) Out-of-network coverage (if any) pro-
2 vided by the plan or coverage.

3 “(C) Any point-of-service option (including
4 any supplemental premium or cost-sharing for
5 such option).

6 “(D) The procedures for participants,
7 beneficiaries, and enrollees to select, access, and
8 change participating primary and specialty pro-
9 viders.

10 “(E) The rights and procedures for obtain-
11 ing referrals (including standing referrals) to
12 participating and nonparticipating providers.

13 “(F) The name, address, and telephone
14 number of participating health care providers
15 and an indication of whether each such provider
16 is available to accept new patients.

17 “(G) How the plan or issuer addresses the
18 needs of participants, beneficiaries, and enroll-
19 ees and others who do not speak English or
20 who have other special communications needs in
21 accessing providers under the plan or coverage,
22 including the provision of information under
23 this subsection.”.

24 (B) TECHNICAL AMENDMENTS.—

1 (i) Section 731(c) of the Employee
 2 Retirement Income Security Act of 1974
 3 (29 U.S.C. 1191(c)) is amended by strik-
 4 ing “section 711” and inserting “sections
 5 711 and 715”.

6 (ii) Section 732(a) of the Employee
 7 Retirement Income Security Act of 1974
 8 (29 U.S.C. 1191a(a)) is amended by strik-
 9 ing “section 711” and inserting “sections
 10 711 and 715”.

11 (iii) The table of contents in section 1
 12 of the Employee Retirement Income Secu-
 13 rity Act of 1974, as amended by section
 14 202, is further amended by inserting after
 15 the item relating to section 714 the fol-
 16 lowing new items:

“Sec. 715. Coverage of cancer screening.

“Sec. 716. Patient access to information.”.

17 (b) INDIVIDUAL HEALTH INSURANCE.—

18 (1) IN GENERAL.—Part B of title XXVII of the
 19 Public Health Service Act is amended by inserting
 20 after section 2753, as added by section 201(b), the
 21 following new section:

1 **“SEC. 2754. STANDARD RELATING PATIENT FREEDOM OF**
2 **CHOICE.**

3 “(a) IN GENERAL.—The provisions of section 2708
4 (other than subsection (d)) shall apply to health insurance
5 coverage offered by a health insurance issuer in the indi-
6 vidual market with respect to an enrollee under such cov-
7 erage in the same manner as they apply to health insur-
8 ance coverage offered by a health insurance issuer in con-
9 nection with a group health plan in the small or large
10 group market to a participant or beneficiary in such plan.

11 “(b) NOTICE.—A health insurance issuer under this
12 part shall comply with the notice requirement under sec-
13 tion 715(d) of the Employee Retirement Income Security
14 Act of 1974 with respect to the requirements referred to
15 in subsection (a) as if such section applied to such issuer
16 and such issuer were a group health plan.

17 **“SEC. 2755. PATIENT ACCESS TO INFORMATION.**

18 “The provisions of section 2709 shall apply health in-
19 surance coverage offered by a health insurance issuer in
20 the individual market with respect to an enrollee under
21 such coverage in the same manner as they apply to health
22 insurance coverage offered by a health insurance issuer
23 in connection with a group health plan in the small or
24 large group market to a participant or beneficiary in such
25 plan.”.

1 (2) TECHNICAL AMENDMENT.—Section
2 2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2))
3 is amended by striking “section 2751” and inserting
4 “sections 2751 and 2754”.

5 (c) EFFECTIVE DATES.—

6 (1) GROUP HEALTH PLANS.—Subject to para-
7 graph (3), the amendments made by subsection (a)
8 shall apply with respect to group health plans for
9 plan years beginning on or after January 1, 2002.

10 (2) INDIVIDUAL PLANS.—The amendment made
11 by subsection (b) shall apply with respect to health
12 insurance coverage offered, sold, issued, renewed, in
13 effect, or operated in the individual market on or
14 after such date.

15 (3) COLLECTIVE BARGAINING AGREEMENT.—In
16 the case of a group health plan maintained pursuant
17 to 1 or more collective bargaining agreements be-
18 tween employee representatives and 1 or more em-
19 ployers ratified before the date of enactment of this
20 Act, the amendments made to subsection (a) shall
21 not apply to plan years beginning before the later
22 of—

23 (A) the date on which the last collective
24 bargaining agreements relating to the plan ter-
25 minates (determined without regard to any ex-

1 tension thereof agreed to after the date of en-
2 actment of this Act), or

3 (B) January 1, 2002.

4 For purposes of subparagraph (A), any plan amend-
5 ment made pursuant to a collective bargaining
6 agreement relating to the plan which amends the
7 plan solely to conform to any requirement added by
8 subsection (a) shall not be treated as a termination
9 of such collective bargaining agreement.

10 (d) COORDINATED REGULATIONS.—Section 104(1)
11 of Health Insurance Portability and Accountability Act of
12 1996 (Public Law 104–191) is amended by striking “this
13 subtitle (and the amendments made by this subtitle and
14 section 401)” and inserting “the provisions of part 7 of
15 subtitle B of title I of the Employee Retirement Income
16 Security Act of 1974, the provisions of parts A and C of
17 title XXVII of the Public Health Service Act, and chapter
18 100 of the Internal Revenue Code of 1986”.

19 (e) MODIFICATION OF COVERAGE.—

20 (1) IN GENERAL.—The Secretary of Health and
21 Human Services may modify the coverage require-
22 ments for the amendments under this subtitle to
23 allow such requirements to incorporate and reflect
24 new scientific and technological advances regarding
25 cancer screening, practice pattern changes in such

1 screening, or other updated medical practices re-
2 garding such screening, such as the use of new tests
3 or other emerging technologies. Such modifications
4 shall not in any way diminish the coverage require-
5 ments listed under this subtitle. Such modifications
6 may be made on the Secretary's own initiative or
7 upon petition to the Secretary by an individual or
8 organization.

9 (2) CONSULTATION.—In modifying coverage re-
10 quirements under paragraph (1), the Secretary of
11 Health and Human Services shall consult with ap-
12 propriate organizations, experts, and agencies.

13 (3) PETITIONS.—The Secretary of Health and
14 Human Services may issue requirements for the pe-
15 titioning process under paragraph (1), including re-
16 quirements that the petition be in writing and in-
17 clude scientific or medical bases for the modification
18 sought. Upon receipt of such a petition, the Sec-
19 retary shall respond to the petitioner and decide
20 whether to propose a regulation proposing a change
21 within 90 days of such receipt. If a regulation is re-
22 quired, the Secretary shall propose such regulation
23 within 6 months of such determination. The Sec-
24 retary shall provide the petitioner the reasons for
25 the decision of the Secretary. The Secretary may

1 make changes requested by a petitioner in whole or
 2 in part.

3 **Subtitle C—Physicians and Quality** 4 **of Care**

5 **SEC. 221. MANAGING PHYSICIANS AND QUALITY OF CARE** 6 **FOR CANCER PATIENTS UNDER THE PUBLIC** 7 **HEALTH SERVICE ACT.**

8 (a) GROUP.—Subpart 2 of part A of title XXVII of
 9 the Public Health Service Act (42 U.S.C. 300gg–4 et
 10 seq.), as amended by sections 201 and 211, is further
 11 amended by adding at the end the following:

12 **“SEC. 2710. MANAGING PHYSICIANS AND QUALITY OF CARE** 13 **FOR CANCER PATIENTS.**

14 “(a) MANAGING PHYSICIAN.—A group health plan,
 15 or health insurance issuer that is providing health insur-
 16 ance coverage, shall ensure that with respect to items or
 17 services provided under the plan or coverage relating to
 18 the treatment of cancer, a lead managing physician be des-
 19 ignated at the time of diagnosis by the provider and paid
 20 a bonus by the plan, in consultation with the participant
 21 or beneficiary, and other providers involved to provide for
 22 the overall coordination and management of the cancer
 23 care of the participant or beneficiary among all providers
 24 who provide items or services to the participant or bene-
 25 ficiary and paid for overall coordination of services.

1 “(b) QUALITY OF CARE.—A group health plan, or
2 health insurance issuer that is providing health insurance
3 coverage, shall require that all participating health care
4 professionals who provide primary care cancer services fol-
5 low the most current quality-of-care cancer care guide-
6 lines, as developed by medical professionals with expertise
7 in the field of medicine for which the guidelines are de-
8 signed and widely recognized as medically necessary and
9 appropriate.

10 “(c) PROHIBITIONS.—A group health plan, and a
11 health insurance issuer offering group health insurance
12 coverage in connection with a group health plan, shall
13 not—

14 “(1) deny to an individual eligibility, or contin-
15 ued eligibility, to enroll or to renew coverage under
16 the terms of the plan, solely for the purpose of
17 avoiding the requirements of this section;

18 “(2) provide monetary payments or rebates to
19 individuals to encourage such individuals to accept
20 less than the minimum protections available under
21 this section;

22 “(3) penalize or otherwise reduce or limit the
23 reimbursement of a provider because such provider
24 provided care to an individual participant or bene-
25 ficiary in accordance with this section; or

1 “(4) provide incentives (monetary or otherwise)
2 to a provider to induce such provider to provide care
3 to an individual participant or beneficiary in a man-
4 ner inconsistent with this section.

5 “(d) RULES OF CONSTRUCTION.—Nothing in this
6 section shall be construed as preventing a group health
7 plan or issuer from imposing deductibles, coinsurance, or
8 other cost-sharing in relation to benefits described in sub-
9 sections (a) or (b) consistent with such subsections, except
10 that such coinsurance or other cost-sharing shall not dis-
11 criminate on any basis related to the coverage required
12 under this section.

13 “(e) NOTICE.—A group health plan under this part
14 shall comply with the notice requirement under section
15 714(d) of the Employee Retirement Income Security Act
16 of 1974 with respect to the requirements of this section
17 as if such section applied to such plan.”.

18 (b) INDIVIDUAL.—Part B of title XXVII of the Pub-
19 lic Health Service Act is amended by inserting after sec-
20 tion 2755, as added by section 211, the following:

21 **“SEC. 2756. MANAGING PHYSICIANS AND QUALITY OF CARE**
22 **FOR CANCER PATIENTS.**

23 “The provisions of section 2710 shall apply to health
24 insurance coverage offered by a health insurance issuer
25 in the individual market in the same manner as such pro-

1 visions apply to health insurance coverage offered by a
2 health insurance issuer in connection with a group health
3 plan.”.

4 **SEC. 222. MANAGING PHYSICIANS AND QUALITY OF CARE**
5 **FOR CANCER PATIENTS UNDER THE EM-**
6 **PLOYEE RETIREMENT INCOME SECURITY**
7 **ACT OF 1974.**

8 (a) IN GENERAL.—Subpart B of part 7 of subtitle
9 B of title I of the Employee Retirement Income Security
10 Act of 1974 (29 U.S.C. 1185 et seq.), as amended by sec-
11 tions 202 and 211, is further amended by adding at the
12 end the following:

13 **“SEC. 717. MANAGING PHYSICIANS AND QUALITY OF CARE**
14 **FOR CANCER PATIENTS.**

15 “(a) MANAGING PHYSICIAN.—A group health plan,
16 or health insurance issuer that is providing health insur-
17 ance coverage, shall ensure that with respect to items or
18 services provided under the plan or coverage relating to
19 the treatment of cancer, a lead managing physician be des-
20 ignated at the time of diagnosis by the participant or bene-
21 ficiary involved to provide for the overall coordination and
22 management of the cancer care of the participant or bene-
23 ficiary among all providers who provide items or services
24 to the participant or beneficiary and paid for overall co-
25 ordination of services.

1 “(b) QUALITY OF CARE.—A group health plan, or
2 health insurance issuer that is providing health insurance
3 coverage, shall require that all participating health care
4 professionals who provide primary care cancer services fol-
5 low the most current quality-of-care cancer care guide-
6 lines, as developed by medical professionals with expertise
7 in the field of medicine for which the guidelines are de-
8 signed and widely recognized as medically necessary and
9 appropriate.

10 “(c) PROHIBITIONS.—A group health plan, and a
11 health insurance issuer offering group health insurance
12 coverage in connection with a group health plan, shall
13 not—

14 “(1) deny to an individual eligibility, or contin-
15 ued eligibility, to enroll or to renew coverage under
16 the terms of the plan, solely for the purpose of
17 avoiding the requirements of this section;

18 “(2) provide monetary payments or rebates to
19 individuals to encourage such individuals to accept
20 less than the minimum protections available under
21 this section;

22 “(3) penalize or otherwise reduce or limit the
23 reimbursement of a provider because such provider
24 provided care to an individual participant or bene-
25 ficiary in accordance with this section; or

1 “(4) provide incentives (monetary or otherwise)
2 to a provider to induce such provider to provide care
3 to an individual participant or beneficiary in a man-
4 ner inconsistent with this section.

5 “(d) RULES OF CONSTRUCTION.—Nothing in this
6 section shall be construed as preventing a group health
7 plan or issuer from imposing deductibles, coinsurance, or
8 other cost-sharing in relation to benefits described in sub-
9 sections (a) or (b) consistent with such subsections, except
10 that such coinsurance or other cost-sharing shall not dis-
11 criminate on any basis related to the coverage required
12 under this section.

13 “(e) NOTICE.—A group health plan under this part
14 shall comply with the notice requirement under section
15 714(d) of the Employee Retirement Income Security Act
16 of 1974 with respect to the requirements of this section
17 as if such section applied to such plan.”.

18 (b) CONFORMING AMENDMENT.—The table of con-
19 tents in section 1 of the Employee Retirement Income Se-
20 curity Act of 1974, as amended by sections 202 and 211,
21 is further amended by inserting after the item relating to
22 section 716 the following new item:

“Sec. 717. Managing physicians and quality of care for cancer patients.”.

