110TH CONGRESS
1ST SESSION

S. 1056

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

IN THE SENATE OF THE UNITED STATES

MARCH 29, 2007

Mrs. FEINSTEIN (for herself and Mr. BROWNBACK) 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 early detection of, 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 2007''.

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

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Cancer killed 6,700,000 people around the world in 2002 and this figure is expected to rise to 10,100,000 in 2020.

(2) In 2007, an estimated 1,444,920 new cancer cases will be diagnosed in the United States. More than 1,000,000 cases of skin cancer are also

expected to be diagnosed this year. Cancer accounts for one in every four deaths, and about 559,650 Americans are expected to die from cancer this year. Approximately 40 percent of all Americans in the United States will be diagnosed with cancer at some point in their lives, 1 of every 2 men and 1 of every 3 women.

(3) The National Institutes of Health estimated the overall cost of cancer for 2006 at $206,300,000,000.

(4) Cancer can strike at any age, but it remains largely a disease of aging. As the American population ages, the number of cancer cases will rise. It is estimated that between 2000 and 2010, the number of cancer diagnoses will increase by 20 percent based on this change in population dynamics and no change in cancer risk. With such increases in the incidence of cancer, not only will costs continue to grow, but there will be a serious shortage of individuals in the workforce to provide cancer care, particularly in long-term care settings.

(5) 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 biol-

ogy and advances in technology have created unprecedented opportunities for understanding cancer and the role of genetics, environmental risk factors, and lifestyle factors in relation to cancer.

(6) Since 1971, mortality rates for some cancers have decreased, while such rates for other cancers remain high. The United States has seen the number of cancer deaths drop for 2 consecutive years, despite an older and larger population. This success is largely due to reductions in smoking prevalence over the past several decades, improvements in cancer screening rates, and the use of increasingly effective treatment regimens.

(7) Since 1971, the United States population has become increasingly diverse and cancer affects various minority, socioeconomic, and ethnic groups disproportionately. For example, in 2003, the death rate from cancer among African American males was 35 percent higher than that among white males and for African American females, it was 18 percent higher than white females.

(8) The quality of cancer care is uneven across the Nation. Many cancer patients do not receive optimal care.

(9) Cancer is the chief cause of death by disease in children between the ages of 1 and 14. Each year, 14,000 children and adolescents are diagnosed with cancer. However, while nearly every childhood cancer diagnosis 20 years ago was fatal, today approximately 80 percent of children diagnosed with cancer survive at least 5 years.

(10) Survivors of childhood cancer are 5 times more likely to suffer moderate to severe health problems in adulthood than their healthy siblings.

(11) Adolescents and young adults diagnosed with cancer between ages 15 and 39 have seen little or no improvement in cancer survival rates in decades and are the least represented population in clinical trials. Survivors in this age range are at risk for many long-term adverse treatments effects such as second primary cancers, heart failure, hearing loss, and cognitive dysfunction.

(12) Cancers that can be prevented or detected earlier by screening account for at least half of all new cancer cases. Screening can detect cancers of the breast, colon, rectum, cervix, prostate, oral cavity and skin at early stages, resulting in a 5-year survival rate of about 86 percent, a reflection of real reductions in mortality as well as earlier diagnosis

because of screening. Cancer screening rates vary by cancer site, population group, and health insurance coverage.

(13) Approximately 10,500,000 cancer survivors are living in the United States. These survivors may experience physical, psychological, social and economic effects as a result of cancer and its treatment.

(14) About 76 percent of all cancers are diagnosed at age 55 and older, and 6 of every 10 cancer diagnoses are at age 65 and above. Medicare plays a critical role in providing cancer care for many Americans.

(15) Scientific advances in cancer treatment since 1971 have helped shift cancer care, such as the administration of chemotherapy, increasingly from inpatient to outpatient settings.

(16) Clinical trials are a critical resource for the discovery of new prevention, diagnostic, and treatment methods for cancer. However, only 3 to 5 percent of the nearly 1,400,000 adult cancer patients each year participate in cancer clinical trials, contrasted with the 60 percent participation rate of children with cancer.

(17) New translational research centers focused on cancer are needed to provide the preclinical and early clinical trial support required to advance scientific discoveries into new drugs and technologies to prevent, detect, treat, and diagnose cancer.

(18) The number of medical researchers is declining, a decrease which will negatively affect the prevention, detection, and treatment of cancer.

