107TH CONGRESS
2D SESSION

S. 1976

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 28, 2002

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''National Cancer Act of 2002''.

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

TITLE V—TOBACCO PRODUCT WARNINGS AND SMOKE CONSTITUENT DISCLOSURE

Subtitle A—Product Warnings, Labeling, and Packaging

Subtitle B—Testing and Reporting of Tobacco Product Smoke Constituents

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Each year 1,300,000 Americans are diagnosed with cancer. Each year 560,000 Americans die from cancer. Approximately 40 percent of all Americans in the United States will be diagnosed with cancer at some point in their lives.

(2) Since 1971, when the National Cancer Act was enacted, and the ''War on Cancer'' was declared, the science of cancer has advanced dramatically. The revolution in molecular and cellular biology has created unprecedented opportunities for understanding cancer and the role of genetics, environmental risk factors, and prevention lifestyle factors in relation to cancer.

(3) Since 1971, mortality rates for some cancers have decreased, while such rates for other cancers have not.

(4) Since 1971, the Nation's population has become increasingly diverse and cancer affects various minority, socioeconomic, and ethnic groups disproportionately.

(5) Cancer screening can reduce cancer mortality, in some cases by 30 percent or more. While effective screening tools have yet to be developed for the majority of cancers, there are some cancers for which screening tools and procedures do exist. Screening for some cancers, such as breast and cervical cancers, has improved dramatically; however, screening rates are still lower than optimal. Cancer screening rates vary by cancer site, population group, and health insurance coverage.

(6) Public and private health insurance coverage offered in the United States has dramatically changed since 1971. Today, managed care coverage is more typical than the fee-for-service coverage that was more common in the past. This change in the form of coverage has introduced more economic considerations into medical decisionmaking, which can affect the quality of all health care provided, including cancer care.

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

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

(8) New translational cancer research centers are needed to provide the preclinical and early clinical trials support required to advance scientific discoveries into new drugs and technologies to prevent, 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.

(12) Since 1971, more cancer care, such as the administration of chemotherapy, has moved from inpatient to outpatient settings.

(13) Since 1971, the conduct of research has involved more collaboration between the public and private sectors and more multidisciplinary approaches. The biotechnology industry has grown and provided a broad array of new treatment options and scientific opportunities for cancer patients, providers, and researchers.

(14) Since 1971, technology and communications have expanded and increased in complexity, transforming research methodologies and making the accessing and transmitting of information more widespread and more readily available.

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

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

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

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

"CHAPTER I—PURPOSE OF INSTITUTE AND NATIONAL CANCER PROGRAMS"; and

(2) by adding at the end the following:

"CHAPTER II—PROGRAMS TO PREVENT AND TREAT CANCER

"SEC. 417D. AUTHORIZATION OF APPROPRIATIONS.

''There is authorized to be appropriated to the National Cancer Institute to carry out this chapter, $4,800,000,000 for fiscal year 2003, $5,300,000,000 for fiscal year 2004, $5,800,000,000 for fiscal year 2005, $6,400,000,000 for fiscal year 2006, and $7,100,000,000 for fiscal year 2007.

"SEC. 417D-1. STUDY AND STRATEGIC PLANS.

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

''(1) behavioral research associated with causing and preventing cancer;

''(2) research regarding prevention of cancer other than behavioral interventions;

''(3) research to reduce disparities among racial and ethnic minorities and other disparity populations;

''(4) research regarding palliative care, pain management;

''(5) research regarding preserving and restoring quality-of-life for cancer patients;

''(6) research regarding environmental risk factors for cancer and gene-environment interactions;

''(7) research regarding management of symptoms;

''(8) research regarding tools for early detection, especially for which there currently is no adequate screening technologies; and

''(9) cancer survivorship.

''(b) PRIORITIES.—The National Cancer Institute shall determine priorities based on scientific opportunities, in consultation with medical, scientific, patient, and provider representatives, and prepare 1 or more strategic plans by July 1, 2004.

''SEC. 417D-2. GRANTS FOR TRANSLATIONAL CANCER RESEARCH.

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

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

''(1) award grants to public or nonprofit private entities to plan and operate a national network of at least 20 existing or new translational cancer research centers to conduct translational, multidisciplinary cancer research;

''(2) establish networks and partnerships linking the translational cancer research centers described in paragraph (1) to community cancer providers (hospitals, clinics, providers' practices, particularly in underserved areas) and expand opportunities for all cancer patients to participate in clinical trials of new agents developed by these centers;

''(3) facilitate the process to award grants, contracts, and cooperative agreements to private entities to conduct translational cancer research in the following areas—

''(A) cancer drugs, biologics, and devices; and

''(B) cancer diagnostic tests, techniques and technology; and

''(4) develop and implement a strategic plan by July 1, 2004, in collaboration with translational centers as authorized in paragraph (7) for intensifying, expanding, and disseminating results of translational research to providers of cancer care.

''(c) GRANTS.—

''(1) IN GENERAL.—The Director shall award grants to public or nonprofit private entities to establish translational cancer research centers to conduct translational, multidisciplinary cancer research. Funds shall not be used for construction of new facilities.

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

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

''(4) APPLICATION.—A public or nonprofit entity desiring a grant under this subsection shall submit an application to the Director at such time, in such manner, and containing such information as the Director may reasonably require.

''(d) DUTIES OF TRANSLATIONAL RESEARCH CENTERS.—The translational research centers shall—

''(1) perform research for discovery and preclinical evaluation of drugs, biologics, devices, tech-

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

''(2) perform clinical research studies on promising cancer treatments or strategies, in appropriate human populations;

''(3) evaluate promising cancer diagnostic tests, techniques, or technologies in individuals being evaluated for the presence of cancer;

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

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

''(6) create systems and external relationships, which do not duplicate capabilities available in the private sector, to accelerate the findings from translational research to a stage that private companies can assume development and commercialization; and

''(7) develop and implement a plan expanding and disseminating the efficacious products of

translational research to providers of cancer care, including products approved by the Food and Drug Administration.

''(e) DEFINITIONS.—In this section:

''(1) CLINICAL TRIAL.—The term 'clinical trial' means a scientifically-designed clinical investigation in which a patient participates in examining the effects of a drug, biologic medical treatment, or medical device for the prevention, diagnosis, or treatment of cancer or the potential side effects of treatment.

''(2) TRANSLATIONAL CANCER RESEARCH.—The term 'translational cancer research' means scientific laboratory and clinical research and testing needed to transform scientific discoveries into new approaches and products that can prevent, control, diagnose, and treat cancer, optimize quality of life, and ultimately, cure cancer.

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

"SEC. 417D-3. CLINICAL TRIALS.

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

''(b) PROGRAM.—The program described in subsection (a) shall include—

''(1) an outreach program;

''(2) a diversity assurance program;

''(3) an assistance program, including recommending sources of funding for patients support costs; and

''(4) culturally appropriate materials.

''(c) OUTREACH PROGRAM.—In carrying out the outreach program described in subsection (a), the Director shall regularly provide information to cancer care providers, professional and patient organizations, including community-based organizations, and patients to increase provider participation and patient enrollment in clinical trials.

''(d) DIVERSITY ASSURANCE PROGRAM.—In carrying out the diversity assurance program described in subsection (a), the Director shall require that all research grant applications include assurances that the applicant will actively recruit a diverse patient population, including disparity populations, to participate in trials, when such recruitment is medically appropriate.

"SEC. 417D-4. CANCER CARE WORKFORCE.

''(a) IN GENERAL.—The Secretary shall establish a program to address current and future cancer care workforce needs.

''(b) PROGRAM.—The program described in subsection (a) shall—

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

''(2) prepare and implement a plan to provide assistance to individuals based on cancer health professions with the most severe shortages;

''(3) award grants, scholarships, fellowships, and loans to eligible individuals to increase the cancer care workforce;

''(4) make awards to eligible individuals to increase cancer care workforce training for all individuals to become cancer care providers, especially but not limited to, such individuals who make a commitment to serve in underserved communities or areas with disproportionately high cancer incidence or mortality and for health professions for which there are anticipated shortages, including providers, pharmacists, nurses for all settings, allied health professionals, physicians, specialists, and public health professionals; and

''(5) be coordinated with existing programs to prevent duplication.

''(c) ELIGIBILITY.—To be eligible to receive a scholarship, loan, or fellowship under this section, an individual shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary reasonably requires. In such application, such individual shall demonstrate the intent to seek training to get a certificate, license, or postsecondary degree in health care, or in the case of licensed health care professionals, the intent to seek professional development to upgrade skills and knowledge or to obtain specialized knowledge according to criteria developed by the Secretary.

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

''(1) care and treatment of cancer patients and survivors;

''(2) quality of life and symptom management;

''(3) cancer screening and early detection;

''(4) cancer prevention;

''(5) genetic testing and counseling;

''(6) language and cultural competency in cancer care; and

''(7) palliative and end-of-life care.

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

''SEC. 417D-5. INSTITUTE OF MEDICINE STUDY ON CANCER.

''(a) INSTITUTE OF MEDICINE STUDY.—The Secretary shall request the Institute of Medicine of the National Academies of Sciences to initiate a study by January 1, 2003, of the feasibility and costs of providing medicare coverage under title XVIII of the Social Security Act to individuals who are diagnosed with cancer and cancer survivors through 5 years of remission of cancer at any age and who have no other means of purchasing health care or health insurance, as determined under criteria established by the Secretary.