1 **SEC. 223. MANAGING PHYSICIANS AND QUALITY OF CARE**
2 **FOR CANCER PATIENTS UNDER MEDICARE.**

3 (a) APPLICATION OF CANCER COVERAGE REQUIRE-
4 MENTS.—Part B of title XVIII of the Social Security Act
5 (42 U.S.C. 1395j et seq.) is amended by adding at the
6 end the following:

7 “APPLICATION OF CANCER COVERAGE REQUIREMENTS
8 “SEC. 1849. The provisions of sections 2707, 2708,
9 and 2710 of the Public Health Service Act shall apply to
10 an individual who has been diagnosed with cancer and who
11 is covered under the insurance program established under
12 this part.”.

13 (b) ADDITIONAL PAYMENT.—Section 1833(m) of the
14 Social Security Act (42 U.S.C. 1395l(m)) is amended—

- 15 (1) by inserting “(1)” after “(m)”; and
16 (2) by adding at the end the following new
17 paragraph:

18 “(2) In the case of physicians’ services furnished to
19 an individual who has been diagnosed with cancer, who
20 is covered under the insurance program established under
21 this part who receives care for such cancer from a team
22 of physicians, and who incurs expenses for physicians’
23 services that are related to that diagnosis, there shall be
24 paid to the physician designated by such team of physi-
25 cians at the time of diagnosis of the individual as the phy-
26 sician responsible for the overall coordination and manage-

1 ment of the medical and other health services provided to
 2 that individual during the period in which that individual
 3 is undergoing treatment for such cancer (or to an em-
 4 ployer or facility in the cases described in clause (A) of
 5 section 1842(b)(6)) (on a monthly or quarterly basis) from
 6 the Federal Supplementary Medical Insurance Trust
 7 Fund a separate and additional payment amount for the
 8 services under this part in addition to any amount other-
 9 wise paid under this part.”.

10 **SEC. 224. MANAGING PHYSICIANS AND QUALITY OF CARE**
 11 **FOR CANCER PATIENTS UNDER MEDICAID**
 12 **AND SCHIP.**

13 (a) MEDICAID.—Section 1902(a) of the Social Secu-
 14 rity Act (42 U.S.C. 1396a(a)) is amended—

15 (1) in paragraph (64), by striking “and” at the
 16 end;

17 (2) in paragraph (65), by striking the period
 18 and inserting “; and”; and

19 (3) by inserting after paragraph (65) the fol-
 20 lowing:

21 “(66) provide—

22 “(A) that the provisions of sections 2707,
 23 2708, and 2710 of the Public Health Service
 24 Act shall apply to individuals eligible for med-

1 ical assistance under the State plan who have
2 been diagnosed with cancer; and

3 “(B) that, in the case of an individual who
4 has been diagnosed with cancer, who is eligible
5 for medical assistance under this title, and who
6 receives care for such cancer from a team of
7 physicians, and who incurs expenses for physi-
8 cians’ services that are related to that diag-
9 nosis, that there shall be paid to the physician
10 designated by such team of physicians at the
11 time of diagnosis of the individual as the physi-
12 cian responsible for the overall coordination and
13 management of the medical and other health
14 services provided to that individual during the
15 period in which that individual is undergoing
16 treatment for such cancer, a separate and addi-
17 tional payment amount for the services provided
18 in addition to any amount otherwise paid under
19 the State plan.”.

20 (b) SCHIP.—Section 2103(f) of the Social Security
21 Act (42 U.S.C. 1397cc(f)) is amended by adding at the
22 end the following:

23 “(3) APPLICATION OF CANCER COVERAGE PRO-
24 VISIONS.—

1 “(A) IN GENERAL.—The provisions of sec-
2 tions 2707, 2708, and 2710 of the Public
3 Health Service Act shall apply to the coverage
4 offered under the State child health plan.

5 “(B) ADDITIONAL PAYMENT.—The State
6 child health plan shall provide in the case of an
7 individual who has been diagnosed with cancer,
8 who is eligible for child health assistance under
9 this title, and who receives care for such cancer
10 from a team of physicians, and who incurs ex-
11 penses for physicians’ services that are related
12 to that diagnosis, that there shall be paid to the
13 physician designated by such team of physicians
14 at the time of diagnosis of the individual as the
15 physician responsible for the overall coordina-
16 tion and management of the medical and other
17 health services provided to that individual dur-
18 ing the period in which that individual is under-
19 going treatment for such cancer, a separate and
20 additional payment amount for the services pro-
21 vided in addition to any amount otherwise paid
22 under the State child health plan.”.

1 **Subtitle D—General Provisions**

2 **SEC. 231. COVERAGE UNDER OTHER PUBLIC HEALTH IN-** 3 **SURANCE.**

4 (a) IN GENERAL.—The coverage described in sub-
5 section (b) shall be provided for any individual, partici-
6 pant, or beneficiary who has coverage under—

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

9 (2) the medicare program under title XVIII of
10 the Social Security Act (42 U.S.C. 1395 et seq.);

11 (3) the State Children’s Health Insurance Pro-
12 gram under title XXI of the Social Security Act (42
13 U.S.C. 1398 et seq.);

14 (4) a health plan offered under chapter 89 of
15 title 5, United States Code;

16 (5) programs offered by the Department of De-
17 fense;

18 (6) a medical care program of the Indian
19 Health Service or of a tribal organization; and

20 (7) a health benefit plan under section 5(e) of
21 the Peace Corps Act (22 U.S.C. 2504(e)).

22 (b) COVERAGE DESCRIBED.—The coverage described
23 in this subsection is—

24 (1) the coverage described in section 2708 of
25 the Public Health Service Act (as added by section

1 211) for individuals participating in cancer screening
2 activities; and

3 (2) the coverage described in section 2710 of
4 the Public Health Service Act (as added by section
5 201) for individuals receiving cancer-related items or
6 services.

7 (c) APPLICATION TO OTHER HEALTH CARE COV-
8 ERAGE.—Chapter 89 of title 5, United States Code, is
9 amended by adding at the end the following:

10 “§ 8915. **Standards relating to coverage of cancer-re-**
11 **lated activities**

12 “(a) The provisions of sections 2707, 2708, 2709,
13 and 2710 of the Public Health Service Act shall apply to
14 the provision of items and services under this chapter.

15 “(b) Nothing in this section or section 2707, 2708,
16 2709, or 2710 of the Public Health Service Act shall be
17 construed as authorizing a health insurance issuer or enti-
18 ty to impose cost sharing with respect to the coverage or
19 benefits required to be provided under such sections that
20 is inconsistent with the cost sharing that is otherwise per-
21 mitted under this chapter.”.

22 **TITLE III—TOBACCO**
23 **REGULATION**

24 **SEC. 301. FINDINGS.**

25 Congress finds the following:

1 (1) The use of tobacco products by the Nation's
2 children is a pediatric disease of epic and worsening
3 proportions that results in new generations of to-
4 bacco-dependent children and adults.

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

9 (3) Nicotine is an addictive drug.

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

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

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

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

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

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

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

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

21 (12) It is in the public interest to restrict
22 throughout the Nation the sale, distribution, mar-
23 keting, and advertising of tobacco products only to
24 persons of legal age to purchase such products.

1 (13) Public health authorities estimate that the
2 benefits to the Nation of enacting Federal legislation
3 to accomplish these goals would be significant in
4 human and economic terms.

5 (14) Reducing the use of tobacco by minors by
6 50 percent would prevent well over 60,000 early
7 deaths each year and save up to \$43 billion each
8 year in reduced medical costs, improved productivity,
9 and the avoidance of premature deaths.

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

17 (16) In 1995, the tobacco industry spent close
18 to \$8,400,000,000, more than \$23,000,000 per day,
19 to attract new users, retain current users, increase
20 current consumption, and generate favorable long-
21 term attitudes toward smoking and tobacco use.

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

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

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

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

16 (21) Tobacco advertising increases the size of
17 the tobacco market by increasing consumption of to-
18 bacco products including increasing tobacco use by
19 young people.

20 (22) Children are more influenced by tobacco
21 advertising than adults, they smoke the most adver-
22 tised brands.

23 (23) Tobacco company documents indicate that
24 young people are an important and often crucial seg-
25 ment of the tobacco market.

1 (24) Comprehensive advertising restrictions will
2 have a positive effect on the smoking rates of young
3 people.

4 (25) Restrictions on advertising are necessary
5 to prevent unrestricted tobacco advertising from un-
6 dermining legislation prohibiting access to young
7 people and providing for education about tobacco
8 use.

9 (26) International experience shows that adver-
10 tising regulations that are stringent and comprehen-
11 sive have a greater impact on overall tobacco use
12 and young people's use than weaker or less com-
13 prehensive ones. Text-only requirements, while not
14 as stringent as a ban, will help reduce underage use
15 of tobacco products while preserving the informa-
16 tional function of advertising.

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

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

24 **SEC. 302. PURPOSE.**

25 The purposes of this title are—

1 (1) to clarify the authority of the Food and
2 Drug Administration to regulate tobacco products
3 under the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C. 301 et seq.), by recognizing it as the pri-
5 mary Federal regulatory authority with respect to
6 the manufacture, marketing, and distribution of to-
7 bacco products;

8 (2) to ensure that the Food and Drug Adminis-
9 tration and the States may continue to address
10 issues of particular concern to public health officials,
11 especially the use of tobacco by young people and de-
12 pendence on tobacco;

13 (3) to impose financial surcharges on tobacco
14 product manufacturers if tobacco use by young peo-
15 ple does not substantially decline;

16 (4) to authorize appropriate agencies of the
17 Federal government to set national standards con-
18 trolling the manufacture of tobacco products and the
19 identity, public disclosure, and amount of ingredi-
20 ents used in such products;

21 (5) to provide new and flexible enforcement au-
22 thority to ensure that the tobacco industry makes ef-
23 forts to develop and introduce less harmful tobacco
24 products;

1 (6) to confirm the Food and Drug Administra-
2 tion's authority to regulate the levels of tar, nicotine,
3 and other harmful components of tobacco products;

4 (7) in order to ensure that adults are better in-
5 formed, to require tobacco product manufacturers to
6 disclose research which has not previously been
7 made available, as well as research generated in the
8 future, relating to the health and dependency effects
9 or safety of tobacco products;

10 (8) to continue to permit the sale of tobacco
11 products to adults in conjunction with measures to
12 ensure that they are not sold or accessible to under-
13 age purchasers; and

14 (9) to impose appropriate regulatory controls on
15 the tobacco industry.

16 **SEC. 303. SCOPE AND EFFECT.**

17 (a) INTENDED EFFECT.—This title is not intended
18 to—

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

22 (2) except as provided in this title, affect any
23 action pending in State, Tribal, or Federal court, or
24 any agreement, consent decree, or contract of any
25 kind.

1 (b) TAXATION.—Notwithstanding any other provision
2 of law, this title and the amendments made by this title
3 shall not affect any authority of the Secretary of the
4 Treasury (including any authority assigned to the Bureau
5 of Alcohol, Tobacco and Firearms) or of State or local gov-
6 ernments with regard to taxation for tobacco or tobacco
7 products.

8 (c) AGRICULTURAL ACTIVITIES.—The provisions of
9 this title which authorize the Secretary to take certain ac-
10 tions with regard to tobacco and tobacco products shall
11 not be construed to affect any authority of the Secretary
12 of Agriculture under existing law regarding the growing,
13 cultivation, or curing of raw tobacco.

14 **SEC. 304. RELATIONSHIP TO OTHER, RELATED FEDERAL,**
15 **STATE, LOCAL, AND TRIBAL LAWS.**

16 (a) AGE RESTRICTIONS.—Nothing in this title or the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
18 et seq.), as amended by this title, shall prevent a Federal
19 agency (including the Armed Forces), a State or its polit-
20 ical subdivisions, or the government of an Indian tribe
21 from adopting and enforcing additional measures that fur-
22 ther restrict or prohibit tobacco product sale to, use by,
23 and accessibility to persons under the legal age of pur-
24 chase established by such agency, State, subdivision, or
25 government of an Indian tribe.

1 (b) **ADDITIONAL MEASURES.**—Except as otherwise
2 expressly provided in this title, nothing in this title, the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
4 et seq.), or rules promulgated under such title or Act, shall
5 limit the authority of a Federal agency (including the
6 Armed Forces), a State or its political subdivisions, or the
7 government of an Indian tribe to enact, adopt, promul-
8 gate, and enforce any law, rule, regulation, or other meas-
9 ure with respect to tobacco products, including laws, rules,
10 regulations, or other measures relating to or prohibiting
11 the sale, distribution, possession, exposure to, or use of
12 tobacco products by persons of any age that are in addi-
13 tion to the provisions of this title and the amendments
14 made by this title. No provision of this title or amendment
15 made by this title shall limit or otherwise affect any State,
16 Tribal, or local taxation of tobacco products.

17 (c) **NO LESS STRINGENT.**—Nothing in this title or
18 the amendments made by this title is intended to super-
19 sede any State, local, or Tribal law that is not less strin-
20 gent than this title, or other Acts as amended by this title.

21 (d) **STATE LAW NOT AFFECTED.**—Except as other-
22 wise expressly provided in this title, nothing in this title,
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
24 et seq.), or rules promulgated under such title or Act, shall

1 supersede the authority of the States, pursuant to State
2 law, to expend funds provided by this title.

3 **SEC. 305. DEFINITIONS.**

4 In this title:

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

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

20 (3) CIGARETTE TOBACCO.—The term “cigarette
21 tobacco” means any product that consists of loose
22 tobacco that is intended for use by consumers in a
23 cigarette. Unless otherwise stated, the requirements
24 for cigarettes shall also apply to cigarette tobacco.

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

5 (5) DISTRIBUTOR.—The term “distributor” as
6 regards a tobacco product means any person who
7 furthers the distribution of cigarette or smokeless to-
8 bacco, whether domestic or imported, at any point
9 from the original place of manufacture to the person
10 who sells or distributes the product to individuals for
11 personal consumption. Common carriers are not con-
12 sidered distributors for purposes of this title.