(19) Since 1971, the conduct of research has involved more collaboration between public and private sectors and more multidisciplinary approaches. The biotechnology pharmaceutical and device industries have grown and provided a broad array of prevention, detection, and treatment approaches and scientific opportunities for cancer patients, providers, and researchers.

(20) In May 2001, Gleevec, the first in what is expected to be a number of targeted cancer treatments, was approved for use by the Food and Drug Administration. It appeared to be effective in stopping the growth of deadly Chronic Myeloid Leukemia cells within 3 months of use. In 2002, Gleevec showed ability to stop growth of gastrointestinal stromal tumors. Trials have now demonstrated that

89 percent of CML patients taking Gleevec are alive 5 years after diagnosis.

(21) Other targeted cancer therapies, such as Avastin, Tarceva, and Herceptin are emerging as promising cancer treatments.

(22) In 2006, the Food and Drug Administration approved the first vaccine to prevent the two strains of Human Papillomavirus (HPV) responsible for 70 percent of cervical cancer cases.

(23) Tobacco use is the leading preventable cause of disease and premature death in the United States, resulting in approximately 1/3 of all cancer deaths, including 87 percent of lung cancer deaths. Smoking alone causes more than $167,000,000 in annual health related costs.

(24) The development of molecular technology and chemopreventative agents to attack precancerous cells before they develop into tumors is a promising way to reduce cancer incidence and death rates.

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

SEC. 101. SENSE OF THE SENATE CONCERNING INVESTMENTS IN CANCER RESEARCH FUNDING.

It is the sense of the Senate that—

(1) past investments in cancer research have resulted in better health, an improved quality of life, and new discoveries; and

(2) to build on, and sustain, the progress made between 1998 and 2003 during which Congress doubled the budget at the National Institutes of Health, the National Cancer Institute requires continued Federal investment, as outlined in the National Cancer Institute Directors Bypass Budget: The Nation's Investment in Cancer, to achieve a balanced research portfolio and to develop more targeted, more effective therapies or drugs and other cancer treatments and to address those rare, deadly cancers lacking effective early detection tests or treatments for a wide range of cancers, commensurable with the National Cancer Institute bypass budget.

SEC. 102. SENSE OF THE SENATE CONCERNING INVESTMENTS IN CANCER RESEARCH TO DEVELOP TARGETED DRUGS.

(a) FINDINGS.—The Senate finds that—

(1) all cells have molecular signatures, unique identifiable characteristics related to a cells' function in the body;

(2) as a normal cell becomes malignant, its signature changes and this change becomes a signal of the presence of cancer; and

(3) with new technologies, scientists are reading cancer-associated signatures and using this information to devise treatments that target specific cells.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that to build on the research currently conducted by the National Institutes of Health, continued funding is necessary to further develop this new generation of low toxicity, high efficacy agents which target only the cancer cells leaving in place the healthy cells.

SEC. 103. EXPANSION OF CANCER-RELATED RESEARCH, PREVENTION, DETECTION, TREATMENT, AND SURVIVORSHIP 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. 417E. STUDY AND STRATEGIC PLANS.

''(a) IN GENERAL.—Not later than 6 months after the date of enactment of the National Cancer Act of 2007, the Institute shall prepare a progress report on the goal of reducing death and suffering from cancer in the next 10 years, that identifies unmet needs, recommends progress goals and benchmarks, recommends programmatic restructuring, and recommends a level of funding necessary in the following areas:

''(1) Understanding the causes of cancer.

''(2) Research regarding cancer prevention.

''(3) Improving early detection and diagnosis of cancer.

''(4) Developing effective and efficient cancer treatments.

''(5) Understanding the factors that influence patient outcomes.

''(6) Improving the quality of cancer care.

''(7) Research regarding the quality of life for cancer patients and survivors.

''(8) Overcoming cancer health disparities.

''(b) DETAILED REPORT.—The Institute shall include in future reports to Congress an accounting for the manner in which Congressional funding for cancer activities described in subsection (a) was used during the 5-fiscal year period preceding the date of enactment of the National Cancer Act of 2007, that includes a detailed description of the type of cancer and the treatment, device, tool, or discovery that was procured and the estimated number of individuals with cancer who benefitted from such activities.

''(c) PRIORITIES.—Not later than 6 months after the date of enactment of the National Cancer Act of 2007, the Institute shall determine priorities based on scientific opportunities, in consultation with medical, scientific, patient, and provider representatives, and prepare 1 or more strategic plans.