''(b) CONTENT.—

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

''(2) FIRST PART.—The first part shall—

''(A) examine options for providing medicare coverage to such individuals;

''(B) estimate the cost to the medicare program and to current and future beneficiaries; and

''(C) identify advantages associated with medicare coverage in terms of access to cancer care, improved quality of care and patient outcomes and assess the feasibility of providing medicare coverage to uninsured cancer patients through 5 years of remission and make a recommendation to Congress about whether Medicare should be expanded to this population group.

''(3) SECOND PART.—The second part shall—

''(A) identify changes in medicare benefits to facilitate the provision of care consistent with quality cancer care standards, including prescription drug benefits and benefits to improve home care, symptom management, psychosocial services, and palliative and hospice care;

''(B) estimate the cost to the medicare program and to beneficiaries; and

''(C) assess the medical advantages and disadvantages associated with expanding benefits.

''(4) DEADLINES.—The first part shall be completed by June 30, 2004, and the second part shall be completed by December 31, 2004.

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

''SEC. 417D-6. CANCER CARE GUIDELINES.

''The Agency for Healthcare Research and Quality shall regularly convene cancer experts, providers, patients, representatives of disparity populations, and other relevant experts, including representatives of the National Cancer Institute, the Health Resources Administration, and the Centers for Disease Control and Prevention, to coordinate the development and regularly update—

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

''(2) quality of care measures to assist providers and patients in making and evaluating treatment decisions; and

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

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

"SEC. 417D-7. RESEARCH AND OTHER ACTIVITIES OF THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY TO IMPROVE THE QUALITY AND OUTCOMES OF CANCER CARE.

''(a) IN GENERAL.—

''(1) RESEARCH.—The Director for Healthcare Research and Quality shall conduct and support research and other activities to build an evidence base regarding effective clinical and organizational intervention strategies to improve the quality and outcomes of cancer care, and access to such care, at all stages of the health care continuum and to facilitate the prompt use of that information to improve practice.

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

''(b) SPECIFIC REQUIREMENTS.—The Agency for Healthcare Research and Quality shall—

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

''(2) regularly assess and synthesize existing scientific evidence on the effectiveness of such interventions;

''(3) ensure the targeted dissemination of the most current scientific evidence in appropriate formats for use by professional societies and organizations representing clinicians and other caregivers, organizations through which health care and support services are delivered, and organizations representing cancer patients and their families;

''(4) facilitate, as appropriate, the prompt use of existing scientific information by the professional societies and organization listed in paragraph (3) to develop guidance, best practices, quality improvement strategies or other initiatives to improve practice;

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

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

''(7) assess effective strategies by which an individual physician can provide overall coordination and management of cancer care.

''(c) COORDINATION OF FEDERAL QUALITY IMPROVEMENT ACTIVITIES AND REPORTING OF DATA.—In carrying out subsection (b)—

''(1) the Director for Healthcare Research and Quality, working through the Quality Interagency Coordination (QUIC) Task Force, and in collaboration with the Director, National Cancer Institute, shall facilitate coordination of Federal research and implementation initiatives to improve the quality and outcomes of cancer care;

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

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

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

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

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

''SEC. 417D-8. CENTERS FOR DISEASE CONTROL AND PREVENTION.

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

''(1) expand and update the National Program of Comprehensive Cancer Control Plans;

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

''(3) assist States, territories, tribal organizations, and the District of Columbia in developing and implementing a cancer prevention and control program so that every State will have an active plan

in place and so that States, territories, tribal organizations, and the District of Columbia will use treatments to prevent and control cancer and so that disparities in specific populations will be addressed;

''(4) coordinate with the National Cancer Institute;

''(5) prepare model programs to prevent and control cancer and improve access to and the quality of cancer care among racial and ethnic minority and medically underserved populations with disproportionate incidence of or death from cancer;

''(6) promote cancer education, prevention, and early detection of cancer; and

''(7) award grants to public and nonprofit organizations for cancer control and prevention.

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

''SEC. 417D-9. CANCER CARE RESEARCHERS.

''(a) SUPPLY OF CANCER RESEARCHERS.—In order to ensure a sufficient number of researchers trained in the prevention, diagnosis, cure, and treatment of cancer in future fiscal years, the Director of the National Cancer In-

stitute, in coordination with the Secretary of Veterans Affairs, shall carry out activities to—

''(1) increase the number and amount of institutional training grants to institutions supporting cancer research; and

''(2) increase the number of career development awards for health professionals, particularly minorities, who intend to have, or who expand, careers in basic, clinical, and translational cancer research, including cancer prevention, cancer information technology, bioinformatics, behavioral research, and research on palliative, psychosocial, and end-of-life care.

''(b) LOAN REPAYMENT.—

''(1) ESTABLISHMENT.—The Director, in consultation with the Director of the National Institutes of Health, shall establish a cancer research loan repayment program.

''(2) CONTRACTS.—Under the program established under paragraph (1), the Director shall enter into contracts with qualified health professionals under which such professionals will agree to conduct cancer research, in consideration of the Federal Government agreeing to repay, for each year of such services, not more than $35,000 of the principal and

interest of the educational loans of such professionals obtained to support training for degrees or licenses, as determined appropriate by the Director.

''(c) POSTDOCTORAL STIPENDS.—

''(1) IN GENERAL.—The Director of the National Cancer Institute, shall develop and implement, for postdoctoral trainees and fellows, a stipend schedule that by October 1, 2003, begins for entry-level positions and individuals with no or limited experience comparable to grade 11 of the Federal general schedule under title 5, United States Code (civil service salary schedule) and that adequately reflects training, education, experience, and comparable salaries or stipends for comparable work in non-Federal settings, and provides for annual cost-of-living adjustments.

''(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $79,000,000 for fiscal year 2003, and $86,000,000 for fiscal year 2004, $95,000,000 for fiscal year 2005, $105,000,000 for fiscal year 2006, and $115,000,000 for fiscal year 2007.

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

$10,500,000 for fiscal year 2003, and $10,500,000 for each of fiscal years 2004 through 2007.''.

SEC. 102. NATIONAL INSTITUTE FOR ENVIRONMENTAL HEALTH SCIENCES.

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

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

SEC. 103. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

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

''SEC. 1511. DEMONSTRATION PROGRAM FOR COLORECTAL CANCER SCREENING.

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

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

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

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

TITLE II—CANCER-RELATED HEALTH INSURANCE COVERAGE

Subtitle A—Clinical Trials Coverage

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

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

"SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING IN CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan, or health insurance issuer that is providing health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

''(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

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

"(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.

"(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

"(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial. Nothing in this section should prevent a qualified individual from participating in a trial even if the plan or issuer does not have an in-network provider participating.

"(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who is referred by the treating physician and meets the following conditions:

''(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

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

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

''(4) Either the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described above in paragraphs (1) through (3), or the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the criteria described above in such paragraphs.

''(c) PAYMENT.—

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

priate Secretary) to be paid for by the sponsors of an approved clinical trial.

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

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

''(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

''(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation—

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

''(A) the National Institutes of Health;

''(B) a cooperative group or center of the National Institutes of Health;

''(C) the Department of Veterans Affairs;

''(D) the Department of Defense;

''(E) the Centers for Disease Control and Prevention; or

''(F) the Agency for Healthcare Research and Quality;

''(2) approved by the Food and Drug Administration; or

''(3) a qualified non-governmental research entity that specifies compliance with the guidelines set forth in section 46 of title 45, Code of Federal Regulations and whose research is reviewed and approved through an institutional review board that—

''(A) has been registered with the Department of Health and Human Services; and

''(B) is an institutional review board of an institution that has received an appropriate Federal assurance from the Department of Health and Human Services assuring compliance with such section of such Code.

''(e) CONDITIONS FOR DEPARTMENTS.—The conditions described in the paragraph for a study or investigation conducted by a department, are that the study or investigation has been reviewed and approved through a system of peer review that the appropriate Secretary determines—

''(1) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and

''(2) assures unbiased review of the highest ethical standards by qualified individuals who have no interest in the outcome of the review.

''(f) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials. Nothing in this section shall be construed to result in a reduction, diminishment, or change in coverage resulting in less coverage.''.

(b) INDIVIDUAL.—Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 (42 U.S.C. 300gg–52) the following:

''SEC. 2753. PATIENT PROTECTION STANDARDS.

''The provisions of section 2707 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan.''.

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

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

"SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan, or health insurance issuer offering group health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

''(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

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

''(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.

''(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

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

clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial. Nothing in this section should prevent a qualified individual from participating in a trial even if the plan or issuer does not have an in-network provider participating.

''(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who is referred by the treating physician and meets the following conditions:

''(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

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

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

''(4) Either the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would

be appropriate based upon the individual meeting the conditions described above in paragraphs (1) through (3) or the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the criteria described above in such paragraphs.

''(c) PAYMENT.—

''(1) IN GENERAL.—Under this section a group health plan or health insurance issuer shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services (as determined by the appropriate Secretary) to be paid for by the sponsors of an approved clinical trial.

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

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

''(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

''(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation—

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

''(A) the National Institutes of Health;

''(B) a cooperative group or center of the National Institutes of Health;

''(C) the Department of Veterans Affairs;

''(D) the Department of Defense;

''(E) the Centers for Disease Control and Prevention; or

''(F) the Agency for Healthcare Research and Quality;

''(2) approved by the Food and Drug Administration; or

''(3) a qualified non-governmental research entity that specifies compliance with the guidelines set forth in section 46 of title 45, Code of Federal Regulations, and whose research is reviewed and approved through an institutional review board that—

''(A) has been registered with the Department of Health and Human Services; and

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

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

''(e) CONDITIONS FOR DEPARTMENTS.—The conditions described in the paragraph for a study or investigation conducted by a department, are that the study or investigation has been reviewed and approved through a system of peer review that the appropriate Secretary determines—

''(1) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and

''(2) assures unbiased review of the highest ethical standards by qualified individuals who have no interest in the outcome of the review.