13 (6) INDIAN COUNTRY; INDIAN LANDS.—The
14 terms “Indian country” and “Indian lands” have the
15 meaning given the term “Indian country” by section
16 1151 of title 18, United States Code, and includes
17 lands owned by an Indian tribe or a member thereof
18 over which the United States exercises jurisdiction
19 on behalf of the tribe or tribal member.

20 (7) INDIAN TRIBE.—The term “Indian tribe”
21 has the meaning given such term in section 4(e) of
22 the Indian Self Determination and Education Assist-
23 ance Act (25 U.S.C. 450b(e)).

24 (8) LITTLE CIGAR.—The term “little cigar” has
25 the meaning given that term by section 3(7) of the

1 Federal Cigarette Labeling and Advertising Act (15
2 U.S.C. 1332(7)).

3 (9) NICOTINE.—The term “nicotine” means the
4 chemical substance named 3-(1-Methyl-2-
5 pyrrolidinyl) pyridine or C[10]H[14]N[2], including
6 any salt or complex of nicotine.

7 (10) PACKAGE.—The term “package” means a
8 pack, box, carton, or container of any kind or, if no
9 other container, any wrapping (including cello-
10 phane), in which cigarettes or smokeless tobacco are
11 offered for sale, sold, or otherwise distributed to con-
12 sumers.

13 (11) POINT-OF-SALE.—The term “point-of-
14 sale” means any location at which a consumer can
15 purchase or otherwise obtain cigarettes or smokeless
16 tobacco for personal consumption.

17 (12) RETAILER.—The term “retailer” means
18 any person who sells cigarettes or smokeless tobacco
19 to individuals for personal consumption, or who op-
20 erates a facility where self-service displays of tobacco
21 products are permitted.

22 (13) ROLL-YOUR-OWN TOBACCO.—The term
23 “roll-your-own tobacco” means any tobacco which,
24 because of its appearance, type, packaging, or label-
25 ing, is suitable for use and likely to be offered to,

1 or purchased by, consumers as tobacco for making
2 cigarettes.

3 (14) SECRETARY.—The term “Secretary”
4 means the Secretary of Health and Human Services.

5 (15) SMOKELESS TOBACCO.—The term “smoke-
6 less tobacco” means any product that consists of
7 cut, ground, powdered, or leaf tobacco and that is
8 intended to be placed in the oral or nasal cavity.

9 (16) STATE.—The term “State” means any
10 State of the United States and, for purposes of this
11 Act, includes the District of Columbia, the Common-
12 wealth of Puerto Rico, Guam, the Virgin Islands,
13 American Samoa, Wake Island, Midway Islands,
14 Kingman Reef, Johnston Atoll, the Northern Mar-
15 iana Islands, and any other trust territory or posses-
16 sion of the United States.

17 (17) TOBACCO PRODUCT.—The term “tobacco
18 product” means cigarettes, cigarette tobacco, smoke-
19 less tobacco, little cigars, roll-your-own tobacco, and
20 fine cut products.

21 (18) TOBACCO PRODUCT MANUFACTURER.—
22 The term “tobacco product manufacturer” means
23 any person, including any repacker or relabeler,
24 who—

1 (A) manufactures, fabricates, assembles,
2 processes, or labels a finished cigarette or
3 smokeless tobacco product; or

4 (B) imports a finished cigarette or smoke-
5 less tobacco product for sale or distribution in
6 the United States.

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

15 **SEC. 306. FTC JURISDICTION NOT AFFECTED.**

16 (a) IN GENERAL.—Except where expressly provided
17 in this title, nothing in this title shall be construed as lim-
18 iting or diminishing the authority of the Federal Trade
19 Commission to enforce the laws under its jurisdiction with
20 respect to the advertising, sale, or distribution of tobacco
21 products.

22 (b) ENFORCEMENT BY FTC.—Any advertising that
23 violates this title or part 897 of title 21, Code of Federal
24 Regulations, is an unfair or deceptive act or practice under
25 section 5(a) of the Federal Trade Commission Act (15

1 U.S.C. 45(a)) and shall be considered a violation of a rule
2 promulgated under section 18 of that Act (15 U.S.C. 57a).

3 **SEC. 307. CONGRESSIONAL REVIEW PROVISIONS.**

4 In accordance with section 801 of title 5, United
5 States Code, the Congress shall review, and may dis-
6 approve, any rule under this title that is subject to section
7 801. This section does not apply to the rule set forth in
8 part 897 of title 21, Code of Federal Regulations.

9 **TITLE IV—REGULATION OF THE**
10 **TOBACCO INDUSTRY**

11 **SEC. 401. AMENDMENT OF FEDERAL FOOD, DRUG, AND**
12 **COSMETIC ACT OF 1938.**

13 (a) DEFINITION OF TOBACCO PRODUCTS.—Section
14 201 of the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 321) is amended by adding at the end the fol-
16 lowing:

17 “(kk) The term ‘tobacco product’ means any
18 product made or derived from tobacco that is in-
19 tended for human consumption, including any com-
20 ponent, part, or accessory of a tobacco product (ex-
21 cept for raw materials other than tobacco used in
22 manufacturing a component, part, or accessory of a
23 tobacco product).”.

1 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—
 2 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 3 301 et seq.) is amended—

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

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

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

8 **“CHAPTER IX—TOBACCO**
 9 **PRODUCTS**

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

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

14 “(1) such products are intended for use in the
 15 diagnosis, cure, mitigation, treatment, or prevention
 16 of disease (within the meaning of section
 17 201(g)(1)(B) or section 201(h)(2)); or

18 “(2) a health claim is made for such products
 19 under section 201(g)(1)(C) or 201(h)(3).

20 “(b) APPLICABILITY.—This chapter shall apply to all
 21 tobacco products subject to the provisions of part 897 of
 22 title 21, Code of Federal Regulations, and to any other
 23 tobacco products that the Secretary by regulation deems
 24 to be subject to this chapter.

25 “(c) SCOPE.—

1 “(1) Nothing in this chapter, any policy issued
2 or regulation promulgated thereunder, or the Na-
3 tional Tobacco Policy and Youth Smoking Reduction
4 Act, shall be construed to affect the Secretary’s au-
5 thority over, or the regulation of, products under
6 this Act that are not tobacco products under chapter
7 V of the Federal Food, Drug and Cosmetic Act or
8 any other chapter of that Act.

9 “(2) The provisions of this chapter shall not
10 apply to tobacco leaf that is not in the possession of
11 the manufacturer, or to the producers of tobacco
12 leaf, including tobacco growers, tobacco warehouses,
13 and tobacco grower cooperatives, nor shall any em-
14 ployee of the Food and Drug Administration have
15 any authority whatsoever to enter onto a farm
16 owned by a producer of tobacco leaf without the
17 written consent of such producer. Notwithstanding
18 any other provision of this subparagraph, if a pro-
19 ducer of tobacco leaf is also a tobacco product man-
20 ufacturer or controlled by a tobacco product manu-
21 facturer, the producer shall be subject to this chap-
22 ter in the producer’s capacity as a manufacturer.
23 Nothing in this chapter shall be construed to grant
24 the Secretary authority to promulgate regulations on
25 any matter that involves the production of tobacco

1 leaf or a producer thereof, other than activities by
2 a manufacturer affecting production. For purposes
3 of the preceding sentence, the term ‘controlled by’
4 means a member of the same controlled group of
5 corporations as that term is used in section 52(a) of
6 the Internal Revenue Code of 1986, or under com-
7 mon control within the meaning of the regulations
8 promulgated under section 52(b) of such Code.

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

10 “A tobacco product shall be deemed to be adulterated
11 if—

12 “(1) it consists in whole or in part of any filthy,
13 putrid, or decomposed substance, or is otherwise
14 contaminated by any poisonous or deleterious sub-
15 stance that may render the product injurious to
16 health;

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

21 “(3) its container is composed, in whole or in
22 part, of any poisonous or deleterious substance
23 which may render the contents injurious to health;

24 “(4) it is, or purports to be or is represented
25 as, a tobacco product which is subject to a perform-

1 ance standard established under section 907 unless
2 such tobacco product is in all respects in conformity
3 with such standard;

4 “(5) it is required by section 910(a) to have
5 premarket approval, is not exempt under section
6 906(f), and does not have an approved application in
7 effect;

8 “(6) the methods used in, or the facilities or
9 controls used for, its manufacture, packing or stor-
10 age are not in conformity with applicable require-
11 ments under section 906(e)(1) or an applicable con-
12 dition prescribed by an order under section
13 906(e)(2); or

14 “(7) it is a tobacco product for which an ex-
15 emption has been granted under section 906(f) for
16 investigational use and the person who was granted
17 such exemption or any investigator who uses such
18 tobacco product under such exemption fails to com-
19 ply with a requirement prescribed by or under such
20 section.

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

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

24 “(1) if its labeling is false or misleading in any
25 particular;

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

3 “(A) the name and place of business of the
4 tobacco product manufacturer, packer, or dis-
5 tributor; and

6 “(B) an accurate statement of the quantity
7 of the contents in terms of weight, measure, or
8 numerical count,

9 except that under subparagraph (B) of this para-
10 graph reasonable variations shall be permitted, and
11 exemptions as to small packages shall be established,
12 by regulations prescribed by the Secretary;

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

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

1 “(5) if the Secretary has issued regulations re-
2 quiring that its labeling bear adequate directions for
3 use, or adequate warnings against use by children,
4 that are necessary for the protection of users unless
5 its labeling conforms in all respects to such regula-
6 tions;

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

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

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

21 “(B) it is sold, distributed, or used in vio-
22 lation of regulations prescribed under section
23 906(d);

24 “(8) unless, in the case of any tobacco product
25 distributed or offered for sale in any State, the man-

1 manufacturer, packer, or distributor thereof includes in
2 all advertisements and other descriptive printed mat-
3 ter issued or caused to be issued by the manufac-
4 turer, packer, or distributor with respect to that to-
5 bacco product—

6 “(A) a true statement of the tobacco prod-
7 uct’s established name as defined in paragraph
8 (4) of this subsection, printed prominently; and

9 “(B) a brief statement of—

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

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

24 “(9) if it is a tobacco product subject to a per-
25 formance standard established under section 907,

1 unless it bears such labeling as may be prescribed in
2 such performance standard; or

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

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

6 “(B) to furnish any material or informa-
7 tion required by or under section 909; or

8 “(C) to comply with a requirement under
9 section 912.

10 “(b) PRIOR APPROVAL OF STATEMENTS ON
11 LABEL.—The Secretary may, by regulation, require prior
12 approval of statements made on the label of a tobacco
13 product. No regulation issued under this subsection may
14 require prior approval by the Secretary of the content of
15 any advertisement and no advertisement of a tobacco
16 product, published after the date of enactment of the Na-
17 tional Tobacco Policy and Youth Smoking Reduction Act
18 shall, with respect to the matters specified in this section
19 or covered by regulations issued hereunder, be subject to
20 the provisions of sections 12 through 15 of the Federal
21 Trade Commission Act (15 U.S.C. 52 through 55). This
22 subsection does not apply to any printed matter which the
23 Secretary determines to be labeling as defined in section
24 201(m).

1 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**
2 **SECRETARY.**

3 “(a) REQUIREMENT.—Not later than 6 months after
4 the date of enactment of the National Tobacco Policy and
5 Youth Smoking Reduction Act, each tobacco product man-
6 ufacturer or importer of tobacco products, or agents there-
7 of, shall submit to the Secretary the following information:

8 “(1) A listing of all tobacco ingredients, sub-
9 stances and compounds that are, on such date,
10 added by the manufacturer to the tobacco, paper, fil-
11 ter, or other component of each tobacco product by
12 brand and by quantity in each brand and subbrand.

13 “(2) A description of the content, delivery, and
14 form of nicotine in each tobacco product measured
15 in milligrams of nicotine.

16 “(3) All documents (including underlying sci-
17 entific information) relating to research activities,
18 and research findings, conducted, supported, or pos-
19 sessed by the manufacturer (or agents thereof) on
20 the health, behavioral, or physiologic effects of to-
21 bacco products, their constituents, ingredients, and
22 components, and tobacco additives, described in
23 paragraph (1).

24 “(4) All documents (including underlying sci-
25 entific information) relating to research activities,
26 and research findings, conducted, supported, or pos-

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

6 “(5) All documents (including underlying sci-
7 entific information) relating to marketing research
8 involving the use of tobacco products.

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

12 “(b) ANNUAL SUBMISSION.—A tobacco product man-
13 ufacturer or importer that is required to submit informa-
14 tion under subsection (a) shall update such information
15 on an annual basis under a schedule determined by the
16 Secretary.

17 “(c) TIME FOR SUBMISSION.—

18 “(1) NEW PRODUCTS.—At least 90 days prior
19 to the delivery for introduction into interstate com-
20 merce of a tobacco product not on the market on the
21 date of enactment of this chapter, the manufacturer
22 of such product shall provide the information re-
23 quired under subsection (a) and such product shall
24 be subject to the annual submission under sub-
25 section (b).

1 “(2) MODIFICATION OF EXISTING PRODUCTS.—

2 If at any time a tobacco product manufacturer adds
3 to its tobacco products a new tobacco additive, in-
4 creases or decreases the quantity of an existing to-
5 bacco additive or the nicotine content, delivery, or
6 form, or eliminates a tobacco additive from any to-
7 bacco product, the manufacturer shall within 60
8 days of such action so advise the Secretary in writ-
9 ing and reference such modification in submissions
10 made under subsection (b).

11 **“SEC. 905. ANNUAL REGISTRATION.**

12 “(a) DEFINITIONS.—As used in this section—

13 “(1) the term ‘manufacture, preparation,
14 compounding, or processing’ shall include repack-
15 aging or otherwise changing the container, wrapper,
16 or labeling of any tobacco product package in fur-
17 therance of the distribution of the tobacco product
18 from the original place of manufacture to the person
19 who makes final delivery or sale to the ultimate con-
20 sumer or user; and

21 “(2) the term ‘name’ shall include in the case
22 of a partnership the name of each partner and, in
23 the case of a corporation, the name of each cor-
24 porate officer and director, and the State of incorpo-
25 ration.