''SEC. 417E–1. GRANTS FOR DEVELOPMENT OF TARGETED DRUGS.

''(a) IN GENERAL.—The Director of the Institute shall carry out a research grant program to provide funding to projects that seek to develop cancer treatments that target cancer cells.

''(b) DUTIES OF DIRECTOR.—In carrying out the program under subsection (a), the Director of the Institute shall—

''(1) award grants and facilitate the process to award grants to public or nonprofit private entities to conduct research to develop a molecularly-oriented, knowledge-based approach to cancer drug discovery and development; and

''(2) not later than 6 months after the date of enactment of the National Cancer Act of 2007, develop and implement a strategic plan for intensifying and expanding research conducted to increase the number of cancer treatments available that are low toxicity, high efficacy agents, and in particular, research to develop treatments that selectively target malignant or cancerous cells.

''(c) LIMITATIONS.—Amounts awarded under grants under this section shall not be used for the construction of facilities.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2008 through 2011.

"SEC. 417E–2. CLINICAL TRIALS.

''(a) IN GENERAL.—For the purpose of enhancing patient access to clinical trials and investigational therapies for the treatment or prevention of cancer, the National Cancer Institute shall establish an education program that provides patients and providers with—

''(1) information about how to access and use the National Cancer Institute clinical trials database online;

''(2) information about the Food and Drug Administration process for approving the use of drugs and biologics for a single patient;

''(3) information targeted to populations of age and cultural demographics that are frequently underrepresented in clinical trials; and

''(4) recommendations regarding logistical support and sources of funding for patients support costs.

''(b) INFORMATION DISSEMINATION.—In carrying out such information dissemination described under this section, the Director of the Institute 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.

''(c) DIVERSITY ASSURANCE.—The Director of the Institute 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.

''(d) SENSE OF THE SENATE ON A CENTRAL INSTITUTIONAL REVIEW BOARD.—It is the sense of the Senate that—

''(1) the current procedure of sending 1 clinical trial through multiple local institutional review boards may not be the most efficient method for the protection of patients enrolled in the trial and may delay the process of bringing lifesaving treatment to cancer patients;

''(2) the National Cancer Institute should be commended for its work in centralizing the institutional review board process and should continue to recommend and support meaningful reform of the existing Central Institutional Review Board Initiative; and

''(3) the research community should continue to streamline the institutional review board process in order to bring lifesaving treatments to patients as quickly as possible.

"SEC. 417E–3. CANCER CARE RESEARCHERS.

''(a) SUPPLY OF CANCER RESEARCHERS.—In order to ensure a sufficient number of researchers who are trained in the prevention, early detection, diagnosis, cure, and treatment of cancer in future fiscal years, the Director of the Institute, in coordination with the Secretary of Veterans Affairs and the National Institute of Nursing Research, shall conduct a study as described in section 417E–4 for the purpose of recommending activities to promote training and education for health care professionals and institutions supporting cancer research.

''(b) LOAN REPAYMENT.—

''(1) IN GENERAL.—The Director of the Institute shall establish a program of entering into contracts with qualified health professionals under which such health professionals agree to engage in cancer prevention research in consideration of the Federal Government agreeing to repay, for each year of engaging in such research, not more than $35,000 of the principal and interest of the educational loans of such health professionals.

''(2) SERVICE PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with paragraph (1), apply to the program established in such paragraph to the same extent and in the same manner as such provisions apply to

the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2008 through 2011.

''SEC. 417E–4. CANCER CARE WORKFORCE.

''(a) IN GENERAL.—

''(1) STUDY.—The Secretary shall conduct a study on the current and future cancer care workforce needs in the following areas:

''(A) Cancer research.

''(B) Care and treatment of cancer patients and survivors.

''(C) Quality of life, symptom management, and pain management.

''(D) Early detection and diagnosis.

''(E) Cancer prevention.

''(F) Genetic testing, counseling, and ethical considerations related to such testing.

''(G) Diversity and appropriate care for disparity populations.

''(H) Palliative and end-of-life care.

''(2) REPORT.—Not later than 1 year after the date of enactment of the National Cancer Act of 2007, the Secretary shall submit to Congress a report that describes the findings of the study conducted under subsection (a).