''(f) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials. Nothing in this section shall be construed to result in a reduction, diminishment, or change in coverage resulting in less coverage.''.

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 713 the following new item:

''Sec. 714. Coverage for individuals participating in clinical trials.''.

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

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

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

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

(3) the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1398 et seq.);

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

(5) programs offered by the Department of Defense;

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

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

Subtitle B—Cancer Screening and Other Coverage

SEC. 211. CANCER SCREENING COVERAGE.

(a) GROUP HEALTH PLANS.—

(1) PUBLIC HEALTH SERVICE ACT AMENDMENTS.—

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

"SEC. 2708. COVERAGE OF CANCER SCREENING.

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

''(1) MAMMOGRAMS.—In the case of a female participant or beneficiary who is 40 years of age or older, or is under 40 years of age but is at high risk (as defined in subsection (e)) of developing breast cancer, an annual mammography (as defined in section 1861(jj) of the Social Security Act) conducted by a facility that has a certificate (or provisional certificate) issued under section 354.

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

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

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

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

"(A) an annual diagnostic laboratory test (popularly known as a 'pap smear') consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and including an interpretation by a qualified health professional of the results of the test; and

"(B) an annual pelvic examination.

"(4) COLORECTAL CANCER SCREENING PROCEDURES.—In the case of a participant or beneficiary who is 50 years of age or older, or who is under 50 years of age and is at risk of developing colorectal

cancer, the procedures described in section 1861(pp)(1) of the Social Security Act (42 U.S.C. 1395x(pp)(1)) or section 4104(a)(2) of the Balanced Budget Act of 1997 (111 Stat. 362), shall be furnished to the individual for the purpose of early detection of colorectal cancer. The group health plan or health insurance issuer shall provide coverage for the method and frequency of colorectal cancer screening determined to be appropriate by a health care provider treating such participant or beneficiary, in consultation with the participant or beneficiary.

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

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

''(6) TOBACCO THERAPY AND COUNSELING.—

''(A) IN GENERAL.—Therapy and counseling for cessation of tobacco use for individuals who use tobacco products or who are being treated for tobacco use that is furnished—

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

''(ii) by any other health care professional—

''(I) who is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished; and

''(II) who, for medicare beneficiaries, is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose.

''(B) LIMITATION.—Subject to subparagraph (C), such therapy and counseling are limited to—

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

"(ii) such other therapy and counseling services that the Secretary recognizes to be effective.

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

"(7) MEDICAL NUTRITION THERAPY SERVICES.—Medical nutrition therapy services, as defined in section 1861(vv) of the Social Security Act (42 U.S.C. 1395x(vv)) for the purpose of improving the health of cancer patients and preventing cancer in other beneficiaries.

"(8) GENETIC TESTS AND GENETIC SERVICES.—

"(A) IN GENERAL.—Genetic tests and genetic services provided by a licensed health care professional to obtain predictive genetic information about an individual at risk of cancer for

purposes of a health assessment, cancer management, cancer prevention, other diagnostic or therapeutic purposes, or genetic education and counseling.

''(B) DEFINITIONS.—In this paragraph:

''(i) FAMILY MEMBER.—The term 'family member' means with respect to an individual—

''(I) the spouse of the individual;

''(II) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

''(III) all other individuals related by blood to the individual or the spouse or child described in subclause (I) or (II).

''(ii) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of such individual (including information about a request for or the receipt of genetic serv-

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

"(iii) GENETIC SERVICES.—The term 'genetic services' means health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

"(iv) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect genotypes, mutations, or chromosomal changes.

"(v) PREDICTIVE GENETIC INFORMATION.—

"(I) IN GENERAL.—The term 'predictive genetic information' means—

"(aa) information about an individual's genetic tests;

"(bb) information about genetic tests of family members of the individual; or

"(cc) information about the occurrence of a disease or disorder in family members.

"(II) LIMITATIONS.—The term 'predictive genetic information' shall not include—

"(aa) information about the sex or age of the individual;

"(bb) information about chemical, blood, or urine analyses of the individual, unless these analyses are genetic tests; or

"(cc) information about physical exams of the individual, and other information relevant to determining the current health status of the individual.

"(9) OTHER TESTS AND PROCEDURES.—Such other tests or procedures for the detection of cancer, and modifications to the tests and procedures, with such frequency, as the Secretary determines to be appropriate, in consultation with appropriate organizations and agencies, for the diagnosis or detection of cancer.

''(b) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not—

''(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

''(2) provide monetary payments or rebates to individuals to encourage such individuals to accept less than the minimum protections available under this section;

''(3) penalize or otherwise reduce or limit the reimbursement of a provider because such provider provided care to an individual participant or beneficiary in accordance with this section; or

''(4) provide incentives (monetary or otherwise) to a provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section.

''(c) RULES OF CONSTRUCTION.—

''(1) Nothing in this section shall be construed to require an individual who is a participant or beneficiary to undergo a procedure, examination, or test described in subsection (a).

''(2) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits described in subsection (a) consistent with such subsection, except that such coinsurance or other cost-sharing shall not discriminate on any basis related to the coverage required under this section.

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

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

''(e) RISK DEFINED.—For purposes of this section, an individual is considered to be at 'risk' of developing a particular type of cancer if, under guidelines developed or recognized by the Secretary based upon scientific evidence, the individual—

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

''(2) has previously had that type of cancer;

''(3) has the presence of an appropriate recognized gene marker that is identified as putting the individual at a higher risk of developing that type of cancer; or

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

For purposes of this subsection, the term 'type of cancer' includes other types of cancer that the Secretary recognizes as closely related for purposes of establishing risk.

''SEC. 2709. PATIENT ACCESS TO INFORMATION.

''(a) DISCLOSURE REQUIREMENT.—A group health plan, and health insurance issuer offering group health insurance coverage shall—

''(1) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b) in printed form;

''(2) provide to participants and beneficiaries, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in sub-

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

''(3) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsection (b) in printed form.

''(b) INFORMATION PROVIDED.—The information described in subsection (a) that shall be disclosed includes the following, as such relates to cancer screening required under section 2708(a):

''(1) BENEFITS.—Benefits offered under the plan or coverage, including—

''(A) covered benefits, including benefit limits and coverage exclusions;

''(B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;

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

''(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network.

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

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

''(B) Out-of-network coverage (if any) provided by the plan or coverage.

''(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

''(D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.

''(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.

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

''(G) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information under this subsection.''.

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

(2) ERISA AMENDMENTS.—

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

''SEC. 715. COVERAGE OF CANCER SCREENING.

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

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

''(1) MAMMOGRAMS.—In the case of a female participant or beneficiary who is 40 years of age or older, or is under 40 years of age but is at high risk (as defined in subsection (e)) of developing breast cancer, an annual mammography (as defined in section 1861(jj) of the Social Security Act) conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act.

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

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

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

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

"(A) an annual diagnostic laboratory test (popularly known as a 'pap smear') consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and including an interpretation by a qualified health professional of the results of the test; and

"(B) an annual pelvic examination.

"(4) COLORECTAL CANCER SCREENING PROCEDURES.—In the case of a participant or beneficiary who is 50 years of age or older, or who is under 50 years of age and is at risk of developing colorectal cancer, the procedures described in section 1861(pp)(1) of the Social Security Act (42 U.S.C. 1395x(pp)(1)) or section 4104(a)(2) of the Balanced Budget Act of 1997 (111 Stat. 362), shall be furnished to the individual for the purpose of early detection of colorectal cancer. The group health plan or health insurance issuer shall provided coverage for the method and frequency of colorectal cancer screening determined to be appropriate by a health care provider treating such participant or beneficiary, in consultation with the participant or beneficiary.

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

''(6) TOBACCO THERAPY AND COUNSELING.—

''(A) IN GENERAL.—Therapy and counseling for cessation of tobacco use for individuals who use tobacco products or who are being treated for tobacco use that is furnished—

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

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

''(I) is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished; and

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

''(B) LIMITATION.—Subject to subparagraph (C), such therapy and counseling are limited to—

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

''(ii) such other therapy and counseling services that the Secretary recognizes to be effective.

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

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

''(7) MEDICAL NUTRITION THERAPY SERVICES.—Medical nutrition therapy services, as defined in section 1861(vv) of the Social Security Act (42 U.S.C. 1395x(vv)) for the purpose of improving the health of cancer patients and preventing cancer in other beneficiaries.

''(8) GENETIC TESTS AND GENETIC SERVICES.—

''(A) IN GENERAL.—Genetic tests and genetic services provided by a licensed health care professional to obtain predictive genetic information about an individual at risk of cancer for purposes of a health assessment, cancer management, cancer prevention, other diagnostic or therapeutic purposes, or genetic education and counseling.

''(B) DEFINITIONS.—In this paragraph:

''(i) FAMILY MEMBER.—The term 'family member' means with respect to an individual—

''(I) the spouse of the individual;

''(II) a dependent child of the individual, including a child who is born

to or placed for adoption with the individual; and

"(III) all other individuals related by blood to the individual or the spouse or child described in subclause (I) or (II).

"(ii) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of such individual (including information about a request for or the receipt of genetic services by such individual or family member of such individual).

"(iii) GENETIC SERVICES.—The term 'genetic services' means health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

"(iv) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect

genotypes, mutations, or chromosomal changes.