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

2 On or before December 31 of each year every person who
3 owns or operates any establishment in any State engaged
4 in the manufacture, preparation, compounding, or proc-
5 essing of a tobacco product or tobacco products shall reg-
6 ister with the Secretary the name, places of business, and
7 all such establishments of that person.

8 “(c) REGISTRATION OF NEW OWNERS AND OPERA-

9 TORS.—Every person upon first engaging in the manufac-
10 ture, preparation, compounding, or processing of a tobacco
11 product or tobacco products in any establishment owned
12 or operated in any State by that person shall immediately
13 register with the Secretary that person’s name, place of
14 business, and such establishment.

15 “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—

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

22 “(e) UNIFORM PRODUCT IDENTIFICATION SYS-

23 TEM.—The Secretary may by regulation prescribe a uni-
24 form system for the identification of tobacco products and
25 may require that persons who are required to list such

1 tobacco products under subsection (i) of this section shall
2 list such tobacco products in accordance with such system.

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

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

18 “(h) FOREIGN ESTABLISHMENTS MAY REGISTER.—
19 Any establishment within any foreign country engaged in
20 the manufacture, preparation, compounding, or processing
21 of a tobacco product or tobacco products, may register
22 under this section under regulations promulgated by the
23 Secretary. Such regulations shall require such establish-
24 ment to provide the information required by subsection (i)
25 of this section and shall include provisions for registration

1 of any such establishment upon condition that adequate
2 and effective means are available, by arrangement with the
3 government of such foreign country or otherwise, to enable
4 the Secretary to determine from time to time whether to-
5 bacco products manufactured, prepared, compounded, or
6 processed in such establishment, if imported or offered for
7 import into the United States, shall be refused admission
8 on any of the grounds set forth in section 801(a).

9 “(i) REGISTRATION INFORMATION.—

10 “(1) PRODUCT LIST.—Every person who reg-
11 isters with the Secretary under subsection (b), (c),
12 or (d) of this section shall, at the time of registra-
13 tion under any such subsection, file with the Sec-
14 retary a list of all tobacco products which are being
15 manufactured, prepared, compounded, or processed
16 by that person for commercial distribution and
17 which has not been included in any list of tobacco
18 products filed by that person with the Secretary
19 under this paragraph or paragraph (2) before such
20 time of registration. Such list shall be prepared in
21 such form and manner as the Secretary may pre-
22 scribe and shall be accompanied by—

23 “(A) in the case of a tobacco product con-
24 tained in the applicable list with respect to
25 which a performance standard has been estab-

1 lished under section 907 or which is subject to
2 section 910, a reference to the authority for the
3 marketing of such tobacco product and a copy
4 of all labeling for such tobacco product;

5 “(B) in the case of any other tobacco prod-
6 uct contained in an applicable list, a copy of all
7 consumer information and other labeling for
8 such tobacco product, a representative sampling
9 of advertisements for such tobacco product,
10 and, upon request made by the Secretary for
11 good cause, a copy of all advertisements for a
12 particular tobacco product; and

13 “(C) if the registrant filing a list has de-
14 termined that a tobacco product contained in
15 such list is not subject to a performance stand-
16 ard established under section 907, a brief state-
17 ment of the basis upon which the registrant
18 made such determination if the Secretary re-
19 quests such a statement with respect to that
20 particular tobacco product.

21 “(2) BIENNIAL REPORT OF ANY CHANGE IN
22 PRODUCT LIST.—Each person who registers with
23 the Secretary under this section shall report to the
24 Secretary once during the month of June of each

1 year and once during the month of December of
2 each year the following:

3 “(A) A list of each tobacco product intro-
4 duced by the registrant for commercial distribu-
5 tion which has not been included in any list
6 previously filed by that person with the Sec-
7 retary under this subparagraph or paragraph
8 (1) of this subsection. A list under this sub-
9 paragraph shall list a tobacco product by its es-
10 tablished name and shall be accompanied by the
11 other information required by paragraph (1).

12 “(B) If since the date the registrant last
13 made a report under this paragraph that person
14 has discontinued the manufacture, preparation,
15 compounding, or processing for commercial dis-
16 tribution of a tobacco product included in a list
17 filed under subparagraph (A) or paragraph (1),
18 notice of such discontinuance, the date of such
19 discontinuance, and the identity of its estab-
20 lished name.

21 “(C) If since the date the registrant re-
22 ported under subparagraph (B) a notice of dis-
23 continuance that person has resumed the manu-
24 facture, preparation, compounding, or proc-
25 essing for commercial distribution of the to-

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

9 “(D) Any material change in any informa-
10 tion previously submitted under this paragraph
11 or paragraph (1).

12 “(j) REPORT PRECEDING INTRODUCTION OF CER-
13 TAIN SUBSTANTIALLY-EQUIVALENT PRODUCTS INTO
14 INTERSTATE COMMERCE.—

15 “(1) IN GENERAL.—Each person who is re-
16 quired to register under this section and who pro-
17 poses to begin the introduction or delivery for intro-
18 duction into interstate commerce for commercial dis-
19 tribution of a tobacco product intended for human
20 use that was not commercially marketed (other than
21 for test marketing) in the United States as of Au-
22 gust 11, 1995, as defined by the Secretary by regu-
23 lation shall, at least 90 days before making such in-
24 troduction or delivery, report to the Secretary (in

1 such form and manner as the Secretary shall by reg-
2 ulation prescribe)—

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 August 11, 1995, that is in compli-
9 ance 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-AUGUST
14 11TH PRODUCTS.—A report under this subsection
15 for a tobacco product that was first introduced or
16 delivered for introduction into interstate commerce
17 for commercial distribution in the United States
18 after August 11, 1995, and before the date of enact-
19 ment of the National Tobacco Policy and Youth
20 Smoking Reduction Act shall be submitted to the
21 Secretary within 6 months after the date of enact-
22 ment of that Act.

1 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**
2 **OF TOBACCO PRODUCTS.**

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

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

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

25 “(2) the period within which interested persons
26 may present their comments on the notice or find-

1 ings (including the need therefor) orally or in writ-
2 ing, which period shall be at least 60 days but may
3 not exceed 90 days unless the time is extended by
4 the Secretary by a notice published in the Federal
5 Register stating good cause therefor.

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

18 “(d) RESTRICTIONS.—

19 “(1) The Secretary may by regulation require
20 that a tobacco product be restricted to sale, distribu-
21 tion, or use upon such conditions, including restric-
22 tions on the access to, and the advertising and pro-
23 motion of, the tobacco product, as the Secretary may
24 prescribe in such regulation if, because of its poten-
25 tiality for harmful effect or the collateral measures

1 necessary to its use, the Secretary determines that
2 such regulation would be appropriate for the protec-
3 tion of the public health. The finding as to whether
4 such regulation would be appropriate for the protec-
5 tion of the public health shall be determined with
6 respect to the risks and benefits to the population
7 as a whole, including users and non-users of the to-
8 bacco product, and taking into account—

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

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

15 No such condition may require that the sale or dis-
16 tribution of a tobacco product be limited to the writ-
17 ten or oral authorization of a practitioner licensed
18 by law to prescribe medical products.

19 “(2) The label of a tobacco product shall bear
20 such appropriate statements of the restrictions re-
21 quired by a regulation under subsection (a) as the
22 Secretary may in such regulation prescribe.

23 “(3) No restriction under paragraph (1) may
24 prohibit the sale of any tobacco product in face-to-

1 face transactions by a specific category of retail out-
2 lets.

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

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

7 “(A) The Secretary may, in accordance
8 with subparagraph (B), prescribe regulations
9 requiring that the methods used in, and the fa-
10 cilities and controls used for, the manufacture,
11 pre-production design validation (including a
12 process to assess the performance of a tobacco
13 product), packing and storage of a tobacco
14 product, conform to current good manufac-
15 turing practice, as prescribed in such regula-
16 tions, to assure that the public health is pro-
17 tected and that the tobacco product is in com-
18 pliance with this chapter.

19 “(B) The Secretary shall—

20 “(i) before promulgating any regula-
21 tion under subparagraph (A), afford an ad-
22 visory committee an opportunity to submit
23 recommendations with respect to the regu-
24 lation 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) Any person subject to any require-
22 ment prescribed under paragraph (1) may peti-
23 tion the Secretary for a permanent or tem-
24 porary exemption or variance from such re-
25 quirement. 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) The Secretary may refer to an advi-
21 sory committee any petition submitted under
22 subparagraph (A). The advisory committee
23 shall report its recommendations to the Sec-
24 retary with respect to a petition referred to it

1 within 60 days after the date of the petition's
2 referral. Within 60 days after—

3 “(i) the date the petition was sub-
4 mitted to the Secretary under subpara-
5 graph (A); or

6 “(ii) the day after the petition was re-
7 ferred to an advisory committee,
8 whichever occurs later, the Secretary shall by
9 order either deny the petition or approve it.

10 “(C) The Secretary may approve—

11 “(i) a petition for an exemption for a
12 tobacco product from a requirement if the
13 Secretary determines that compliance with
14 such requirement is not required to assure
15 that the tobacco product will be in compli-
16 ance with this chapter; and

17 “(ii) a petition for a variance for a to-
18 bacco product from a requirement if the
19 Secretary determines that the methods to
20 be used in, and the facilities and controls
21 to be used for, the manufacture, packing,
22 and storage of the tobacco product in lieu
23 of the methods, controls, and facilities pre-
24 scribed by the requirement are sufficient to

1 assure that the tobacco product will be in
2 compliance with this chapter.

3 “(D) An order of the Secretary approving
4 a petition for a variance shall prescribe such
5 conditions respecting the methods used in, and
6 the facilities and controls used for, the manu-
7 facture, packing, and storage of the tobacco
8 product to be granted the variance under the
9 petition as may be necessary to assure that the
10 tobacco product will be in compliance with this
11 chapter.

12 “(E) After the issuance of an order under
13 subparagraph (B) respecting a petition, the pe-
14 titioner shall have an opportunity for an infor-
15 mal hearing on such order.

16 “(3) Compliance with requirements under this
17 subsection shall not be required before the period
18 ending 3 years after the date of enactment of the
19 National Tobacco Policy and Youth Smoking Reduc-
20 tion Act.

21 “(f) EXEMPTION FOR INVESTIGATIONAL USE.—The
22 Secretary may exempt tobacco products intended for in-
23 vestigational use from this chapter under such conditions
24 as the Secretary may prescribe by regulation.

1 “(g) RESEARCH AND DEVELOPMENT.—The Sec-
2 retary may enter into contracts for research, testing, and
3 demonstrations respecting tobacco products and may ob-
4 tain tobacco products for research, testing, and dem-
5 onstration purposes without regard to section 3324(a) and
6 (b) of title 31, United States Code, and section 5 of title
7 41, United States Code.

8 **“SEC. 907. PERFORMANCE STANDARDS.**

9 “(a) IN GENERAL.—

10 “(1) FINDING REQUIRED.—The Secretary may
11 adopt performance standards for a tobacco product
12 if the Secretary finds that a performance standard
13 is appropriate for the protection of the public health.
14 This finding shall be determined with respect to the
15 risks and benefits to the population as a whole, in-
16 cluding users and non-users of the tobacco product,
17 and taking into account—

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

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

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

4 “(A) shall include provisions to provide
5 performance that is appropriate for the protec-
6 tion of the public health, including provisions,
7 where appropriate—

8 “(i) for the reduction or elimination of
9 nicotine yields of the product;

10 “(ii) for the reduction or elimination
11 of other constituents or harmful compo-
12 nents of the product; or

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

15 “(B) shall, where necessary to be appro-
16 priate for the protection of the public health,
17 include—

18 “(i) provisions respecting the con-
19 struction, components, ingredients, and
20 properties of the tobacco product;

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

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

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

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

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

20 “(3) PERIODIC RE-EVALUATION OF PERFORM-
21 ANCE STANDARDS.—The Secretary shall provide for
22 periodic evaluation of performance standards estab-
23 lished under this section to determine whether such
24 standards should be changed to reflect new medical,
25 scientific, or other technological data. The Secretary

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

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

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

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

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

20 “(b) ESTABLISHMENT OF STANDARDS.—

21 “(1) NOTICE.—

22 (A) The Secretary shall publish in the
23 Federal Register a notice of proposed rule-
24 making for the establishment, amendment, or

1 revocation of any performance standard for a
2 tobacco product.

3 “(B) A notice of proposed rulemaking for
4 the establishment or amendment of a perform-
5 ance standard for a tobacco product shall—

6 “(i) set forth a finding with sup-
7 porting justification that the performance
8 standard is appropriate for the protection
9 of the public health;

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

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

19 “(C) A notice of proposed rulemaking for
20 the revocation of a performance standard shall
21 set forth a finding with supporting justification
22 that the performance standard is no longer nec-
23 essary to be appropriate for the protection of
24 the public health.

1 “(D) The Secretary shall consider all infor-
2 mation submitted in connection with a proposed
3 standard, including information concerning the
4 countervailing effects of the performance stand-
5 ard on the health of adolescent tobacco users,
6 adult tobacco users, or non-tobacco users, such
7 as the creation of a significant demand for con-
8 traband or other tobacco products that do not
9 meet the requirements of this chapter and the
10 significance of such demand, and shall issue the
11 standard if the Secretary determines that the
12 standard would be appropriate for the protec-
13 tion of the public health.

14 “(E) The Secretary shall provide for a
15 comment period of not less than 60 days.