''(b) PROGRAM.—

''(1) ESTABLISHMENT.—The Secretary shall issue programmatic recommendations and establish a program to carry out activities based on the results of the study conducted under subsection (a).

''(2) RECOMMENDATIONS.—The programmatic recommendations described in paragraph (1) shall—

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

''(B) prepare and implement a plan to assist to cancer healthcare professions with the most severe shortages, under which awards will be made under this section to eligible individuals to increase cancer care workforce training for individuals to become cancer care providers, which may include such individuals who make a commitment to serve in underserved communities or areas with disproportionately high cancer incidence or mortality and for health profes-

sions for which there are anticipated shortages; and

"(C) be coordinated with existing programs to prevent duplication.

"(c) ELIGIBILITY.—To be eligible to receive assistance 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 obtain a certificate, license, or postsecondary degree as the Secretary provides in the report under subsection (a), 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.—The use of funds by a recipient of assistance under this section shall be deemed by the Secretary and reported to Congress not later than 1 year after the issuance of the report under subsection (a).

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary in each year for each of fiscal years 2008 through and 2011.

"SEC. 417F–5. CANCER SURVIVORSHIP.

''(a) IN GENERAL.—The Secretary, acting through the Director of the National Cancer Institute, shall conduct a study of the unique health challenges associated with cancer survivorship and carry out projects and interventions to improve the long-term health status of cancer survivors. Such projects shall be carried out directly or through the awarding of grants or contracts.

''(b) ACTIVITIES.—Activities that may be carried out under subsection (a) include—

''(1) the coordination of a partnership between the National Cancer Institute and the Centers for Disease Control and Prevention to assess the unique challenges associated with cancer survivorship and the enhancement of cancer related surveillance systems to track the status of cancer survivors and determine whether cancer survivors are at-risk for other chronic and disabling conditions;

''(2) the development of a national cancer survivorship action plan, in partnership with health organizations focused on cancer survivorship, including further support for the Childhood Cancer Survivors Study, to be carried out in coordination with the State-based comprehensive cancer control program of the Centers for Disease Control and Prevention to—

"(A) develop unique and innovative post-treatment programs, services, and demonstrations designed to support and advance cancer survivorship through—

"(i) promotion of physical activity and healthy lifestyles;

"(ii) educational outreach programs for health care providers;

"(iii) support for innovative programs to improve the quality of life among cancer survivors;

"(iv) home and community-based interventions;

"(v) peer support and mentor programs;

"(vi) public awareness and outreach campaigns; and

"(vii) information dissemination to inform health care providers and cancer survivors of their health care options and available survivorship programs; and

"(B) develop unique cancer survivorship demonstration programs designed to address the needs of underserved populations, including

minorities, children, and individuals residing in rural areas.

''(c) COORDINATION OF ACTIVITIES.—The Secretary shall ensure that activities carried out under this section are coordinated as appropriate with other agencies of the Public Health Service.

''(d) REPORT TO CONGRESS.—Not later than October 1, 2008, the Secretary shall submit to Congress a report describing the results of the study conducted under subsection (a), and as applicable, the strategies developed under such subsection.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2008 through 2011.

''SEC. 417G–6. MONITORING AND EVALUATING CANCER CARE IN CANCER SURVIVORSHIP.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Institute and the Director of the National Cancer Institute, shall make grants to eligible entities for the purpose of enabling such entities to develop, monitor, and evaluate information concerning quality cancer care in cancer survivorship.

''(b) ELIGIBLE ENTITIES.—An entity shall be eligible for a grant under this section for a fiscal year if such entity—

''(1) operates a statewide cancer registry with funds from a grant made under section 399B for such fiscal year; or

''(2) has the capacities for ideal systems and the ability to link data on phases of cancer care that go beyond medical record data (on initial course of cancer diagnosis and treatment) to longer term care and to also allow for ascertaining patient's needs and perspectives.

''(c) CONTRACTING AUTHORITY.—In carrying the purpose described in subsection (a), an eligible entity may expend a grant under such subsection to enter into contracts with academic institutions, cancer centers, and other entities, when determined appropriate by the Secretary.

''(d) APPLICATION.—To be eligible for a grant under subsection (a), an eligible entity shall submit to the Secretary an application at such time, in such manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(e) AUTHORITY OF SECRETARY REGARDING USE OF GRANT FUNDS.—The Secretary shall determine the appropriate uses of grant funds under subsection (a) to achieve the purpose described in such subsection.

''(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2007 through 2011.