"(v) PREDICTIVE GENETIC INFORMATION.—

"(I) IN GENERAL.—The term 'predictive genetic information' means—

"(aa) information about an individual's genetic tests;

"(bb) information about genetic tests of family members of the individual; or

"(cc) information about the occurrence of a disease or disorder in family members.

"(II) LIMITATIONS.—The term 'predictive genetic information' shall not include—

"(aa) information about the sex or age of the individual;

"(bb) information about chemical, blood, or urine analyses of the individual, unless these analyses are genetic tests; or

''(cc) information about physical exams of the individual, and other information relevant to determining the current health status of the individual.

''(9) OTHER TESTS AND PROCEDURES.—Such other tests or procedures for the detection of cancer, and modifications to the tests and procedures, with such frequency, as the Secretary determines to be appropriate, in consultation with appropriate organizations and agencies, for the diagnosis or detection of cancer.

''(b) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not—

''(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

''(2) provide monetary payments or rebates to individuals to encourage such individuals to accept less than the minimum protections available under this section;

''(3) penalize or otherwise reduce or limit the reimbursement of a provider because such provider provided care to an individual participant or beneficiary in accordance with this section; or

''(4) provide incentives (monetary or otherwise) to a provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section.

''(c) RULES OF CONSTRUCTION.—

''(1) Nothing in this section shall be construed to require an individual who is a participant or beneficiary to undergo a procedure, examination, or test described in subsection (a).

''(2) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits described in subsection (a) consistent with such subsection, except that such coinsurance or other cost-sharing shall not discriminate on any basis related to the coverage required under this section.

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

''(d) NOTICE UNDER GROUP HEALTH PLAN.—The imposition of the requirement of this section shall be treated as a material modification in the terms of the plan described in section 102(a), for purposes of assuring notice of such requirements under the plan; except that the summary description required to be provided under the last sentence of section 104(b)(1) with respect to such modification shall be provided by not later than 60 days after the first day of the first plan year in which such requirement apply.

''(e) RISK DEFINED.—For purposes of this section, an individual is considered to be at 'risk' of developing a particular type of cancer if, under guidelines developed or recognized by the Secretary based upon scientific evidence, the individual—

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

''(2) has previously had that type of cancer;

''(3) has the presence of an appropriate recognized gene marker that is identified as putting the individual at a higher risk of developing that type of cancer; or

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

For purposes of this subsection, the term 'type of cancer' includes other types of cancer that the Secretary recognizes as closely related for purposes of establishing risk.

"SEC. 716. PATIENT ACCESS TO INFORMATION.

"(a) DISCLOSURE REQUIREMENT.—A group health plan, and health insurance issuer offering group health insurance coverage shall—

"(1) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b) in printed form;

"(2) provide to participants and beneficiaries, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form regarding such significant changes; and

"(3) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsection (b) in printed form.

"(b) INFORMATION PROVIDED.—The information described in subsection (a) that shall be disclosed includes

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

''(1) BENEFITS.—Benefits offered under the plan or coverage, including—

''(A) covered benefits, including benefit limits and coverage exclusions;

''(B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;

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

''(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network.

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

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

''(B) Out-of-network coverage (if any) provided by the plan or coverage.

''(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

''(D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.

''(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.

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

''(G) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information under this subsection.''.

(B) TECHNICAL AMENDMENTS.—

(i) Section 731(c) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191(c)) is amended by striking ''section 711'' and inserting ''sections 711 and 715''.

(ii) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 715''.

(iii) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by section 202, is further amended by inserting after the item relating to section 714 the following new items:

''Sec. 715. Coverage of cancer screening.
''Sec. 716. Patient access to information.''.

(b) INDIVIDUAL HEALTH INSURANCE.—

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

"SEC. 2754. STANDARD RELATING PATIENT FREEDOM OF CHOICE.

''(a) IN GENERAL.—The provisions of section 2708 (other than subsection (d)) shall apply to health insurance coverage offered by a health insurance issuer in the individual market with respect to an enrollee under such coverage in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market to a participant or beneficiary in such plan.

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

"SEC. 2755. PATIENT ACCESS TO INFORMATION.

''The provisions of section 2709 shall apply health insurance coverage offered by a health insurance issuer in the individual market with respect to an enrollee under such coverage in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market to a participant or beneficiary in such plan.''.

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

(c) EFFECTIVE DATES.—

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

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

(3) COLLECTIVE BARGAINING AGREEMENT.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made to subsection (a) shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any ex-

tension thereof agreed to after the date of enactment of this Act), or

(B) January 1, 2002.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by subsection (a) shall not be treated as a termination of such collective bargaining agreement.

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

(e) MODIFICATION OF COVERAGE.—

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

screening, or other updated medical practices regarding such screening, such as the use of new tests or other emerging technologies. Such modifications shall not in any way diminish the coverage requirements listed under this subtitle. Such modifications may be made on the Secretary's own initiative or upon petition to the Secretary by an individual or organization.

(2) CONSULTATION.—In modifying coverage requirements under paragraph (1), the Secretary of Health and Human Services shall consult with appropriate organizations, experts, and agencies.

(3) PETITIONS.—The Secretary of Health and Human Services may issue requirements for the petitioning process under paragraph (1), including requirements that the petition be in writing and include scientific or medical bases for the modification sought. Upon receipt of such a petition, the Secretary shall respond to the petitioner and decide whether to propose a regulation proposing a change within 90 days of such receipt. If a regulation is required, the Secretary shall propose such regulation within 6 months of such determination. The Secretary shall provide the petitioner the reasons for the decision of the Secretary. The Secretary may

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

Subtitle C—Physicians and Quality of Care

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

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

"SEC. 2710. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS.

''(a) MANAGING PHYSICIAN.—A group health plan, or health insurance issuer that is providing health insurance coverage, shall ensure that with respect to items or services provided under the plan or coverage relating to the treatment of cancer, a lead managing physician be designated at the time of diagnosis by the provider and paid a bonus by the plan, in consultation with the participant or beneficiary, and other providers involved to provide for the overall coordination and management of the cancer care of the participant or beneficiary among all providers who provide items or services to the participant or beneficiary and paid for overall coordination of services.

''(b) QUALITY OF CARE.—A group health plan, or health insurance issuer that is providing health insurance coverage, shall require that all participating health care professionals who provide primary care cancer services follow the most current quality-of-care cancer care guidelines, as developed by medical professionals with expertise in the field of medicine for which the guidelines are designed and widely recognized as medically necessary and appropriate.

''(c) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not—

''(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

''(2) provide monetary payments or rebates to individuals to encourage such individuals to accept less than the minimum protections available under this section;

''(3) penalize or otherwise reduce or limit the reimbursement of a provider because such provider provided care to an individual participant or beneficiary in accordance with this section; or

''(4) provide incentives (monetary or otherwise) to a provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section.

''(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits described in subsections (a) or (b) consistent with such subsections, except that such coinsurance or other cost-sharing shall not discriminate on any basis related to the coverage required under this section.

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

(b) INDIVIDUAL.—Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2755, as added by section 211, the following:

''SEC. 2756. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS.

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

visions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan.''.

SEC. 222. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

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

''SEC. 717. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS.

''(a) MANAGING PHYSICIAN.—A group health plan, or health insurance issuer that is providing health insurance coverage, shall ensure that with respect to items or services provided under the plan or coverage relating to the treatment of cancer, a lead managing physician be designated at the time of diagnosis by the participant or beneficiary involved to provide for the overall coordination and management of the cancer care of the participant or beneficiary among all providers who provide items or services to the participant or beneficiary and paid for overall coordination of services.

''(b) QUALITY OF CARE.—A group health plan, or health insurance issuer that is providing health insurance coverage, shall require that all participating health care professionals who provide primary care cancer services follow the most current quality-of-care cancer care guidelines, as developed by medical professionals with expertise in the field of medicine for which the guidelines are designed and widely recognized as medically necessary and appropriate.

''(c) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not—

''(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

''(2) provide monetary payments or rebates to individuals to encourage such individuals to accept less than the minimum protections available under this section;

''(3) penalize or otherwise reduce or limit the reimbursement of a provider because such provider provided care to an individual participant or beneficiary in accordance with this section; or

''(4) provide incentives (monetary or otherwise) to a provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section.

''(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits described in subsections (a) or (b) consistent with such subsections, except that such coinsurance or other cost-sharing shall not discriminate on any basis related to the coverage required under this section.

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

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by sections 202 and 211, is further amended by inserting after the item relating to section 716 the following new item:

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

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

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

''APPLICATION OF CANCER COVERAGE REQUIREMENTS

''SEC. 1849. The provisions of sections 2707, 2708, and 2710 of the Public Health Service Act shall apply to an individual who has been diagnosed with cancer and who is covered under the insurance program established under this part.''.

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

(1) by inserting ''(1)'' after ''(m)''; and

(2) by adding at the end the following new paragraph:

''(2) In the case of physicians' services furnished to an individual who has been diagnosed with cancer, who is covered under the insurance program established under this part who receives care for such cancer from a team of physicians, and who incurs expenses for physicians' services that are related to that diagnosis, there shall be paid to the physician designated by such team of physicians at the time of diagnosis of the individual as the physician responsible for the overall coordination and manage-

ment of the medical and other health services provided to that individual during the period in which that individual is undergoing treatment for such cancer (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund a separate and additional payment amount for the services under this part in addition to any amount otherwise paid under this part.''.

SEC. 224. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS UNDER MEDICAID AND SCHIP.