16 “(2) PROMULGATION.—

17 “(A) After the expiration of the period for
18 comment on a notice of proposed rulemaking
19 published under paragraph (1) respecting a per-
20 formance standard and after consideration of
21 such comments and any report from an advi-
22 sory committee, the Secretary shall—

23 “(i) promulgate a regulation estab-
24 lishing a performance standard and pub-

1 lish in the Federal Register findings on the
2 matters referred to in paragraph (1); or

3 “(ii) publish a notice terminating the
4 proceeding for the development of the
5 standard together with the reasons for
6 such termination.

7 “(B) A regulation establishing a perform-
8 ance standard shall set forth the date or dates
9 upon which the standard shall take effect, but
10 no such regulation may take effect before one
11 year after the date of its publication unless the
12 Secretary determines that an earlier effective
13 date is necessary for the protection of the pub-
14 lic health. Such date or dates shall be estab-
15 lished so as to minimize, consistent with the
16 public health, economic loss to, and disruption
17 or dislocation of, domestic and international
18 trade.

19 “(3) SPECIAL RULE FOR STANDARD BANNING
20 CLASS OF PRODUCT OR ELIMINATING NICOTINE CON-
21 TENT.—Because of the importance of a decision of
22 the Secretary to issue a regulation establishing a
23 performance standard—

1 “(A) eliminating all cigarettes, all smoke-
2 less tobacco products, or any similar class of to-
3 bacco products, or

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

6 it is appropriate for the Congress to have the oppor-
7 tunity to review such a decision. Therefore, any such
8 standard may not take effect before a date that is
9 2 years after the President notifies the Congress
10 that a final regulation imposing the restriction has
11 been issued.

12 “(4) AMENDMENT; REVOCATION.—

13 “(A) The Secretary, upon the Secretary’s
14 own initiative or upon petition of an interested
15 person may by a regulation, promulgated in ac-
16 cordance with the requirements of paragraphs
17 (1) and (2)(B) of this subsection, amend or re-
18 voke a performance standard.

19 “(B) The Secretary may declare a pro-
20 posed amendment of a performance standard to
21 be effective on and after its publication in the
22 Federal Register and until the effective date of
23 any final action taken on such amendment if
24 the Secretary determines that making it so ef-
25 fective is in the public interest.

1 “(5) REFERENCE TO ADVISORY COMMITTEE.—

2 The Secretary—

3 “(A) may, on the Secretary’s own initia-
4 tive, refer a proposed regulation for the estab-
5 lishment, amendment, or revocation of a per-
6 formance standard; or

7 “(B) shall, upon the request of an inter-
8 ested person which demonstrates good cause for
9 referral and which is made before the expiration
10 of the period for submission of comments on
11 such proposed regulation,

12 refer such proposed regulation to an advisory committee,
13 for a report and recommendation with respect to any mat-
14 ter involved in the proposed regulation which requires the
15 exercise of scientific judgment. If a proposed regulation
16 is referred under this subparagraph to the advisory com-
17 mittee, the Secretary shall provide the advisory committee
18 with the data and information on which such proposed
19 regulation is based. The advisory committee shall, within
20 60 days after the referral of a proposed regulation and
21 after independent study of the data and information fur-
22 nished to it by the Secretary and other data and informa-
23 tion before it, submit to the Secretary a report and rec-
24 ommendation respecting such regulation, together with all
25 underlying data and information and a statement of the

1 reason or basis for the recommendation. A copy of such
2 report and recommendation shall be made public by the
3 Secretary.

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

5 “(a) NOTIFICATION.—If the Secretary determines
6 that—

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

11 “(2) notification under this subsection is nec-
12 essary to eliminate the unreasonable risk of such
13 harm and no more practicable means is available
14 under the provisions of this chapter (other than this
15 section) to eliminate such risk,

16 the Secretary may issue such order as may be necessary
17 to assure that adequate notification is provided in an ap-
18 propriate form, by the persons and means best suited
19 under the circumstances involved, to all persons who
20 should properly receive such notification in order to elimi-
21 nate such risk. The Secretary may order notification by
22 any appropriate means, including public service announce-
23 ments. Before issuing an order under this subsection, the
24 Secretary shall consult with the persons who are to give
25 notice under the order.

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

8 “(c) RECALL AUTHORITY.—

9 “(1) IN GENERAL.—If the Secretary finds that
10 there is a reasonable probability that a tobacco prod-
11 uct contains a manufacturing or other defect not or-
12 dinarily contained in tobacco products on the market
13 that would cause serious, adverse health con-
14 sequences or death, the Secretary shall issue an
15 order requiring the appropriate person (including
16 the manufacturers, importers, distributors, or retail-
17 ers of the tobacco product) to immediately cease dis-
18 tribution of such tobacco product. The order shall
19 provide the person subject to the order with an op-
20 portunity for an informal hearing, to be held not
21 later than 10 days after the date of the issuance of
22 the order, on the actions required by the order and
23 on whether the order should be amended to require
24 a recall of such tobacco product. If, after providing
25 an opportunity for such a hearing, the Secretary de-

1 termines that inadequate grounds exist to support
2 the actions required by the order, the Secretary shall
3 vacate the order.

4 “(2) AMENDMENT OF ORDER TO REQUIRE RE-
5 CALL.—

6 “(A) If, after providing an opportunity for
7 an informal hearing under paragraph (1), the
8 Secretary determines that the order should be
9 amended to include a recall of the tobacco prod-
10 uct with respect to which the order was issued,
11 the Secretary shall, except as provided in sub-
12 paragraph (B), amend the order to require a
13 recall. The Secretary shall specify a timetable in
14 which the tobacco product recall will occur and
15 shall require periodic reports to the Secretary
16 describing the progress of the recall.

17 “(B) An amended order under subpara-
18 graph (A)—

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

21 “(ii) shall provide for notice to per-
22 sons subject to the risks associated with
23 the use of such tobacco product.

24 In providing the notice required by clause (ii),
25 the Secretary may use the assistance of retail-

1 ers and other persons who distributed such to-
2 bacco product. If a significant number of such
3 persons cannot be identified, the Secretary shall
4 notify such persons under section 705(b).

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

8 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**
9 **UCTS.**

10 “(a) IN GENERAL.—Every person who is a tobacco
11 product manufacturer or importer of a tobacco product
12 shall establish and maintain such records, make such re-
13 ports, and provide such information, as the Secretary may
14 by regulation reasonably require to assure that such to-
15 bacco product is not adulterated or misbranded and to
16 otherwise protect public health. Regulations prescribed
17 under the preceding sentence—

18 “(1) may require a tobacco product manufac-
19 turer or importer to report to the Secretary when-
20 ever the manufacturer or importer receives or other-
21 wise becomes aware of information that reasonably
22 suggests that one of its marketed tobacco products
23 may have caused or contributed to a serious unex-
24 pected adverse experience associated with the use of
25 the product or any significant increase in the fre-

1 quency of a serious, expected adverse product experi-
2 ence;

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

6 “(3) shall not impose requirements unduly bur-
7 densome to a tobacco product manufacturer or im-
8 porter, taking into account the cost of complying
9 with such requirements and the need for the protec-
10 tion of the public health and the implementation of
11 this chapter;

12 “(4) when prescribing the procedure for making
13 requests for reports or information, shall require
14 that each request made under such regulations for
15 submission of a report or information to the Sec-
16 retary state the reason or purpose for such request
17 and identify to the fullest extent practicable such re-
18 port or information;

19 “(5) when requiring submission of a report or
20 information to the Secretary, shall state the reason
21 or purpose for the submission of such report or in-
22 formation and identify to the fullest extent prac-
23 ticable such report or information; and

24 “(6) may not require that the identity of any
25 patient or user be disclosed in records, reports, or

1 information required under this subsection unless re-
2 quired for the medical welfare of an individual, to
3 determine risks to public health of a tobacco prod-
4 uct, or to verify a record, report, or information sub-
5 mitted under this chapter.

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

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

14 (1) Except as provided in paragraph (3), the
15 Secretary shall by regulation require a tobacco prod-
16 uct manufacturer or importer of a tobacco product
17 to report promptly to the Secretary any corrective
18 action taken or removal from the market of a to-
19 bacco product undertaken by such manufacturer or
20 importer if the removal or correction was
21 undertaken—

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

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

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

9 “(2) No report of the corrective action or re-
10 moval of a tobacco product may be required under
11 paragraph (1) if a report of the corrective action or
12 removal is required and has been submitted under
13 subsection (a) of this section.

14 **“SEC. 910. PREMARKET REVIEW OF CERTAIN TOBACCO**
15 **PRODUCTS.**

16 “(a) IN GENERAL.—

17 “(1) PREMARKET APPROVAL REQUIRED.—Ap-
18 proval under this section of an application for pre-
19 market approval for any tobacco product that is not
20 commercially marketed (other than for test mar-
21 keting) in the United States as of the date of intro-
22 duction of the National Cancer Act of 2002, such
23 approval, is required unless the manufacturer has
24 submitted a report under section 905(j), and the
25 Secretary has issued an order that the tobacco prod-

1 uct is substantially equivalent to a tobacco product
2 commercially marketed (other than for test mar-
3 keting) in the United States as of the date of intro-
4 duction of the National Cancer Act of 2002, that is
5 in compliance with the requirements of this Act.

6 “(2) SUBSTANTIALLY EQUIVALENT DEFINED.—

7 “(A) For purposes of this section and sec-
8 tion 905(j), the term ‘substantially equivalent’
9 or ‘substantial equivalence’ mean, with respect
10 to the tobacco product being compared to the
11 predicate tobacco product, that the Secretary by
12 order has found that the tobacco product—

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

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

23 “(B) For purposes of subparagraph (A),
24 the term ‘characteristics’ means the materials,

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

3 “(C) A tobacco product may not be found
4 to be substantially equivalent to a predicate to-
5 bacco product that has been removed from the
6 market at the initiative of the Secretary or that
7 has been determined by a judicial order to be
8 misbranded or adulterated.

9 “(3) HEALTH INFORMATION.—

10 “(A) As part of a submission under section
11 905(j) respecting a tobacco product, the person
12 required to file a premarket notification under
13 such section shall provide an adequate summary
14 of any health information related to the tobacco
15 product or state that such information will be
16 made available upon request by any person.

17 “(B) Any summary under subparagraph
18 (A) respecting a tobacco product shall contain
19 detailed information regarding data concerning
20 adverse health effects and shall be made avail-
21 able to the public by the Secretary within 30
22 days of the issuance of a determination that
23 such tobacco product is substantially equivalent
24 to another tobacco 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 investiga-
6 tions which have been made to show the health
7 risks of such tobacco product and whether such
8 tobacco product presents less risk than other
9 tobacco products;

10 “(B) a full statement of the components,
11 ingredients, and properties, and of the principle
12 or principles of operation, of such tobacco prod-
13 uct;

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 per-
20 formance standard under section 907 which
21 would be applicable to any aspect of such to-
22 bacco product, and either adequate information
23 to show that such aspect of such tobacco prod-
24 uct fully meets such performance standard or

1 adequate information to justify any deviation
2 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 ADVISORY COMMITTEE.—
12 Upon receipt of an application meeting the require-
13 ments set forth in paragraph (1), the Secretary—

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

16 “(B) shall, upon the request of an appli-
17 cant,

18 refer such application to an advisory committee and
19 for submission (within such period as the Secretary
20 may establish) of a report and recommendation re-
21 specting approval of the application, together with
22 all underlying data and the reasons or basis for the
23 recommendation.

24 “(c) ACTION ON APPLICATION.—

25 “(1) DEADLINE.—

1 “(A) As promptly as possible, but in no
2 event later than 180 days after the receipt of
3 an application under subsection (b) of this sec-
4 tion, the Secretary, after considering the report
5 and recommendation submitted under para-
6 graph (2) of such subsection, shall—

7 “(i) issue an order approving the ap-
8 plication if the Secretary finds that none of
9 the grounds for denying approval specified
10 in paragraph (2) of this subsection applies;
11 or

12 “(ii) deny approval of the application
13 if the Secretary finds (and sets forth the
14 basis for such finding as part of or accom-
15 panying such denial) that one or more
16 grounds for denial specified in paragraph
17 (2) of this subsection apply.

18 “(B) An order approving an application for
19 a tobacco product may require as a condition to
20 such approval that the sale and distribution of
21 the tobacco product be restricted but only to
22 the extent that the sale and distribution of a to-
23 bacco product may be restricted under a regula-
24 tion under section 906(d).

1 “(2) DENIAL OF APPROVAL.—The Secretary
2 shall deny approval of an application for a tobacco
3 product if, upon the basis of the information sub-
4 mitted to the Secretary as part of the application
5 and any other information before the Secretary with
6 respect to such tobacco product, the Secretary finds
7 that—

8 “(A) there is a lack of a showing that per-
9 mitting such tobacco product to be marketed
10 would be appropriate for the protection of the
11 public health;

12 “(B) the methods used in, or the facilities
13 or controls used for, the manufacture, proc-
14 essing, or packing of such tobacco product do
15 not conform to the requirements of section
16 906(e);

17 “(C) based on a fair evaluation of all mate-
18 rial facts, the proposed labeling is false or mis-
19 leading in any particular; or

20 “(D) such tobacco product is not shown to
21 conform in all respects to a performance stand-
22 ard in effect under section 907, compliance with
23 which is a condition to approval of the applica-
24 tion, and there is a lack of adequate informa-
25 tion to justify the deviation from such standard.

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

9 “(4) BASIS FOR FINDING.—For purposes of
10 this section, the finding as to whether approval of a
11 tobacco product is appropriate for the protection of
12 the public health shall be determined with respect to
13 the risks and benefits to the population as a whole,
14 including users and non-users of the tobacco prod-
15 uct, and taking into account—

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

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

22 “(5) BASIS FOR ACTION.—

23 “(A) For purposes of paragraph (2)(A),
24 whether permitting a tobacco product to be
25 marketed would be appropriate for the protec-

1 tion of the public health shall, when appro-
2 priate, be determined on the basis of well-con-
3 trolled investigations, which may include one or
4 more clinical investigations by experts qualified
5 by training and experience to evaluate the to-
6 bacco product.