''SEC. 417E–7. CANCER CARE GUIDELINES.

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

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

''(2) guidelines for providing patients with multidisciplinary consultation before treatment is initiated to provide overall coordination and management

of cancer care among all providers of the patient's treatment and services.

"SEC. 417E–8. OTHER ACTIVITIES TO IMPROVE OUTCOMES OF CANCER CARE.

''(a) IN GENERAL.—

''(1) RESEARCH.—The Director of the Institute, in consultation with the entities described in section 417E–8, 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.

''(2) FACTORS.—In carrying out paragraph (1), the Director of the Institute 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 Director of the Institute shall—

''(1) ensure the targeted dissemination of the most current scientific evidence in appropriate formats for use by organizations representing cancer

patients and their families, professional societies and organizations representing cancer care providers, and organizations through which health care and support services are delivered; and

''(2) develop effective strategies to facilitate patient communication with health care providers regarding such protocols and guidelines and to ensure overall coordination and management of cancer care by providers.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2007 through 2011.''.

SEC. 104. NATIONAL INSTITUTE FOR ENVIRONMENTAL HEALTH SCIENCES.

(a) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, 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, progress goals and benchmarks, and the level of funding necessary for research on environmental risk factors for cancer and gene-environment interactions.

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

SEC. 105. NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES.

Not later than 6 months after the date of enactment of this Act, the Director of the National Cancer Institute, in coordination with the National Center on Minority Health and Health Disparities, shall prepare a strategic plan that identifies progress goals, benchmarks, and needed resources for research on disparities in cancer treatment, control, and prevention.

SEC. 106. COMPREHENSIVE CANCER CONTROL PLANS.

Section 412 of the Public Health Service Act (42 U.S.C. 285a–1) is amended—

(1) in the first sentence, by inserting ‘‘, for survivorship,’’ after ‘‘treatment of cancer’’;

(2) in paragraph (1)(B), by striking ‘‘cancer patients’’ and all that follows and inserting the following: ‘‘cancer patients, families of cancer patients, and cancer survivors, and’’; and

(3) in paragraph (3), by inserting ‘‘and concerning cancer survivorship programs,’’ after ‘‘control of cancer’’.

SEC. 107. LUNG CANCER EARLY DETECTION AND RESEARCH DEMONSTRATION PROJECT.

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. LUNG CANCER EARLY DETECTION AND RESEARCH DEMONSTRATION PROJECT.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award not less than 10 competitive grants to public and non-profit private entities to enable such entities to establish demonstration programs pursuant to the general authority under title III to carry out lung cancer early detection and research activities using Computer Tomography (CT) scanning within a high risk population utilizing the comprehensive protocol that encompasses prediagnosis and post-diagnosis, that was developed under the best published clinical practices, and that was established by the multi-institutional, multi-disciplinary research program initiated in the year 1993. Such demonstration programs shall continue and enhance the research initiated by such protocol into all aspects of early detection and disease management, the incorporation of technological advances in imaging and the development of computer assisted diagnostic tools, and shall include the provision of appropriate referral and case management for

the medical treatment of individuals screened pursuant to this section to ensure appropriate follow-up services for abnormal tests, diagnostic and therapeutic services, and treatment for detected cancers subject to the requirements of this section.

''(b) REQUIREMENTS.—

''(1) IN GENERAL.—To be eligible for a grant under this section, an entity shall agree to adopt the protocol as defined in subsection (a) for the selection of participants in the program funded under the grant, the scanning equipment used in such program, the personnel involved in the scanning and diagnoses provided under such program, the method of diagnosing used in the program, the scans utilized under the program, and the follow-up procedures used under such program.

''(2) COLLECTION OF IMAGING DATA.—To be eligible for a grant under this section, an entity shall agree to collect, transmit, and preserve imaging data as required under the protocol as defined in subsection (a). Prior to such collection, transmission, and preservation of imaging data, patient consent shall be obtained from participating entities as defined by subsection (a).

''(3) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—To be eligible for a grant under this section, an entity shall agree that grant funds will not be expended to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

''(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

''(B) by an entity that provides health service on a prepaid basis.

''(4) RECORDS AND AUDITS.—To be eligible for a grant under this section, an entity shall—

''(A) establish such fiscal control and fund accounting procedures as may be necessary to ensure proper disbursal of, and accounting for, amounts received under this section; and

''(B) provide agreed upon annual reports to the Secretary or the Comptroller General of the United States for the purposes of auditing the expenditures of the entity.