(a) MEDICAID.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(1) in paragraph (64), by striking ''and'' at the end;

(2) in paragraph (65), by striking the period and inserting ''; and''; and

(3) by inserting after paragraph (65) the following:

''(66) provide—

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

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

''(B) that, in the case of an individual who has been diagnosed with cancer, who is eligible for medical assistance under this title, and who receives care for such cancer from a team of physicians, and who incurs expenses for physicians' services that are related to that diagnosis, that there shall be paid to the physician designated by such team of physicians at the time of diagnosis of the individual as the physician responsible for the overall coordination and management of the medical and other health services provided to that individual during the period in which that individual is undergoing treatment for such cancer, a separate and additional payment amount for the services provided in addition to any amount otherwise paid under the State plan.''.

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

''(3) APPLICATION OF CANCER COVERAGE PROVISIONS.—

"(A) IN GENERAL.—The provisions of sections 2707, 2708, and 2710 of the Public Health Service Act shall apply to the coverage offered under the State child health plan.

"(B) ADDITIONAL PAYMENT.—The State child health plan shall provide in the case of an individual who has been diagnosed with cancer, who is eligible for child health assistance under this title, and who receives care for such cancer from a team of physicians, and who incurs expenses for physicians' services that are related to that diagnosis, that there shall be paid to the physician designated by such team of physicians at the time of diagnosis of the individual as the physician responsible for the overall coordination and management of the medical and other health services provided to that individual during the period in which that individual is undergoing treatment for such cancer, a separate and additional payment amount for the services provided in addition to any amount otherwise paid under the State child health plan.".

Subtitle D—General Provisions

SEC. 231. COVERAGE UNDER OTHER PUBLIC HEALTH INSURANCE.

(a) IN GENERAL.—The coverage described in subsection (b) shall be provided for any individual, participant, or beneficiary who has coverage under—

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

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

(3) the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1398 et seq.);

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

(5) programs offered by the Department of Defense;

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

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

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

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

211) for individuals participating in cancer screening activities; and

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

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

"§ 8915. Standards relating to coverage of cancer-related activities

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

''(b) Nothing in this section or section 2707, 2708, 2709, or 2710 of the Public Health Service Act shall be construed as authorizing a health insurance issuer or entity to impose cost sharing with respect to the coverage or benefits required to be provided under such sections that is inconsistent with the cost sharing that is otherwise permitted under this chapter.''.

TITLE III—TOBACCO REGULATION

SEC. 301. FINDINGS.

Congress finds the following:

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

(2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

(3) Nicotine is an addictive drug.

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

(5) Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.

(6) Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.

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

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

(9) Under article I, section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.

(10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.

(11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products.

(12) It is in the public interest to restrict throughout the Nation the sale, distribution, marketing, and advertising of tobacco products only to persons of legal age to purchase such products.

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

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

(15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.

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

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

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

(19) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

(20) Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

(21) Tobacco advertising increases the size of the tobacco market by increasing consumption of tobacco products including increasing tobacco use by young people.

(22) Children are more influenced by tobacco advertising than adults, they smoke the most advertised brands.

(23) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market.

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

(25) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

(26) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones. Text-only requirements, while not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising.

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

(28) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.

SEC. 302. PURPOSE.

The purposes of this title are—

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

(2) to ensure that the Food and Drug Administration and the States may continue to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to impose financial surcharges on tobacco product manufacturers if tobacco use by young people does not substantially decline;

(4) to authorize appropriate agencies of the Federal government to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(5) to provide new and flexible enforcement authority to ensure that the tobacco industry makes efforts to develop and introduce less harmful tobacco products;

(6) to confirm the Food and Drug Administration's authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

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

(8) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers; and

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

SEC. 303. SCOPE AND EFFECT.

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

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

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

(b) TAXATION.—Notwithstanding any other provision of law, this title and the amendments made by this title shall not affect any authority of the Secretary of the Treasury (including any authority assigned to the Bureau of Alcohol, Tobacco and Firearms) or of State or local governments with regard to taxation for tobacco or tobacco products.

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

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

(a) AGE RESTRICTIONS.—Nothing in this title or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended by this title, shall prevent a Federal agency (including the Armed Forces), a State or its political subdivisions, or the government of an Indian tribe from adopting and enforcing additional measures that further restrict or prohibit tobacco product sale to, use by, and accessibility to persons under the legal age of purchase established by such agency, State, subdivision, or government of an Indian tribe.

(b) ADDITIONAL MEASURES.—Except as otherwise expressly provided in this title, nothing in this title, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or rules promulgated under such title or Act, shall limit the authority of a Federal agency (including the Armed Forces), a State or its political subdivisions, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products, including laws, rules, regulations, or other measures relating to or prohibiting the sale, distribution, possession, exposure to, or use of tobacco products by persons of any age that are in addition to the provisions of this title and the amendments made by this title. No provision of this title or amendment made by this title shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

(c) NO LESS STRINGENT.—Nothing in this title or the amendments made by this title is intended to supersede any State, local, or Tribal law that is not less stringent than this title, or other Acts as amended by this title.

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

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

SEC. 305. DEFINITIONS.

In this title:

(1) BRAND.—The term ''brand'' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, or packaging, logo, registered trademark or brand name, identifiable pattern of colors, or any combination of such attributes.

(2) CIGARETTE.—The term ''cigarette'' has the meaning given that term by section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)), but also includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

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

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

(5) DISTRIBUTOR.—The term ''distributor'' as regards a tobacco product means any person who furthers the distribution of cigarette or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this title.

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

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

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

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

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

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

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

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

(13) ROLL-YOUR-OWN TOBACCO.—The term ''roll-your-own tobacco'' means any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to,

or purchased by, consumers as tobacco for making cigarettes.

(14) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

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

(16) STATE.—The term ''State'' means any State of the United States and, for purposes of this Act, includes the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

(17) TOBACCO PRODUCT.—The term ''tobacco product'' means cigarettes, cigarette tobacco, smokeless tobacco, little cigars, roll-your-own tobacco, and fine cut products.

(18) TOBACCO PRODUCT MANUFACTURER.—The term ''tobacco product manufacturer'' means any person, including any repacker or relabeler, who—

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

(B) imports a finished cigarette or smokeless tobacco product for sale or distribution in the United States.

(19) UNITED STATES.—The term ''United States'' means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

SEC. 306. FTC JURISDICTION NOT AFFECTED.

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

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

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

SEC. 307. CONGRESSIONAL REVIEW PROVISIONS.

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

TITLE IV—REGULATION OF THE TOBACCO INDUSTRY

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

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

''(kk) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).''.

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

(1) by redesignating chapter IX as chapter X;

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

(3) by inserting after section 803 the following:

"CHAPTER IX—TOBACCO PRODUCTS

"SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS

"(a) IN GENERAL.—Tobacco products shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V, unless—

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

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

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

"(c) SCOPE.—

''(1) Nothing in this chapter, any policy issued or regulation promulgated thereunder, or the National Tobacco Policy and Youth Smoking Reduction Act, shall be construed to affect the Secretary's authority over, or the regulation of, products under this Act that are not tobacco products under chapter V of the Federal Food, Drug and Cosmetic Act or any other chapter of that Act.

''(2) The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of the manufacturer, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority whatsoever to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer. Notwithstanding any other provision of this subparagraph, if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer. Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco

leaf or a producer thereof, other than activities by a manufacturer affecting production. For purposes of the preceding sentence, the term 'controlled by' means a member of the same controlled group of corporations as that term is used in section 52(a) of the Internal Revenue Code of 1986, or under common control within the meaning of the regulations promulgated under section 52(b) of such Code.

"SEC. 902. ADULTERATED TOBACCO PRODUCTS.

''A tobacco product shall be deemed to be adulterated if—

''(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any poisonous or deleterious substance that may render the product injurious to health;

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

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

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

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

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

''(6) the methods used in, or the facilities or controls used for, its manufacture, packing or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or

''(7) it is a tobacco product for which an exemption has been granted under section 906(f) for investigational use and the person who was granted such exemption or any investigator who uses such tobacco product under such exemption fails to comply with a requirement prescribed by or under such section.

''SEC. 903. MISBRANDED TOBACCO PRODUCTS.

''(a) IN GENERAL.—A tobacco product shall be deemed to be misbranded—

''(1) if its labeling is false or misleading in any particular;

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

''(A) the name and place of business of the tobacco product manufacturer, packer, or distributor; and

''(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count,

except that under subparagraph (B) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

''(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

''(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

''(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

''(6) if it was manufactured, prepared, propagated, compounded, or processed in any State in an establishment not duly registered under section 905(b), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;

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

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

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

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

ufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

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

''(B) a brief statement of—

''(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

''(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

''(9) if it is a tobacco product subject to a performance standard established under section 907,

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

"(10) if there was a failure or refusal—

"(A) to comply with any requirement prescribed under section 904 or 908;

"(B) to furnish any material or information required by or under section 909; or

"(C) to comply with a requirement under section 912.

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

"SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

"(a) REQUIREMENT.—Not later than 6 months after the date of enactment of the National Tobacco Policy and Youth Smoking Reduction Act, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit to the Secretary the following information:

"(1) A listing of all tobacco ingredients, substances and compounds that are, on such date, added by the manufacturer to the tobacco, paper, filter, or other component of each tobacco product by brand and by quantity in each brand and subbrand.

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

"(3) All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, behavioral, or physiologic effects of tobacco products, their constituents, ingredients, and components, and tobacco additives, described in paragraph (1).

"(4) All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or pos-

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

''(5) All documents (including underlying scientific information) relating to marketing research involving the use of tobacco products.

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

''(b) ANNUAL SUBMISSION.—A tobacco product manufacturer or importer that is required to submit information under subsection (a) shall update such information on an annual basis under a schedule determined by the Secretary.