7 “(B) If the Secretary determines that
8 there exists valid scientific evidence (other than
9 evidence derived from investigations described
10 in subparagraph (A)) which is sufficient to
11 evaluate the tobacco product the Secretary may
12 authorize that the determination for purposes
13 of paragraph (2)(A) be made on the basis of
14 such evidence.

15 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

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

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

1 “(B) that the application contained or was
2 accompanied by an untrue statement of a mate-
3 rial fact;

4 “(C) that the applicant—

5 “(i) has failed to establish a system
6 for maintaining records, or has repeatedly
7 or deliberately failed to maintain records
8 or to make reports, required by an applica-
9 ble regulation under section 909;

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

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

15 “(D) on the basis of new information be-
16 fore the Secretary with respect to such tobacco
17 product, evaluated together with the evidence
18 before the Secretary when the application was
19 approved, that the methods used in, or the fa-
20 cilities and controls used for, the manufacture,
21 processing, packing, or installation of such to-
22 bacco product do not conform with the require-
23 ments of section 906(e) and were not brought
24 into conformity with such requirements within a

1 reasonable time after receipt of written notice
2 from the Secretary of nonconformity;

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

12 “(F) on the basis of new information be-
13 fore the Secretary, evaluated together with the
14 evidence before the Secretary when the applica-
15 tion was approved, that such tobacco product is
16 not shown to conform in all respects to a per-
17 formance standard which is in effect under sec-
18 tion 907, compliance with which was a condi-
19 tion to approval of the application, and that
20 there is a lack of adequate information to jus-
21 tify the deviation from such standard.

22 “(2) APPEAL.—The holder of an application
23 subject to an order issued under paragraph (1) with-
24 drawing approval of the application may, by petition
25 filed on or before the thirtieth day after the date

1 upon which he receives notice of such withdrawal,
2 obtain review thereof in accordance with subsection
3 (e) of this section.

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

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

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

21 “(2) by mailing the order by registered mail or
22 certified mail addressed to the applicant at the ap-
23 plicant’s last known address in the records of the
24 Secretary.

1 **“SEC. 911. JUDICIAL REVIEW.**

2 “(a) IN GENERAL.—Not later than 30 days after—

3 “(1) the promulgation of a regulation under
4 section 907 establishing, amending, or revoking a
5 performance standard for a tobacco product; or

6 “(2) a denial of an application for approval
7 under section 910(c),

8 any person adversely affected by such regulation or order
9 may file a petition with the United States Court of Ap-
10 peals for the District of Columbia or for the circuit where-
11 in such person resides or has his principal place of busi-
12 ness for judicial review of such regulation or order. A copy
13 of the petition shall be transmitted by the clerk of the
14 court to the Secretary or other officer designated by the
15 Secretary for that purpose. The Secretary shall file in the
16 court the record of the proceedings on which the Secretary
17 based the Secretary’s regulation or order and each record
18 or order shall contain a statement of the reasons for its
19 issuance and the basis, on the record, for its issuance. For
20 purposes of this section, the term ‘record’ means all no-
21 tices and other matter published in the Federal Register
22 with respect to the regulation or order reviewed, all infor-
23 mation submitted to the Secretary with respect to such
24 regulation or order, proceedings of any panel or advisory
25 committee with respect to such regulation or order, any
26 hearing held with respect to such regulation or order, and

1 any other information identified by the Secretary, in the
2 administrative proceeding held with respect to such regu-
3 lation or order, as being relevant to such regulation or
4 order.

5 “(b) COURT MAY ORDER SECRETARY TO MAKE AD-
6 DITIONAL FINDINGS.—If the petitioner applies to the
7 court for leave to adduce additional data, views, or argu-
8 ments respecting the regulation or order being reviewed
9 and shows to the satisfaction of the court that such addi-
10 tional data, views, or arguments are material and that
11 there were reasonable grounds for the petitioner’s failure
12 to adduce such data, views, or arguments in the pro-
13 ceedings before the Secretary, the court may order the
14 Secretary to provide additional opportunity for the oral
15 presentation of data, views, or arguments and for written
16 submissions. The Secretary may modify the Secretary’s
17 findings, or make new findings by reason of the additional
18 data, views, or arguments so taken and shall file with the
19 court such modified or new findings, and the Secretary’s
20 recommendation, if any, for the modification or setting
21 aside of the regulation or order being reviewed, with the
22 return of such additional data, views, or arguments.

23 “(c) STANDARD OF REVIEW.—Upon the filing of the
24 petition under subsection (a) of this section for judicial
25 review of a regulation or order, the court shall have juris-

1 diction to review the regulation or order in accordance
2 with chapter 7 of title 5, United States Code, and to grant
3 appropriate relief, including interim relief, as provided in
4 such chapter. A regulation or order described in paragraph
5 (1) or (2) of subsection (a) of this section shall not be
6 affirmed if it is found to be unsupported by substantial
7 evidence on the record taken as a whole.

8 “(d) 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 “(e) 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 “(f) REGULATIONS AND ORDERS MUST RECITE
18 BASIS IN RECORD.—To facilitate judicial review under
19 this section or under any other provision of law of a regu-
20 lation or order issued under section 906, 907, 908, 909,
21 910, or 914, each such regulation or order shall contain
22 a statement of the reasons for its issuance and the basis,
23 in the record of the proceedings held in connection with
24 its issuance, for its issuance.

1 **“SEC. 912. POSTMARKET SURVEILLANCE**

2 “(a) DISCRETIONARY SURVEILLANCE.—The Sec-
3 retary may require a tobacco product manufacturer to
4 conduct postmarket surveillance for a tobacco product of
5 the manufacturer if the Secretary determines that
6 postmarket surveillance of the tobacco product is nec-
7 essary to protect the public health or is necessary to pro-
8 vide information regarding the health risks and other safe-
9 ty issues involving the tobacco product.

10 “(b) SURVEILLANCE APPROVAL.—Each tobacco
11 product manufacturer required to conduct a surveillance
12 of a tobacco product under subsection (a) of this section
13 shall, within 30 days after receiving notice that the manu-
14 facturer is required to conduct such surveillance, submit,
15 for the approval of the Secretary, a protocol for the re-
16 quired surveillance. The Secretary, within 60 days of the
17 receipt of such protocol, shall determine if the principal
18 investigator proposed to be used in the surveillance has
19 sufficient qualifications and experience to conduct such
20 surveillance and if such protocol will result in collection
21 of useful data or other information necessary to protect
22 the public health. The Secretary may not approve such
23 a protocol until it has been reviewed by an appropriately
24 qualified scientific and technical review committee estab-
25 lished by the Secretary.

1 **“SEC. 913. REDUCED RISK TOBACCO PRODUCTS.**

2 “(a) REQUIREMENTS.—

3 “(1) IN GENERAL.—For purposes of this sec-
4 tion, the term ‘reduced risk tobacco product’ means
5 a tobacco product designated by the Secretary under
6 paragraph (2).

7 “(2) DESIGNATION.—

8 “(A) IN GENERAL.—A product may be
9 designated by the Secretary as a reduced risk
10 tobacco product if the Secretary finds that the
11 product will significantly reduce harm to indi-
12 viduals caused by a tobacco product and is oth-
13 erwise appropriate to protect public health,
14 based on an application submitted by the manu-
15 facturer of the product (or other responsible
16 person) that—

17 “(i) demonstrates through testing on
18 animals and short-term human testing that
19 use of such product results in ingestion or
20 inhalation of a substantially lower yield of
21 toxic substances than use of conventional
22 tobacco products in the same category as
23 the proposed reduced risk product; and

24 “(ii) if required by the Secretary, in-
25 cludes studies of the long-term health ef-
26 fects of the product.

1 If such studies are required, the manufacturer
2 may consult with the Secretary regarding proto-
3 cols for conducting the studies.

4 “(B) BASIS FOR FINDING.—In making the
5 finding under subparagraph (A), the Secretary
6 shall take into account—

7 “(i) the risks and benefits to the pop-
8 ulation as a whole, including both users of
9 tobacco products and non-users of tobacco
10 products;

11 “(ii) the increased or decreased likeli-
12 hood that existing users of tobacco prod-
13 ucts will stop using such products includ-
14 ing reduced risk tobacco products;

15 “(iii) the increased or decreased likeli-
16 hood that those who do not use tobacco
17 products will start to use such products,
18 including reduced risk tobacco products;
19 and

20 “(iv) the risks and benefits to con-
21 sumers from the use of a reduced risk to-
22 bacco product as compared to the use of
23 products approved under chapter V to re-
24 duce exposure to tobacco.

1 “(3) MARKETING REQUIREMENTS.—A tobacco
2 product may be marketed and labeled as a reduced
3 risk tobacco product if it—

4 “(A) has been designated as a reduced risk
5 tobacco product by the Secretary under para-
6 graph (2);

7 “(B) bears a label prescribed by the Sec-
8 retary concerning the product’s contribution to
9 reducing harm to health; and

10 “(C) complies with requirements prescribed
11 by the Secretary relating to marketing and ad-
12 vertising of the product, and other provisions of
13 this chapter as prescribed by the Secretary.

14 “(b) REVOCATION OF DESIGNATION.—At any time
15 after the date on which a tobacco product is designated
16 as a reduced risk tobacco product under this section the
17 Secretary may, after providing an opportunity for an in-
18 formal hearing, revoke such designation if the Secretary
19 determines, based on information not available at the time
20 of the designation, that—

21 “(1) the finding made under subsection (a)(2)
22 is no longer valid; or

23 “(2) the product is being marketed in violation
24 of subsection (a)(3).

1 “(c) **LIMITATION.**—A tobacco product that is des-
2 ignated as a reduced risk tobacco product that is in com-
3 pliance with subsection (a) shall not be regulated as a
4 drug or device.

5 “(d) **DEVELOPMENT OF REDUCED RISK TOBACCO**
6 **PRODUCT TECHNOLOGY.**—A tobacco product manufac-
7 turer shall provide written notice to the Secretary upon
8 the development or acquisition by the manufacturer of any
9 technology that would reduce the risk of a tobacco product
10 to the health of the user for which the manufacturer is
11 not seeking designation as a ‘reduced risk tobacco product’
12 under subsection (a).

13 **“SEC. 914. PRESERVATION OF STATE AND LOCAL AUTHOR-**
14 **ITY.**

15 “(a) **ADDITIONAL REQUIREMENTS.**—

16 “(1) **IN GENERAL.**—Except as provided in para-
17 graph (2), nothing in this Act shall be construed as
18 prohibiting a State or political subdivision thereof
19 from adopting or enforcing a requirement applicable
20 to a tobacco product that is in addition to, or more
21 stringent than, requirements established under this
22 chapter.

23 “(2) **PREEMPTION OF CERTAIN STATE AND**
24 **LOCAL REQUIREMENTS.**—

1 “(A) Except as provided in subparagraph
2 (B), no State or political subdivision of a State
3 may establish or continue in effect with respect
4 to a tobacco product any requirement which is
5 different from, or in addition to, any require-
6 ment applicable under the provisions of this
7 chapter relating to performance standards, pre-
8 market approval, adulteration, misbranding,
9 registration, reporting, good manufacturing
10 standards, or reduced risk products.

11 “(B) Subparagraph (A) does not apply to
12 requirements relating to the sale, use, or dis-
13 tribution of a tobacco product including require-
14 ments related to the access to, and the adver-
15 tising and promotion of, a tobacco product.

16 “(b) RULE OF CONSTRUCTION REGARDING PRODUCT
17 LIABILITY.—No provision of this chapter relating to a to-
18 bacco product shall be construed to modify or otherwise
19 affect any action or the liability of any person under the
20 product liability law of any State.

21 “(c) WAIVERS.—Upon the application of a State or
22 political subdivision thereof, the Secretary may, by regula-
23 tion promulgated after notice and an opportunity for an
24 oral hearing, exempt from subsection (a), under such con-
25 ditions as may be prescribed in such regulation, a require-

1 ment of such State or political subdivision applicable to
 2 a tobacco product if—

3 “(1) the requirement is more stringent than a
 4 requirement applicable under the provisions de-
 5 scribed in subsection (a)(3) which would be applica-
 6 ble to the tobacco product if an exemption were not
 7 in effect under this subsection; or

8 “(2) the requirement—

9 “(A) is required by compelling local condi-
 10 tions; and

11 “(B) compliance with the requirement
 12 would not cause the tobacco product to be in
 13 violation of any applicable requirement of this
 14 chapter.

15 **“SEC. 915. EQUAL TREATMENT OF RETAIL OUTLETS.**

16 “The Secretary shall issue regulations to require that
 17 retail establishments for which the predominant business
 18 is the sale of tobacco products comply with any advertising
 19 restrictions applicable to retail establishments accessible
 20 to individuals under the age of 18.”.

21 **SEC. 402. CONFORMING AND OTHER AMENDMENTS TO GEN-**
 22 **ERAL PROVISIONS.**

23 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND
 24 COSMETIC ACT.—Except as otherwise expressly provided,
 25 whenever in this section an amendment is expressed in

1 terms of an amendment to, or repeal of, a section or other
2 provision, the reference is to a section or other provision
3 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 301 et seq.).