''(5) REPORTS.—To be eligible for a grant under subsection (a) an entity shall agree to submit

to the Secretary such reports as the Secretary deems appropriate.

''(c) DEFINITION.—In this section, the term 'high risk population' means those individuals over the age of 50 with a smoking history of 20 pack years or a family history of lung cancer, or those individuals whose occupation or military service exposed them to asbestos, Agent Orange and other herbicides, beryllium, radon, nuclear fuels or waste, or other lung cancer carcinogens.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2007 through 2011.''.

SEC. 108. COLORECTAL CANCER SCREENING.

Title XV of the Public Health Service Act (42 U.S.C. 300k et seq.), as amended by section 106, is further amended by adding at the end the following:

''SEC. 1512. COLORECTAL CANCER SCREENING DEMONSTRATION PROJECT.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award competitive grants to public and nonprofit private entities to enable such entities to establish demonstration programs pursuant to the general authority

of title III to carry out colorectal screening activities including—

''(1) screening asymptomatic individuals for colorectal cancer as a preventive health measure according to scientific evidence-based screening guidelines;

''(2) providing the full continuum of cancer care for individuals screened pursuant to this section and to ensure the appropriate follow-up services for abnormal tests, diagnostic and therapeutic services, and treatment for detected cancers, subject to the requirements of subsection (c)(2);

''(3) activities to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of colorectal cancer;

''(4) activities to evaluate the programs under this section through appropriate surveillance or program monitoring activities;

''(5) the development and dissemination of findings derived through such evaluations through public and professional education; and

''(6) activities to promote participation in the colorectal cancer screening under this section.

''(b) USE OF CERTAIN STANDARDS UNDER MEDICARE PROGRAM.—A grant may be awarded under subsection (a) only if the applicant involved agrees that—

''(1) screenings under subsection (a)(1) will be carried out as preventive health measures in accordance with evidence-based screening procedures as specified in section 1861(pp)(1) of the Social Security Act;

''(2) an individual will be considered high risk for purposes of subsection (a)(1)(B)(ii) only if the individual is high risk within the meaning of section 1861(pp)(2) of such Act; and

''(3) the payment made from the grant for a screening procedure under subsection (a)(1) will not exceed the amount that would be paid under part B of title XVIII of such Act if payment were made under such part for furnishing the procedure to an individual enrolled under such part.

''(c) REQUIREMENTS.—

''(1) PRIORITY.—To be eligible for a grant under subsection (a), an entity shall agree to give priority with respect to activities and services under the grant to a low-income—

''(A) individual who is at least 50 years of age; or

''(B) individual at high risk for colorectal cancer (as defined in section 1861(pp)(2) of the Social Security Act) and is under 50 years of age.

''(2) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—To be eligible for a grant under subsection (a), an entity shall agree that grant funds will not be expended to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

''(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

''(B) by an entity that provides health service on a prepaid basis.

''(3) RECORDS AND AUDITS.—To be eligible for a grant under subsection (a), an entity shall agree that the entity will—

''(A) establish such fiscal control and fund accounting procedures as may be necessary to ensure proper disbursal of, and accounting for, amounts received under this section; and

''(B) provide agreed upon annual reports to the Secretary or the Comptroller General of

the United States for the purposes of auditing the expenditures by the entity.

''(4) REPORTS.—To be eligible for a grant under subsection (a), an entity shall agree to submit to the Secretary such reports as the Secretary determines appropriate.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each of the fiscal years 2007 through 2011.''.

SEC. 109. NATIONAL PROGRAM OF CANCER REGISTRIES.

Part M of title III of the Public Health Service Act (42 U.S.C. 280e et seq.) is amended by inserting after section 399B the following:

''SEC. 399B–1. ENHANCING CANCER REGISTRIES AND PREPARING FOR THE FUTURE.

''Not later than 1 year after the date of enactment of the National Cancer Act of 2007 the Secretary shall develop a plan and submit a report to Congress that outlines strategies by which the State cancer registries funded with grants under section 399B and the Surveillance, Epidemiology, and End Results program of the National Cancer Institute (in this section referred to as the 'SEER program') can share information to ensure more comprehen-

sive cancer data. The report shall include ways in which the Secretary will—

''(1) standardize data between State cancer registries and the SEER program;

''(2) increase the portability and usability of data files from each registry for researchers and public health planners;

''(3) ensure data collection from the greatest number of health care facilities possible;

''(4) maximize the use of State registry data and data from the SEER program in State and regional public health planning processes; and

''(5) promote the use of data to—

''(A) improve the health status of cancer survivors; and

''(B) research quality of cancer care and access to that care.