''(c) TIME FOR SUBMISSION.—

''(1) NEW PRODUCTS.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of this chapter, the manufacturer of such product shall provide the information required under subsection (a) and such product shall be subject to the annual submission under subsection (b).

''(2) MODIFICATION OF EXISTING PRODUCTS.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive, increases or decreases the quantity of an existing tobacco additive or the nicotine content, delivery, or form, or eliminates a tobacco additive from any tobacco product, the manufacturer shall within 60 days of such action so advise the Secretary in writing and reference such modification in submissions made under subsection (b).

"SEC. 905. ANNUAL REGISTRATION.

''(a) DEFINITIONS.—As used in this section—

''(1) the term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

''(2) the term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

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

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

''(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

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

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

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

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

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

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

''(i) REGISTRATION INFORMATION.—

''(1) PRODUCT LIST.—Every person who registers with the Secretary under subsection (b), (c), or (d) of this section shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which has not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

''(A) in the case of a tobacco product contained in the applicable list with respect to which a performance standard has been estab-

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

''(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

''(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a performance standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

''(2) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each

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

"(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

"(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

"(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the to-

bacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

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

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

''(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of August 11, 1995, as defined by the Secretary by regulation shall, at least 90 days before making such introduction or delivery, report to the Secretary (in

such form and manner as the Secretary shall by regulation prescribe)—

"(A) the basis for such person's determination that the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of August 11, 1995, that is in compliance with the requirements of this Act; and

"(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

"(2) APPLICATION TO CERTAIN POST-AUGUST 11TH PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after August 11, 1995, and before the date of enactment of the National Tobacco Policy and Youth Smoking Reduction Act shall be submitted to the Secretary within 6 months after the date of enactment of that Act.

"SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

"(a) IN GENERAL.—Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, or subsection (d) of this section shall not apply to such tobacco product.

"(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking under section 907, 908, 909, or 910, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

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

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

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

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

''(d) RESTRICTIONS.—

''(1) The Secretary may by regulation require that a tobacco product be restricted to sale, distribution, or use upon such conditions, including restrictions on the access to, and the advertising and promotion of, the tobacco product, as the Secretary may prescribe in such regulation if, because of its potentiality for harmful effect or the collateral measures

necessary to its use, the Secretary determines that such regulation would be appropriate for the protection of the public health. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

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

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

No such condition may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

"(2) The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

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

face transactions by a specific category of retail outlets.

''(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

''(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

''(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a tobacco product), packing and storage of a tobacco product, conform to current good manufacturing practice, as prescribed in such regulations, to assure that the public health is protected and that the tobacco product is in compliance with this chapter.

''(B) The Secretary shall—

''(i) before promulgating any regulation under subparagraph (A), afford an advisory committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

''(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

''(iii) provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and

''(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities; and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices.

''(2) EXEMPTIONS; VARIANCES.—

''(A) Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted

to the Secretary in such form and manner as the Secretary shall prescribe and shall—

''(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter;

''(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

''(iii) contain such other information as the Secretary shall prescribe.

''(B) The Secretary may refer to an advisory committee any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it

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

"(i) the date the petition was submitted to the Secretary under subparagraph (A); or

"(ii) the day after the petition was referred to an advisory committee,

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

"(C) The Secretary may approve—

"(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this chapter; and

"(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to

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

''(D) An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.

''(E) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

''(3) Compliance with requirements under this subsection shall not be required before the period ending 3 years after the date of enactment of the National Tobacco Policy and Youth Smoking Reduction Act.

''(f) EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from this chapter under such conditions as the Secretary may prescribe by regulation.

''(g) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes without regard to section 3324(a) and (b) of title 31, United States Code, and section 5 of title 41, United States Code.

''SEC. 907. PERFORMANCE STANDARDS.

''(a) IN GENERAL.—

''(1) FINDING REQUIRED.—The Secretary may adopt performance standards for a tobacco product if the Secretary finds that a performance standard is appropriate for the protection of the public health. This finding shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

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

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

''(2) CONTENT OF PERFORMANCE STANDARDS.—A performance standard established under this section for a tobacco product—

''(A) shall include provisions to provide performance that is appropriate for the protection of the public health, including provisions, where appropriate—

''(i) for the reduction or elimination of nicotine yields of the product;

''(ii) for the reduction or elimination of other constituents or harmful components of the product; or

''(iii) relating to any other requirement under (B);

''(B) shall, where necessary to be appropriate for the protection of the public health, include—

''(i) provisions respecting the construction, components, ingredients, and properties of the tobacco product;

''(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

''(iii) provisions for the measurement of the performance characteristics of the tobacco product;

''(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

''(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d); and

''(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product.

''(3) PERIODIC RE-EVALUATION OF PERFORMANCE STANDARDS.—The Secretary shall provide for periodic evaluation of performance standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary

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

''(4) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall, to the maximum extent practicable—

''(A) use personnel, facilities, and other technical support available in other Federal agencies;

''(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities; and

''(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in the Secretary's judgment can make a significant contribution.

''(b) ESTABLISHMENT OF STANDARDS.—

''(1) NOTICE.—

(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or

revocation of any performance standard for a tobacco product.

''(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a tobacco product shall—

''(i) set forth a finding with supporting justification that the performance standard is appropriate for the protection of the public health;

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

''(iii) invite interested persons to submit an existing performance standard for the tobacco product, including a draft or proposed performance standard, for consideration by the Secretary.

''(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to be appropriate for the protection of the public health.

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

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

''(2) PROMULGATION.—

''(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee, the Secretary shall—

''(i) promulgate a regulation establishing a performance standard and pub-

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

"(ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

"(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.

"(3) SPECIAL RULE FOR STANDARD BANNING CLASS OF PRODUCT OR ELIMINATING NICOTINE CONTENT.—Because of the importance of a decision of the Secretary to issue a regulation establishing a performance standard—

"(A) eliminating all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or

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

it is appropriate for the Congress to have the opportunity to review such a decision. Therefore, any such standard may not take effect before a date that is 2 years after the President notifies the Congress that a final regulation imposing the restriction has been issued.

"(4) AMENDMENT; REVOCATION.—

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

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

''(5) REFERENCE TO ADVISORY COMMITTEE.—The Secretary—

''(A) may, on the Secretary's own initiative, refer a proposed regulation for the establishment, amendment, or revocation of a performance standard; or

''(B) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation,

refer such proposed regulation to an advisory committee, for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to the advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within 60 days after the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the

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

"SEC. 908. NOTIFICATION AND OTHER REMEDIES.

"(a) NOTIFICATION.—If the Secretary determines that—

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

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

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

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

''(c) RECALL AUTHORITY.—

''(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary de-

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

''(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

''(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(B) An amended order under subparagraph (A)—

''(i) shall not include recall of a tobacco product from individuals; and

''(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

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

ers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

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

''SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

''(a) IN GENERAL.—Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence—

''(1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the fre-

quency of a serious, expected adverse product experience;

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

''(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

''(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

''(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

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

information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

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

''(b) REPORTS OF REMOVALS AND CORRECTIONS.—

(1) Except as provided in paragraph (3), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—

''(A) to reduce a risk to health posed by the tobacco product; or

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

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

''(2) No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a) of this section.

''SEC. 910. PREMARKET REVIEW OF CERTAIN TOBACCO PRODUCTS.

''(a) IN GENERAL.—

''(1) PREMARKET APPROVAL REQUIRED.—Approval under this section of an application for premarket approval for any tobacco product that is not commercially marketed (other than for test marketing) in the United States as of the date of introduction of the National Cancer Act of 2002, such approval, is required unless the manufacturer has submitted a report under section 905(j), and the Secretary has issued an order that the tobacco prod-

uct is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of the date of introduction of the National Cancer Act of 2002, that is in compliance with the requirements of this Act.

''(2) SUBSTANTIALLY EQUIVALENT DEFINED.—

''(A) For purposes of this section and section 905(j), the term 'substantially equivalent' or 'substantial equivalence' mean, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

''(i) has the same characteristics as the predicate tobacco product; or

''(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

''(B) For purposes of subparagraph (A), the term 'characteristics' means the materials,

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

''(C) A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

''(3) HEALTH INFORMATION.—

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

''(B) Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

''(b) APPLICATION.—

''(1) CONTENTS.—An application for premarket approval shall contain—

''(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

''(B) a full statement of the components, ingredients, and properties, and of the principle or principles of operation, of such tobacco product;

''(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

''(D) an identifying reference to any performance standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such performance standard or

adequate information to justify any deviation from such standard;

"(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

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

"(G) such other information relevant to the subject matter of the application as the Secretary may require.

"(2) REFERENCE TO ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

"(A) may, on the Secretary's own initiative; or

"(B) shall, upon the request of an applicant,

refer such application to an advisory committee and for submission (within such period as the Secretary may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

"(c) ACTION ON APPLICATION.—

"(1) DEADLINE.—

"(A) As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b) of this section, the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

"(i) issue an order approving the application if the Secretary finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

"(ii) deny approval of the application if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

"(B) An order approving an application for a tobacco product may require as a condition to such approval that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d).

''(2) DENIAL OF APPROVAL.—The Secretary shall deny approval of an application for a tobacco product if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

''(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

''(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

''(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

''(D) such tobacco product is not shown to conform in all respects to a performance standard in effect under section 907, compliance with which is a condition to approval of the application, and there is a lack of adequate information to justify the deviation from such standard.

