

107TH CONGRESS  
2D SESSION

# H. R. 4596

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

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 25, 2002

Mrs. CAPPS (for herself, Mrs. ROUKEMA, Mr. DINGELL, Mr. JEFFERSON, Mrs. MALONEY of New York, Mr. KENNEDY of Rhode Island, Mr. MCNULTY, Mr. TOWNS, Ms. BROWN of Florida, Mr. FILNER, Mr. SERRANO, and Mr. LYNCH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To 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 clinical trials support required to advance scientific discoveries into new drugs and technologies to prevent,  
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treat, and diagnose cancer.

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

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

(11) The number of medical researchers entering medical research is declining, a decrease which will negatively affect the prevention and treatment of 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 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           “(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 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 **“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 has 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           every 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 the 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 the 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 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 the  
23          Secretary under this section shall report to the Sec-  
24          retary once during the month of June of each year

1 and once during the month of December of each  
2 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 igned 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”.

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