''SEC. 399B–2. NATIONAL CHILDHOOD CANCER REGISTRY.

''(a) IN GENERAL.—The Director of the National Institute of Health (in this section referred to as the 'Director') shall, through the awarding of a grant to, or contract or cooperative agreement with, support the existing National Cancer Institute-designated multi-center national infrastructure for collaborative pediatric cancer research to support a national population-based childhood cancer

database, the Childhood Cancer Research Network, in order to—

''(1) formalize the consent process by which pediatric cancer patients enroll on to a clinical trial or receive treatment within the multi-center infrastructure;

''(2) conduct non-therapeutic studies, monitor and evaluate the incidence, survival rate, and long-term health outcomes of childhood cancer patients, develop information concerning best practices in pediatric cancer care; and

''(3) evaluate the quality of pediatric cancer care, and monitor long-term pediatric cancer survivorship.

''(b) COORDINATION.—The Director shall carry out this section jointly through the Director of the Centers for Disease Control and Prevention and the Director of the National Cancer Institute.

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

SEC. 110. OTHER TRANSACTIONS AUTHORITY.

Section 402(i) of the Public Health Service Act (42 U.S.C. 282(i)) is amended by adding at the end the following:

''(4) Notwithstanding any other provision of law, the Director of the National Cancer Institute may use amounts appropriated under section 417B(a) to enter into transactions (other than contracts, cooperative agreements, or grants) to carry out research in support of the development of advanced technologies leading to the expedited delivery of clinical products to benefit the cancer patient.''.

TITLE II—EXPANDING ACCESS TO CANCER DRUGS AND TREATMENT

SEC. 201. DRUGS TO PREVENT CANCER.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subtitle G—Chemoprevention Drugs

''SEC. 581. RECOMMENDATIONS FOR INVESTIGATIONS OF CHEMOPREVENTION DRUGS.

''(a) IN GENERAL.—The sponsor of a chemoprevention drug in the States may request the Secretary to provide written recommendations for the nonclinical and clinical investigations which must be conducted with the drug before—

''(1) it may be approved under section 505 for the high-risk condition that the drug is designed to treat; or

''(2) if the drug is a biological product, it may be licensed under section 351 of the Public Health Service Act for such condition.

If the Secretary has reason to believe that a drug for which a request is made under this section is a chemoprevention drug, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request under this section, would be necessary for approval under section 505 or licensing under section 351 of the Public Health Service Act of such chemoprevention drug for the high-risk condition that such drug is designed to treat.

''(b) REGULATIONS.—The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

''SEC. 582. DESIGNATION OF CHEMOPREVENTION DRUGS.

''(a) DESIGNATION.—

''(1) IN GENERAL.—The manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a chemoprevention drug. A re-

quest for designation of a drug shall be made before the submission of an application under section 505(b) for the drug or the submission of an application for licensing of the drug under section 351 of the Public Health Service Act. If the Secretary finds that a drug for which a request is submitted under this subsection is a chemoprevention drug that is being or will be investigated for a high-risk condition and—

"(A) if an application for such drug is approved under section 505; or

"(B) if a license for such drug is issued under section 351 of the Public Health Service Act,

the approval or license would be for use for such high-risk condition, the Secretary shall designate the drug as a chemoprevention drug for such high-risk condition. A request for a designation of a drug under this subsection shall contain the consent of the applicant to notice being given by the Secretary under subsection (b) respecting the designation of the drug.

"(2) DEFINITIONS.—In this subtitle:

"(A) CHEMOPREVENTION DRUG.—The term 'chemoprevention drug' means a drug designed to treat a high-risk condition.