''(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

''(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether approval of a tobacco product is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

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

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

''(5) BASIS FOR ACTION.—

''(A) For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protec-

tion of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include one or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

''(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

''(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

''(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from an advisory committee, and after due notice and opportunity for informal hearing to the holder of an approved application for a tobacco product, issue an order withdrawing approval of the application if the Secretary finds—

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

''(B) that the application contained or was accompanied by an untrue statement of a material fact;

''(C) that the applicant—

''(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;

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

''(iii) has not complied with the requirements of section 905;

''(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a

reasonable time after receipt of written notice from the Secretary of nonconformity;

''(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

''(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that such tobacco product is not shown to conform in all respects to a performance standard which is in effect under section 907, compliance with which was a condition to approval of the application, and that there is a lack of adequate information to justify the deviation from such standard.

''(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date

upon which he receives notice of such withdrawal, obtain review thereof in accordance with subsection (e) of this section.

''(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an approved application would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

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

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

''(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

"SEC. 911. JUDICIAL REVIEW.

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

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

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

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based the Secretary's regulation or order and each record or order shall contain a statement of the reasons for its issuance and the basis, on the record, for its issuance. For purposes of this section, the term 'record' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and

any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

''(b) COURT MAY ORDER SECRETARY TO MAKE ADDITIONAL FINDINGS.—If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify the Secretary's findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and the Secretary's recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

''(c) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have juris-

diction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation or order described in paragraph (1) or (2) of subsection (a) of this section shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

''(d) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

''(e) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

''(f) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 906, 907, 908, 909, 910, or 914, each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

"SEC. 912. POSTMARKET SURVEILLANCE

"(a) DISCRETIONARY SURVEILLANCE.—The Secretary may require a tobacco product manufacturer to conduct postmarket surveillance for a tobacco product of the manufacturer if the Secretary determines that postmarket surveillance of the tobacco product is necessary to protect the public health or is necessary to provide information regarding the health risks and other safety issues involving the tobacco product.

"(b) SURVEILLANCE APPROVAL.—Each tobacco product manufacturer required to conduct a surveillance of a tobacco product under subsection (a) of this section shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of useful data or other information necessary to protect the public health. The Secretary may not approve such a protocol until it has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.

"SEC. 913. REDUCED RISK TOBACCO PRODUCTS.

''(a) REQUIREMENTS.—

''(1) IN GENERAL.—For purposes of this section, the term 'reduced risk tobacco product' means a tobacco product designated by the Secretary under paragraph (2).

''(2) DESIGNATION.—

''(A) IN GENERAL.—A product may be designated by the Secretary as a reduced risk tobacco product if the Secretary finds that the product will significantly reduce harm to individuals caused by a tobacco product and is otherwise appropriate to protect public health, based on an application submitted by the manufacturer of the product (or other responsible person) that—

''(i) demonstrates through testing on animals and short-term human testing that use of such product results in ingestion or inhalation of a substantially lower yield of toxic substances than use of conventional tobacco products in the same category as the proposed reduced risk product; and

''(ii) if required by the Secretary, includes studies of the long-term health effects of the product.

If such studies are required, the manufacturer may consult with the Secretary regarding protocols for conducting the studies.

"(B) BASIS FOR FINDING.—In making the finding under subparagraph (A), the Secretary shall take into account—

"(i) the risks and benefits to the population as a whole, including both users of tobacco products and non-users of tobacco products;

"(ii) the increased or decreased likelihood that existing users of tobacco products will stop using such products including reduced risk tobacco products;

"(iii) the increased or decreased likelihood that those who do not use tobacco products will start to use such products, including reduced risk tobacco products; and

"(iv) the risks and benefits to consumers from the use of a reduced risk tobacco product as compared to the use of products approved under chapter V to reduce exposure to tobacco.

''(3) MARKETING REQUIREMENTS.—A tobacco product may be marketed and labeled as a reduced risk tobacco product if it—

''(A) has been designated as a reduced risk tobacco product by the Secretary under paragraph (2);

''(B) bears a label prescribed by the Secretary concerning the product's contribution to reducing harm to health; and

''(C) complies with requirements prescribed by the Secretary relating to marketing and advertising of the product, and other provisions of this chapter as prescribed by the Secretary.

''(b) REVOCATION OF DESIGNATION.—At any time after the date on which a tobacco product is designated as a reduced risk tobacco product under this section the Secretary may, after providing an opportunity for an informal hearing, revoke such designation if the Secretary determines, based on information not available at the time of the designation, that—

''(1) the finding made under subsection (a)(2) is no longer valid; or

''(2) the product is being marketed in violation of subsection (a)(3).

''(c) LIMITATION.—A tobacco product that is designated as a reduced risk tobacco product that is in compliance with subsection (a) shall not be regulated as a drug or device.

''(d) DEVELOPMENT OF REDUCED RISK TOBACCO PRODUCT TECHNOLOGY.—A tobacco product manufacturer shall provide written notice to the Secretary upon the development or acquisition by the manufacturer of any technology that would reduce the risk of a tobacco product to the health of the user for which the manufacturer is not seeking designation as a 'reduced risk tobacco product' under subsection (a).

"SEC. 914. PRESERVATION OF STATE AND LOCAL AUTHORITY.

''(a) ADDITIONAL REQUIREMENTS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), nothing in this Act shall be construed as prohibiting a State or political subdivision thereof from adopting or enforcing a requirement applicable to a tobacco product that is in addition to, or more stringent than, requirements established under this chapter.

''(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

''(A) Except as provided in subparagraph (B), no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement applicable under the provisions of this chapter relating to performance standards, premarket approval, adulteration, misbranding, registration, reporting, good manufacturing standards, or reduced risk products.

''(B) Subparagraph (A) does not apply to requirements relating to the sale, use, or distribution of a tobacco product including requirements related to the access to, and the advertising and promotion of, a tobacco product.

''(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''(c) WAIVERS.—Upon the application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and an opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a require-

ment of such State or political subdivision applicable to a tobacco product if—

''(1) the requirement is more stringent than a requirement applicable under the provisions described in subsection (a)(3) which would be applicable to the tobacco product if an exemption were not in effect under this subsection; or

''(2) the requirement—

''(A) is required by compelling local conditions; and

''(B) compliance with the requirement would not cause the tobacco product to be in violation of any applicable requirement of this chapter.

''SEC. 915. EQUAL TREATMENT OF RETAIL OUTLETS.

''The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.''.

SEC. 402. CONFORMING AND OTHER AMENDMENTS TO GENERAL PROVISIONS.

(a) AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise expressly provided, whenever in this section an amendment is expressed in

terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended—

(1) by inserting ''tobacco product,'' in subsection (a) after ''device,'';

(2) by inserting ''tobacco product,'' in subsection (b) after ''device,'';

(3) by inserting ''tobacco product,'' in subsection (c) after ''device,'';

(4) by striking ''515(f), or 519'' in subsection (e) and inserting ''515(f), 519, or 909'';

(5) by inserting ''tobacco product,'' in subsection (g) after ''device,'';

(6) by inserting ''tobacco product,'' in subsection (h) after ''device,'';

(7) by striking ''708, or 721'' in subsection (j) and inserting ''708, 721, 904, 905, 906, 907, 908, or 909'';

(8) by inserting ''tobacco product,'' in subsection (k) after ''device,'';

(9) by striking subsection (p) and inserting the following:

''(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(J)(2).'';

(10) by striking subsection (q)(1) and inserting the following:

''(q)(1) The failure or refusal—

''(A) to comply with any requirement prescribed under section 518, 520(g), 906(f), or 908;

''(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 906(f), or 909; or

''(C) to comply with a requirement under section 522 or 912.'';

(11) by striking ''device,'' in subsection (q)(2) and inserting ''device or tobacco product,'';

(12) by inserting ''or tobacco product'' in subsection (r) after ''device'' each time that it appears; and

(13) by adding at the end thereof the following:

''(aa) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).''.

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

(1) by amending the caption to read as follows: ''(f) CIVIL PENALTIES; NO-TOBACCO-SALE ORDERS.—'';

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

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

''(3) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1).'';

(4) by striking ''assessed'' the first time it appears in subparagraph (A) of paragraph (4), as redesignated, and inserting ''assessed, or a no-tobacco-sale order may be imposed,'';

(5) by striking ''penalty'' in such subparagraph and inserting ''penalty, or upon whom a no-tobacco-order is to be imposed,'';

(6) by inserting after ''penalty,'' in subparagraph (B) of paragraph (4), as redesignated, the following: ''or the period to be covered by a no-tobacco-sale order,'';

(7) by adding at the end of such subparagraph the following: ''A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.'';

(8) by adding at the end of paragraph (4), as redesignated, the following:

''(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.'';

(9) by striking ''(3)(A)'' in paragraph (5), as redesignated, and inserting ''(4)(A)'';

(10) by inserting ''or the imposition of a no-tobacco-sale order'' after ''penalty'' the first 2 places it appears in such paragraph;

(11) by striking ''issued.'' in such paragraph and inserting ''issued, or on which the no-tobacco-sale order was imposed, as the case may be.''; and

(12) by striking ''paragraph (4)'' each place it appears in paragraph (6), as redesignated, and inserting ''paragraph (5)''.

(d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) by striking ''and'' before ''(D)'' in subsection (a)(2);

(2) by striking ''device.'' in subsection (a)(2) and inserting a comma and ''(E) Any adulterated or misbranded tobacco product.'';

(3) by inserting ''tobacco product,'' in subsection (d)(1) after ''device,'';

(4) by inserting ''or tobacco product'' in subsection (g)(1) after ''device'' each place it appears; and

(5) by inserting ''or tobacco product'' in subsection (g)(2)(A) after ''device'' each place it appears.