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

7 (1) by inserting “tobacco product,” in sub-
8 section (a) after “device,”;

9 (2) by inserting “tobacco product,” in sub-
10 section (b) after “device,”;

11 (3) by inserting “tobacco product,” in sub-
12 section (c) after “device,”;

13 (4) by striking “515(f), or 519” in subsection
14 (e) and inserting “515(f), 519, or 909”;

15 (5) by inserting “tobacco product,” in sub-
16 section (g) after “device,”;

17 (6) by inserting “tobacco product,” in sub-
18 section (h) after “device,”;

19 (7) by striking “708, or 721” in subsection (j)
20 and inserting “708, 721, 904, 905, 906, 907, 908,
21 or 909”;

22 (8) by inserting “tobacco product,” in sub-
23 section (k) after “device,”;

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

1 “(p) The failure to register in accordance with section
2 510 or 905, the failure to provide any information re-
3 quired by section 510(j), 510(k), 905(i), or 905(j), or the
4 failure to provide a notice required by section 510(j)(2)
5 or 905(J)(2).”;

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

8 “(q)(1) The failure or refusal—

9 “(A) to comply with any requirement prescribed
10 under section 518, 520(g), 906(f), or 908;

11 “(B) to furnish any notification or other mate-
12 rial or information required by or under section 519,
13 520(g), 904, 906(f), or 909; or

14 “(C) to comply with a requirement under sec-
15 tion 522 or 912.”;

16 (11) by striking “device,” in subsection (q)(2)
17 and inserting “device or tobacco product,”;

18 (12) by inserting “or tobacco product” in sub-
19 section (r) after “device” each time that it appears;
20 and

21 (13) by adding at the end thereof the following:

22 “(aa) The sale of tobacco products in violation
23 of a no-tobacco-sale order issued under section
24 303(f).”.

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

3 (1) by amending the caption to read as follows:

4 “(f) CIVIL PENALTIES; NO-TOBACCO-SALE OR-
5 DERS.—”;

6 (2) by inserting “or tobacco products” after
7 “devices” in paragraph (1)(A);

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

11 “(3) If the Secretary finds that a person has
12 committed repeated violations of restrictions promul-
13 gated under section 906(d) at a particular retail out-
14 let then the Secretary may impose a no-tobacco-sale
15 order on that person prohibiting the sale of tobacco
16 products in that outlet. A no-tobacco-sale order may
17 be imposed with a civil penalty under paragraph
18 (1).”;

19 (4) by striking “assessed” the first time it ap-
20 pears in subparagraph (A) of paragraph (4), as re-
21 designated, and inserting “assessed, or a no-tobacco-
22 sale order may be imposed,”;

23 (5) by striking “penalty” in such subparagraph
24 and inserting “penalty, or upon whom a no-tobacco-
25 order is to be imposed,”;

1 (6) by inserting after “penalty,” in subpara-
2 graph (B) of paragraph (4), as redesignated, the fol-
3 lowing: “or the period to be covered by a no-tobacco-
4 sale order,”;

5 (7) by adding at the end of such subparagraph
6 the following: “A no-tobacco-sale order permanently
7 prohibiting an individual retail outlet from selling to-
8 bacco products shall include provisions that allow
9 the outlet, after a specified period of time, to request
10 that the Secretary compromise, modify, or terminate
11 the order.”;

12 (8) by adding at the end of paragraph (4), as
13 redesignated, the following:

14 “(D) The Secretary may compromise, mod-
15 ify, or terminate, with or without conditions,
16 any no-tobacco-sale order.”;

17 (9) by striking “(3)(A)” in paragraph (5), as
18 redesignated, and inserting “(4)(A)”;

19 (10) by inserting “or the imposition of a no-to-
20 bacco-sale order” after “penalty” the first 2 places
21 it appears in such paragraph;

22 (11) by striking “issued.” in such paragraph
23 and inserting “issued, or on which the no-tobacco-
24 sale order was imposed, as the case may be.”; and

1 (12) by striking “paragraph (4)” each place it
2 appears in paragraph (6), as redesignated, and in-
3 serting “paragraph (5)”.

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

6 (1) by striking “and” before “(D)” in sub-
7 section (a)(2);

8 (2) by striking “device.” in subsection (a)(2)
9 and inserting a comma and “(E) Any adulterated or
10 misbranded tobacco product.”;

11 (3) by inserting “tobacco product,” in sub-
12 section (d)(1) after “device,”;

13 (4) by inserting “or tobacco product” in sub-
14 section (g)(1) after “device” each place it appears;
15 and

16 (5) by inserting “or tobacco product” in sub-
17 section (g)(2)(A) after “device” each place it ap-
18 pears.

19 (e) SECTION 702.—Section 702(a) (21 U.S.C.
20 372(a)) is amended—

21 (1) by inserting “(1)” after “(a)”; and

22 (2) by adding at the end thereof the following:

23 “(2) For a tobacco product, to the extent feasible,
24 the Secretary shall contract with the States in accordance

1 with paragraph (1) to carry out inspections of retailers
2 in connection with the enforcement of this Act.”.

3 (f) SECTION 703.—Section 703 (21 U.S.C. 373) is
4 amended—

5 (1) by inserting “tobacco product,” after “de-
6 vice,” each place it appears; and

7 (2) by inserting “tobacco products,” after “de-
8 vices,” each place it appears.

9 (g) SECTION 704.—Section 704 (21 U.S.C. 374) is
10 amended—

11 (1) by inserting “tobacco products,” in sub-
12 section (a)(1)(A) after “devices,” each place it ap-
13 pears;

14 (2) by inserting “or tobacco products” in sub-
15 section (a)(1)(B) after “restricted devices” each
16 place it appears; and

17 (3) by inserting “tobacco product,” in sub-
18 section (b) after “device,”.

19 (h) SECTION 705.—Section 705(b) (21 U.S.C.
20 375(b)) is amended by inserting “tobacco products,” after
21 “devices,”.

22 (i) SECTION 709.—Section 709 (21 U.S.C. 379) is
23 amended by inserting “or tobacco product” after “device”.

24 (j) SECTION 801.—Section 801 (21 U.S.C. 381) is
25 amended—

1 (1) by inserting “tobacco products,” after “de-
2 vices,” in subsection (a) the first time it appears;

3 (2) by inserting “or subsection (j) of section
4 905” in subsection (a) after “section 510”;

5 (3) by striking “drugs or devices” each time it
6 appears in subsection (a) and inserting “drugs, de-
7 vices, or tobacco products”;

8 (4) by inserting “tobacco product,” in sub-
9 section (e)(1) after “device,”; and

10 (5) by redesignating paragraph (4) of sub-
11 section (e) as paragraph (5) and inserting after
12 paragraph (3), the following:

13 “(4) Paragraph (1) does not apply to any to-
14 bacco product—

15 “(A) which does not comply with an appli-
16 cable requirement of section 907 or 910; or

17 “(B) which under section 906(f) is exempt
18 from either such section.

19 This paragraph does not apply if the Secretary has
20 determined that the exportation of the tobacco prod-
21 uct is not contrary to the public health and safety
22 and has the approval of the country to which it is
23 intended for export or the tobacco product is eligible
24 for export under section 802.”.

1 (k) SECTION 802.—Section 802 (21 U.S.C. 382) is
2 amended—

3 (1) by striking “device—” in subsection (a) and
4 inserting “device or tobacco product—”;

5 (2) by striking “and” after the semicolon in
6 subsection (a)(1)(C);

7 (3) by striking subparagraph (C) of subsection
8 (a)(2) and all that follows in that subsection and in-
9 serting the following:

10 “(C) is a banned device under section 516;

11 or

12 “(3) which, in the case of a tobacco product—

13 “(A) does not comply with an applicable
14 requirement of section 907 or 910; or

15 “(B) under section 906(f) is exempt from
16 either such section,

17 is adulterated, misbranded, and in violation of such

18 sections or Act unless the export of the drug, device,

19 or tobacco product is, except as provided in sub-

20 section (f), authorized under subsection (b), (c), (d),

21 or (e) of this section or section 801(e)(2) or

22 801(e)(4). If a drug, device, or tobacco product de-

23 scribed in paragraph (1), (2), or (3) may be ex-

24 ported under subsection (b) and if an application for

25 such drug or device under section 505, 515, or 910

1 of this Act or section 351 of the Public Health Serv-
 2 ice Act (42 U.S.C. 262) was disapproved, the Sec-
 3 retary shall notify the appropriate public health offi-
 4 cial of the country to which such drug, device, or to-
 5 bacco product will be exported of such disapproval.”;

6 (4) by inserting “or tobacco product” in sub-
 7 section (b)(1)(A) after “device” each time it ap-
 8 pears;

9 (5) by inserting “or tobacco product” in sub-
 10 section (c) after “device” and inserting “or section
 11 906(f)” after “520(g).”;

12 (6) by inserting “or tobacco product” in sub-
 13 section (f) after “device” each time it appears; and

14 (7) by inserting “or tobacco product” in sub-
 15 section (g) after “device” each time it appears.

16 (l) SECTION 1003.—Section 1003(d)(2)(C) (as reded-
 17 icated by section 101(a)) is amended—

18 (1) by striking “and” after “cosmetics,”; and

19 (2) inserting a comma and “and tobacco prod-
 20 ucts” after “devices”.

21 (m) EFFECTIVE DATE FOR NO-TOBACCO-SALE
 22 ORDER AMENDMENTS.—The amendments made by sub-
 23 section (c), other than the amendment made by paragraph
 24 (2) thereof, shall take effect only upon the promulgation
 25 of final regulations by the Secretary—

1 (1) defining the term “repeated violation”, as
2 used in section 303(f) of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 333(f)) as amended by
4 subsection (c), by identifying the number of viola-
5 tions of particular requirements over a specified pe-
6 riod of time that constitute a repeated violation;

7 (2) providing for notice to the retailer of each
8 violation at a particular retail outlet;

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

13 (4) establishing a period of time during which,
14 if there are no violations by a particular retail out-
15 let, that outlet will not be considered to have been
16 the site of repeated violations when the next viola-
17 tion occurs; and

18 (5) providing that good faith reliance on false
19 identification does not constitute a violation of any
20 minimum age requirement for the sale of tobacco
21 products.

22 **SEC. 403. FDA RULE IN EFFECT.**

23 The final regulations promulgated by the Secretary
24 in the August 28, 1996, issue of the Federal Register (62
25 Fed. Reg. 44615–44618) and codified at part 897 of title

1 21, Code of Federal Regulations, are hereby deemed to
 2 be lawful and to have been lawfully promulgated by the
 3 Secretary under chapter IX and section 701 of the Federal
 4 Food, Drug, and Cosmetic Act, as amended by this title,
 5 and not under chapter V of the Federal Food, Drug, and
 6 Cosmetic Act. Such regulations shall apply to all tobacco
 7 products and shall take effect upon such date as the Sec-
 8 retary determines by order, not later than 12 months after
 9 enactment of this title. The Secretary shall amend the des-
 10 ignation of authority in such regulations in accordance
 11 with this subsection.

12 **TITLE V—TOBACCO PRODUCT**
 13 **WARNINGS AND SMOKE CON-**
 14 **STITUENT DISCLOSURE**

15 **Subtitle A—Product Warnings,**
 16 **Labeling, and Packaging**

17 **SEC. 501. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

18 (a) IN GENERAL.—Section 4 of the Federal Cigarette
 19 Labeling and Advertising Act (15 U.S.C. 1333) is amend-
 20 ed to read as follows:

21 **“SEC. 4. LABELING.**

22 **“(a) LABEL REQUIREMENTS.—**

23 **“(1) IN GENERAL.—**It shall be unlawful for any
 24 person to manufacture, package, or import for sale
 25 or distribution within the United States any ciga-

1 rettes the package of which fails to bear, in accord-
2 ance with the requirements of this section, one of
3 the following labels:

4 “WARNING: Cigarettes are addictive”

5 “WARNING: Tobacco smoke can harm your chil-
6 dren”

7 “WARNING: Cigarettes cause fatal lung disease”

8 “WARNING: Cigarettes cause cancer”

9 “WARNING: Cigarettes cause strokes and heart
10 disease”

11 “WARNING: Smoking during pregnancy can harm
12 your baby”

13 “WARNING: Smoking can kill you”

14 “WARNING: Tobacco smoke causes fatal lung dis-
15 ease in non-smokers”

16 “WARNING: Quitting smoking now greatly reduces
17 serious risks to your health”

18 “(2) PLACEMENT; TYPOGRAPHY; ETC.—

19 “(A) IN GENERAL.—Each label statement
20 required by paragraph (1) shall be located in
21 the upper portion of the front and rear panels
22 of the package, directly on the package under-
23 neath the cellophane or other clear wrapping.
24 Except as provided in subparagraph (B), each
25 label statement shall comprise at least the top

1 25 percent of the front and rear panels of the
2 package. The word “WARNING” shall appear
3 in capital letters and all text shall be in con-
4 spicuous and legible 17-point type, unless the
5 text of the label statement would occupy more
6 than 70 percent of such area, in which case the
7 text may be in a smaller conspicuous and leg-
8 ible type size, provided that at least 60 percent
9 of such area is occupied by required text. The
10 text shall be black on a white background, or
11 white on a black background, in a manner that
12 contrasts, by typography, layout, or color, with
13 all other printed material on the package, in an
14 alternating fashion under the plan submitted
15 under subsection (b)(4).

16 “(B) FLIP-TOP BOXES.—For any cigarette
17 brand package manufactured or distributed be-
18 fore January 1, 2000, which employs a flip-top
19 style (if such packaging was used for that
20 brand in commerce prior to June 21, 1997), the
21 label statement required by paragraph (1) shall
22 be located on the flip-top area of the package,
23 even if such area is less than 25 percent of the
24 area of the front panel. Except as provided in

1 this paragraph, the provisions of this subsection
2 shall apply to such packages.

3 “(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not
4 apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture,
5 package, or import cigarettes for sale or distribution
6 within the United States.

9 “(b) ADVERTISING REQUIREMENTS.—

10 “(1) IN GENERAL.—It shall be unlawful for any
11 tobacco product manufacturer, importer, distributor,
12 or retailer of cigarettes to advertise or cause to be
13 advertised within the United States any cigarette
14 unless its advertising bears, in accordance with the
15 requirements of this section, one of the labels specified in subsection (a) of this section.