(e) SECTION 702.—Section 702(a) (21 U.S.C. 372(a)) is amended—

(1) by inserting ''(1)'' after ''(a)''; and

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

''(2) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance

with paragraph (1) to carry out inspections of retailers in connection with the enforcement of this Act.''.

(f) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by inserting ''tobacco product,'' after ''device,'' each place it appears; and

(2) by inserting ''tobacco products,'' after ''devices,'' each place it appears.

(g) SECTION 704.—Section 704 (21 U.S.C. 374) is amended—

(1) by inserting ''tobacco products,'' in subsection (a)(1)(A) after ''devices,'' each place it appears;

(2) by inserting ''or tobacco products'' in subsection (a)(1)(B) after ''restricted devices'' each place it appears; and

(3) by inserting ''tobacco product,'' in subsection (b) after ''device,''.

(h) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting ''tobacco products,'' after ''devices,''.

(i) SECTION 709.—Section 709 (21 U.S.C. 379) is amended by inserting ''or tobacco product'' after ''device''.

(j) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—

(1) by inserting ''tobacco products,'' after ''devices,'' in subsection (a) the first time it appears;

(2) by inserting ''or subsection (j) of section 905'' in subsection (a) after ''section 510'';

(3) by striking ''drugs or devices'' each time it appears in subsection (a) and inserting ''drugs, devices, or tobacco products'';

(4) by inserting ''tobacco product,'' in subsection (e)(1) after ''device,''; and

(5) by redesignating paragraph (4) of subsection (e) as paragraph (5) and inserting after paragraph (3), the following:

''(4) Paragraph (1) does not apply to any tobacco product—

''(A) which does not comply with an applicable requirement of section 907 or 910; or

''(B) which under section 906(f) is exempt from either such section.

This paragraph does not apply if the Secretary has determined that the exportation of the tobacco product is not contrary to the public health and safety and has the approval of the country to which it is intended for export or the tobacco product is eligible for export under section 802.''.

(k) SECTION 802.—Section 802 (21 U.S.C. 382) is amended—

(1) by striking ''device—'' in subsection (a) and inserting ''device or tobacco product—'';

(2) by striking ''and'' after the semicolon in subsection (a)(1)(C);

(3) by striking subparagraph (C) of subsection (a)(2) and all that follows in that subsection and inserting the following:

''(C) is a banned device under section 516; or

''(3) which, in the case of a tobacco product—

''(A) does not comply with an applicable requirement of section 907 or 910; or

''(B) under section 906(f) is exempt from either such section,

is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug, device, or tobacco product is, except as provided in subsection (f), authorized under subsection (b), (c), (d), or (e) of this section or section 801(e)(2) or 801(e)(4). If a drug, device, or tobacco product described in paragraph (1), (2), or (3) may be exported under subsection (b) and if an application for such drug or device under section 505, 515, or 910

of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262) was disapproved, the Secretary shall notify the appropriate public health official of the country to which such drug, device, or tobacco product will be exported of such disapproval.'';

(4) by inserting ''or tobacco product'' in subsection (b)(1)(A) after ''device'' each time it appears;

(5) by inserting ''or tobacco product'' in subsection (c) after ''device'' and inserting ''or section 906(f)'' after ''520(g).'';

(6) by inserting ''or tobacco product'' in subsection (f) after ''device'' each time it appears; and

(7) by inserting ''or tobacco product'' in subsection (g) after ''device'' each time it appears.

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

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

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

(m) EFFECTIVE DATE FOR NO-TOBACCO-SALE ORDER AMENDMENTS.—The amendments made by subsection (c), other than the amendment made by paragraph (2) thereof, shall take effect only upon the promulgation of final regulations by the Secretary—

(1) defining the term ''repeated violation'', as used in section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) as amended by subsection (c), by identifying the number of violations of particular requirements over a specified period of time that constitute a repeated violation;

(2) providing for notice to the retailer of each violation at a particular retail outlet;

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

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

(5) providing that good faith reliance on false identification does not constitute a violation of any minimum age requirement for the sale of tobacco products.

SEC. 403. FDA RULE IN EFFECT.

The final regulations promulgated by the Secretary in the August 28, 1996, issue of the Federal Register (62 Fed. Reg. 44615–44618) and codified at part 897 of title

21, Code of Federal Regulations, are hereby deemed to be lawful and to have been lawfully promulgated by the Secretary under chapter IX and section 701 of the Federal Food, Drug, and Cosmetic Act, as amended by this title, and not under chapter V of the Federal Food, Drug, and Cosmetic Act. Such regulations shall apply to all tobacco products and shall take effect upon such date as the Secretary determines by order, not later than 12 months after enactment of this title. The Secretary shall amend the designation of authority in such regulations in accordance with this subsection.

TITLE V—TOBACCO PRODUCT WARNINGS AND SMOKE CONSTITUENT DISCLOSURE

Subtitle A—Product Warnings, Labeling, and Packaging

SEC. 501. CIGARETTE LABEL AND ADVERTISING WARNINGS.

(a) IN GENERAL.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"SEC. 4. LABELING.

"(a) LABEL REQUIREMENTS.—

"(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any ciga-

rettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

''WARNING: Cigarettes are addictive''

''WARNING: Tobacco smoke can harm your children''

''WARNING: Cigarettes cause fatal lung disease''

''WARNING: Cigarettes cause cancer''

''WARNING: Cigarettes cause strokes and heart disease''

''WARNING: Smoking during pregnancy can harm your baby''

''WARNING: Smoking can kill you''

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

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

''(2) PLACEMENT; TYPOGRAPHY; ETC.—

''(A) IN GENERAL.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Except as provided in subparagraph (B), each label statement shall comprise at least the top

25 percent of the front and rear panels of the package. The word ''WARNING'' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(4).

''(B) FLIP-TOP BOXES.—For any cigarette brand package manufactured or distributed before January 1, 2000, which employs a flip-top style (if such packaging was used for that brand in commerce prior to June 21, 1997), the label statement required by paragraph (1) shall be located on the flip-top area of the package, even if such area is less than 25 percent of the area of the front panel. Except as provided in

this paragraph, the provisions of this subsection shall apply to such packages.

''(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a) of this section.

''(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) of this section in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and

location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word ''WARNING'' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under paragraph (4) of this subsection. The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital ''W'' of the word ''WARNING'' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20

centimeter by 2 column advertisement. The label statements shall be in English, except that in the case of—

"(A) an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

"(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

"(3) ADJUSTMENT BY SECRETARY.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section or the text, format, and type sizes of any required tar, nicotine yield, or other constituent disclosures, or to establish the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et. seq.). The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2) of this subsection. The Secretary

shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

''(4) MARKETING REQUIREMENTS.—

''(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraph (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.''.

(b) REPEAL OF PROHIBITION ON STATE RESTRICTION.—Section 5 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334) is amended—

(1) by striking ''(a) ADDITIONAL STATEMENTS.—'' in subsection (a); and

(2) by striking subsection (b).

SEC. 502. AUTHORITY TO REVISE CIGARETTE WARNING LABEL STATEMENTS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 301 of this title, is further amended by adding at the end the following:

''(c) CHANGE IN REQUIRED STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the warning label statements required by subsection (a) of this section, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.''.

SEC. 503. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

''SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

''WARNING: This product can cause mouth cancer''

''WARNING: This product can cause gum disease and tooth loss''

''WARNING: This product is not a safe alternative to cigarettes''

''WARNING: Smokeless tobacco is addictive''

''(2) Each label statement required by paragraph (1) shall be—

''(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 25 percent of each such display panel; and

''(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

''(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

''(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(b) REQUIRED LABELS.—

''(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required

statement relating to tar, nicotine, or other constituent yield shall—

"(A) comprise at least 20 percent of the area of the advertisement, and the warning area shall be delineated by a dividing line of contrasting color from the advertisement; and

"(B) the word "WARNING" shall appear in capital letters and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

"(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

"(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of

smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraph (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.''.

SEC. 504. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT WARNING LABEL STATEMENTS.

Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by section 303 of this title, is further amended by adding at the end the following:

''(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the warning label statements required by subsection (a) of this section, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.''.

SEC. 505. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.

Section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333 (a)), as amended by section 301 of this title, is further amended by adding at the end the following:

''(4)(A) The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the ad-

vertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

''(B) Any differences between the requirements established by the Secretary under subparagraph (A) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

''(C) In addition to the disclosures required by subparagraph (A) of this paragraph, the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette

package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).''.

Subtitle B—Testing and Reporting of Tobacco Product Smoke Constituents

SEC. 511. REGULATION REQUIREMENT.

(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 24 months after the date of enactment of this title, the Secretary, through the Commissioner of the Food and Drug Administration, shall promulgate regulations under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that meet the requirements of subsection (b).

(b) CONTENTS OF RULES.—The rules promulgated under subsection (a) of this section shall require the testing, reporting, and disclosure of tobacco product smoke constituents and ingredients that the Secretary determines should be disclosed to the public in order to protect the public health. Such constituents shall include tar, nicotine, carbon monoxide, and such other smoke constituents or ingredients as the Secretary may determine to be appro-

priate. The rule may require that tobacco product manufacturers, packagers, or importers make such disclosures relating to tar and nicotine through labels or advertising, and make such disclosures regarding other smoke constituents or ingredients as the Secretary determines are necessary to protect the public health.

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

SEC. 512. FDA AMENDMENT.

Section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)) is amended by inserting ''or targets and mechanisms of pathogenesis of diseases'' after ''disease or condition''.

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