17 “(2) TYPOGRAPHY, ETC.—Each label statement
18 required by subsection (a) of this section in cigarette
19 advertising shall comply with the standards set forth
20 in this paragraph. For press and poster advertisements, each such statement and (where applicable)
21 any required statement relating to tar, nicotine, or
22 other constituent yield shall comprise at least 20
23 percent of the area of the advertisement and shall
24 appear in a conspicuous and prominent format and
25

1 location at the top of each advertisement within the
2 trim area. The Secretary may revise the required
3 type sizes in such area in such manner as the Sec-
4 retary determines appropriate. The word “WARN-
5 ING” shall appear in capital letters, and each label
6 statement shall appear in conspicuous and legible
7 type. The text of the label statement shall be black
8 if the background is white and white if the back-
9 ground is black, under the plan submitted under
10 paragraph (4) of this subsection. The label state-
11 ments shall be enclosed by a rectangular border that
12 is the same color as the letters of the statements
13 and that is the width of the first downstroke of the
14 capital “W” of the word “WARNING” in the label
15 statements. The text of such label statements shall
16 be in a typeface pro rata to the following require-
17 ments: 45-point type for a whole-page broadsheet
18 newspaper advertisement; 39-point type for a half-
19 page broadsheet newspaper advertisement; 39-point
20 type for a whole-page tabloid newspaper advertise-
21 ment; 27-point type for a half-page tabloid news-
22 paper advertisement; 31.5-point type for a double
23 page spread magazine or whole-page magazine ad-
24 vertisement; 22.5-point type for a 28 centimeter by
25 3 column advertisement; and 15-point type for a 20

1 centimeter by 2 column advertisement. The label
2 statements shall be in English, except that in the
3 case of—

4 “(A) an advertisement that appears in a
5 newspaper, magazine, periodical, or other publi-
6 cation that is not in English, the statements
7 shall appear in the predominant language of the
8 publication; and

9 “(B) in the case of any other advertise-
10 ment that is not in English, the statements
11 shall appear in the same language as that prin-
12 cipally used in the advertisement.

13 “(3) ADJUSTMENT BY SECRETARY.—The Sec-
14 retary may, through a rulemaking under section 553
15 of title 5, United States Code, adjust the format and
16 type sizes for the label statements required by this
17 section or the text, format, and type sizes of any re-
18 quired tar, nicotine yield, or other constituent disclo-
19 sures, or to establish the text, format, and type sizes
20 for any other disclosures required under the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et.
22 seq.). The text of any such label statements or dis-
23 closures shall be required to appear only within the
24 20 percent area of cigarette advertisements provided
25 by paragraph (2) of this subsection. The Secretary

1 shall promulgate regulations which provide for ad-
2 justments in the format and type sizes of any text
3 required to appear in such area to ensure that the
4 total text required to appear by law will fit within
5 such area.

6 “(4) MARKETING REQUIREMENTS.—

7 “(A) The label statements specified in sub-
8 section (a)(1) shall be randomly displayed in
9 each 12-month period, in as equal a number of
10 times as is possible on each brand of the prod-
11 uct and be randomly distributed in all areas of
12 the United States in which the product is mar-
13 keted in accordance with a plan submitted by
14 the tobacco product manufacturer, importer,
15 distributor, or retailer and approved by the Sec-
16 retary.

17 “(B) The label statements specified in sub-
18 section (a)(1) shall be rotated quarterly in al-
19 ternating sequence in advertisements for each
20 brand of cigarettes in accordance with a plan
21 submitted by the tobacco product manufacturer,
22 importer, distributor, or retailer to, and ap-
23 proved by, the Secretary.

1 “(C) The Secretary shall review each plan
2 submitted under subparagraph (B) and approve
3 it if the plan—

4 “(i) will provide for the equal distribu-
5 tion and display on packaging and the ro-
6 tation required in advertising under this
7 subsection; and

8 “(ii) assures that all of the labels re-
9 quired under this section will be displayed
10 by the tobacco product manufacturer, im-
11 porter, distributor, or retailer at the same
12 time.”.

13 (b) REPEAL OF PROHIBITION ON STATE RESTRIC-
14 TION.—Section 5 of the Federal Cigarette Labeling and
15 Advertising Act (15 U.S.C. 1334) is amended—

16 (1) by striking “(a) ADDITIONAL STATE-
17 MENTS.—” in subsection (a); and

18 (2) by striking subsection (b).

19 **SEC. 502. AUTHORITY TO REVISE CIGARETTE WARNING**
20 **LABEL STATEMENTS.**

21 Section 4 of the Federal Cigarette Labeling and Ad-
22 vertising Act (15 U.S.C. 1333), as amended by section
23 301 of this title, is further amended by adding at the end
24 the following:

1 “(c) CHANGE IN REQUIRED STATEMENTS.—The Sec-
2 retary may, by a rulemaking conducted under section 553
3 of title 5, United States Code, adjust the format, type size,
4 and text of any of the warning label statements required
5 by subsection (a) of this section, or establish the format,
6 type size, and text of any other disclosures required under
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
8 et seq.), if the Secretary finds that such a change would
9 promote greater public understanding of the risks associ-
10 ated with the use of smokeless tobacco products.”.

11 **SEC. 503. SMOKELESS TOBACCO LABELS AND ADVERTISING**
12 **WARNINGS.**

13 Section 3 of the Comprehensive Smokeless Tobacco
14 Health Education Act of 1986 (15 U.S.C. 4402) is amend-
15 ed to read as follows:

16 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

17 “(a) GENERAL RULE.—

18 “(1) It shall be unlawful for any person to man-
19 ufacture, package, or import for sale or distribution
20 within the United States any smokeless tobacco
21 product unless the product package bears, in accord-
22 ance with the requirements of this Act, one of the
23 following labels:

24 “WARNING: This product can cause mouth cancer”

1 “WARNING: This product can cause gum disease
2 and tooth loss”

3 “WARNING: This product is not a safe alternative
4 to cigarettes”

5 “WARNING: Smokeless tobacco is addictive”

6 “(2) Each label statement required by para-
7 graph (1) shall be—

8 “(A) located on the 2 principal display
9 panels of the package, and each label statement
10 shall comprise at least 25 percent of each such
11 display panel; and

12 “(B) in 17-point conspicuous and legible
13 type and in black text on a white background,
14 or white text on a black background, in a man-
15 ner that contrasts by typography, layout, or
16 color, with all other printed material on the
17 package, in an alternating fashion under the
18 plan submitted under subsection (b)(3), except
19 that if the text of a label statement would oc-
20 cupy more than 70 percent of the area specified
21 by subparagraph (A), such text may appear in
22 a smaller type size, so long as at least 60 per-
23 cent of such warning area is occupied by the
24 label statement.

1 “(3) The label statements required by para-
2 graph (1) shall be introduced by each tobacco prod-
3 uct manufacturer, packager, importer, distributor, or
4 retailer of smokeless tobacco products concurrently
5 into the distribution chain of such products.

6 “(4) The provisions of this subsection do not
7 apply to a tobacco product manufacturer or dis-
8 tributor of any smokeless tobacco product that does
9 not manufacture, package, or import smokeless to-
10 bacco products for sale or distribution within the
11 United States.

12 “(b) REQUIRED LABELS.—

13 “(1) It shall be unlawful for any tobacco prod-
14 uct manufacturer, packager, importer, distributor, or
15 retailer of smokeless tobacco products to advertise or
16 cause to be advertised within the United States any
17 smokeless tobacco product unless its advertising
18 bears, in accordance with the requirements of this
19 section, one of the labels specified in subsection (a).

20 “(2) Each label statement required by sub-
21 section (a) in smokeless tobacco advertising shall
22 comply with the standards set forth in this para-
23 graph. For press and poster advertisements, each
24 such statement and (where applicable) any required

1 statement relating to tar, nicotine, or other con-
2 stituent yield shall—

3 “(A) comprise at least 20 percent of the
4 area of the advertisement, and the warning area
5 shall be delineated by a dividing line of con-
6 trasting color from the advertisement; and

7 “(B) the word “WARNING” shall appear
8 in capital letters and each label statement shall
9 appear in conspicuous and legible type. The text
10 of the label statement shall be black on a white
11 background, or white on a black background, in
12 an alternating fashion under the plan submitted
13 under paragraph (3).

14 “(3)(A) The label statements specified in sub-
15 section (a)(1) shall be randomly displayed in each
16 12-month period, in as equal a number of times as
17 is possible on each brand of the product and be ran-
18 domly distributed in all areas of the United States
19 in which the product is marketed in accordance with
20 a plan submitted by the tobacco product manufac-
21 turer, importer, distributor, or retailer and approved
22 by the Secretary.

23 “(B) The label statements specified in sub-
24 section (a)(1) shall be rotated quarterly in alter-
25 nating sequence in advertisements for each brand of

1 smokeless tobacco product in accordance with a plan
2 submitted by the tobacco product manufacturer, im-
3 porter, distributor, or retailer to, and approved by,
4 the Secretary.

5 “(C) The Secretary shall review each plan sub-
6 mitted under subparagraph (B) and approve it if the
7 plan—

8 “(i) will provide for the equal distribution
9 and display on packaging and the rotation re-
10 quired in advertising under this subsection; and

11 “(ii) assures that all of the labels required
12 under this section will be displayed by the to-
13 bacco product manufacturer, importer, dis-
14 tributor, or retailer at the same time.

15 “(c) TELEVISION AND RADIO ADVERTISING.—It is
16 unlawful to advertise smokeless tobacco on any medium
17 of electronic communications subject to the jurisdiction of
18 the Federal Communications Commission.”.

19 **SEC. 504. AUTHORITY TO REVISE SMOKELESS TOBACCO**
20 **PRODUCT WARNING LABEL STATEMENTS.**

21 Section 3 of the Comprehensive Smokeless Tobacco
22 Health Education Act of 1986 (15 U.S.C. 4402), as
23 amended by section 303 of this title, is further amended
24 by adding at the end the following:

1 “(d) AUTHORITY TO REVISE WARNING LABEL
2 STATEMENTS.—The Secretary may, by a rulemaking con-
3 ducted under section 553 of title 5, United States Code,
4 adjust the format, type size, and text of any of the warn-
5 ing label statements required by subsection (a) of this sec-
6 tion, or establish the format, type size, and text of any
7 other disclosures required under the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary
9 finds that such a change would promote greater public un-
10 derstanding of the risks associated with the use of smoke-
11 less tobacco products.”.

12 **SEC. 505. TAR, NICOTINE, AND OTHER SMOKE CON-**
13 **STITUENT DISCLOSURE TO THE PUBLIC.**

14 Section 4(a) of the Federal Cigarette Labeling and
15 Advertising Act (15 U.S.C. 1333 (a)), as amended by sec-
16 tion 301 of this title, is further amended by adding at
17 the end the following:

18 “(4)(A) The Secretary shall, by a rulemaking
19 conducted under section 553 of title 5, United
20 States Code, determine (in the Secretary’s sole dis-
21 cretion) whether cigarette and other tobacco product
22 manufacturers shall be required to include in the
23 area of each cigarette advertisement specified by
24 subsection (b) of this section, or on the package
25 label, or both, the tar and nicotine yields of the ad-

1 advertised or packaged brand. Any such disclosure
2 shall be in accordance with the methodology estab-
3 lished under such regulations, shall conform to the
4 type size requirements of subsection (b) of this sec-
5 tion, and shall appear within the area specified in
6 subsection (b) of this section.

7 “(B) Any differences between the requirements
8 established by the Secretary under subparagraph (A)
9 and tar and nicotine yield reporting requirements es-
10 tablished by the Federal Trade Commission shall be
11 resolved by a memorandum of understanding be-
12 tween the Secretary and the Federal Trade Commis-
13 sion.

14 “(C) In addition to the disclosures required by
15 subparagraph (A) of this paragraph, the Secretary
16 may, under a rulemaking conducted under section
17 553 of title 5, United States Code, prescribe disclo-
18 sure requirements regarding the level of any ciga-
19 rette or other tobacco product smoke constituent.
20 Any such disclosure may be required if the Secretary
21 determines that disclosure would be of benefit to the
22 public health, or otherwise would increase consumer
23 awareness of the health consequences of the use of
24 tobacco products, except that no such prescribed dis-
25 closure shall be required on the face of any cigarette

1 package or advertisement. Nothing in this section
2 shall prohibit the Secretary from requiring such pre-
3 scribed disclosure through a cigarette or other to-
4 bacco product package or advertisement insert, or by
5 any other means under the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 301 et seq.).”.

7 **Subtitle B—Testing and Reporting**
8 **of Tobacco Product Smoke Con-**
9 **stituents**

10 **SEC. 511. REGULATION REQUIREMENT.**

11 (a) TESTING, REPORTING, AND DISCLOSURE.—Not
12 later than 24 months after the date of enactment of this
13 title, the Secretary, through the Commissioner of the Food
14 and Drug Administration, shall promulgate regulations
15 under the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 301 et seq.) that meet the requirements of sub-
17 section (b).

18 (b) CONTENTS OF RULES.—The rules promulgated
19 under subsection (a) of this section shall require the test-
20 ing, reporting, and disclosure of tobacco product smoke
21 constituents and ingredients that the Secretary determines
22 should be disclosed to the public in order to protect the
23 public health. Such constituents shall include tar, nicotine,
24 carbon monoxide, and such other smoke constituents or
25 ingredients as the Secretary may determine to be appro-

1 piate. The rule may require that tobacco product manu-
2 facturers, packagers, or importers make such disclosures
3 relating to tar and nicotine through labels or advertising,
4 and make such disclosures regarding other smoke con-
5 stituents or ingredients as the Secretary determines are
6 necessary to protect the public health.

7 (c) **AUTHORITY.**—The Food and Drug Administra-
8 tion shall have authority to conduct or to require the test-
9 ing, reporting, or disclosure of tobacco product smoke con-
10 stituents.

11 **SEC. 512. FDA AMENDMENT.**

12 Section 526(a)(2) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 360bb(a)(2)) is amended by in-
14 serting “or targets and mechanisms of pathogenesis of dis-
15 eases” after “disease or condition”.

○