"(B) HIGH-RISK CONDITION.—The term 'high-risk condition' means a medical condition that—

"(i) has been diagnosed in individuals who have not been diagnosed with cancer or who do not currently have progressive, life-threatening cancer; and

"(ii) unless treated, could develop into progressive and life-threatening cancer

"(C) DETERMINATION.—Determinations under subparagraphs (A) and (B) with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

"(b) CONDITIONS OF DESIGNATION.—A designation of a drug under subsection (a) shall be subject to the condition that—

"(1) if an application was approved for the drug under section 505(b) or a license was issued for the drug under section 351 of the Public Health Service Act, the manufacturer of the drug will notify

the Secretary of any discontinuance of the production of the drug at least 1 year before discontinuance; and

''(2) if an application has not been approved for the drug under section 505(b) or a license has not been issued for the drug under section 351 of the Public Health Service Act and if preclinical investigations or investigations under section 505(i) are being conducted with the drug, the manufacturer or sponsor of the drug will notify the Secretary of any decision to discontinue active pursuit of approval of an application under section 505(b) or approval of a license under section 351 of the Public Health Service Act.

''(c) NOTICE.—Notice respecting the designation of a drug under subsection (a) shall be made available to the public.

''(d) REGULATIONS.—The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

''SEC. 583. PROTECTION FOR CHEMOPREVENTION DRUGS.

''(a) IN GENERAL.—Except as provided in subsection (b), if the Secretary—

''(1) approves an application filed pursuant to section 505(b); or

''(2) issues a license under section 351 of the Public Health Service Act,

for a drug designated as a chemoprevention drug under section 582, the Secretary may not approve another application under section 505(b) or issue another license under section 351 of the Public Health Service Act for such drug for the high-risk condition that such drug is designated for a person who is not the holder of such approved application or of such license until the expiration 7 years from the date of the approval of the approved application or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

''(b) OTHER APPLICATION APPROVAL.—If an application filed pursuant to section 505(b) is approved for a drug designated as a chemoprevention drug under section 582 or if a license is issued under section 351 of the Public Health Service Act for such a drug, the Secretary may, during the 7-year period beginning on the date of the application approval or of the issuance of the license, approve another application under section 505(b) or issue a license under section 351 of the Public Health Service Act, for such drug for the high-risk condition that such drug is designated for a person who is not the holder of such approved application or of such license if—

''(1) the Secretary finds, after providing the holder notice and opportunity for the submission of views, that in such period the holder of the approved application or of the license cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with such high-risk condition for which the drug was designated; or

''(2) such holder provides the Secretary in writing the consent of such holder for the approval of other applications or the issuance of other licenses before the expiration of such 7-year period.

''(c) MARKET EXCLUSIVITY FOR CHEMOPREVENTION DRUGS DESIGNATED FOR A HIGH-RISK CONDITION.—If the Secretary designates a drug as a chemoprevention drug for a high-risk condition under section 582—

''(1)(A) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be twelve years rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be eleven years, one hundred thirty-two months, and fourteen and one-half years, respectively; or

"(B) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be ten years rather than three years;

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505; or

"(ii) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of seven years after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the

period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of seven years after the date the patent expires (including any patent extensions); and

''(3) with respect to a drug that is so designated that is also subject to market exclusivity extension under section 505A, the extension of the periods described under paragraphs (1) and (2) of this subsection shall be increased by six months in accordance with such section 505A.

''SEC. 584. OPEN PROTOCOLS FOR INVESTIGATIONS OF CHEMOPREVENTION DRUGS.

''If a drug is designated under section 582 as a chemoprevention drug and if notice of a claimed exemption under section 505(i) or regulations issued thereunder is filed for such drug, the Secretary shall encourage the sponsor of such drug to design protocols for clinical investigations of the drug which may be conducted under the exemption to permit the addition to the investigations of persons with the high-risk condition for which such drug was designated.''.

(b) GRANTS AND CONTRACTS FOR DEVELOPMENT OF CHEMOPREVENTION DRUGS.—

(1) IN GENERAL.—The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in—

(A) defraying the costs of qualified clinical testing expenses incurred in connection with the development of chemoprevention drugs;

(B) defraying the costs of developing chemoprevention devices; and

(C) defraying the costs of developing chemoprevention foods.

(2) DEFINITIONS.—For purposes of this subsection:

(A) CHEMOPREVENTION DEVICE.—The term ''chemoprevention device'' means a device to be approved to treat a high-risk condition.

(B) CHEMOPREVENTION DRUG.—The term ''chemoprevention drug'' means a drug designed to treat a high-risk condition.

(C) CHEMOPREVENTION FOOD.—The term ''chemoprevention food'' means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a type of high-risk condition for which distinctive nutritional requirements,

based on recognized scientific principles, are established by medical evaluation.

(D) HIGH-RISK CONDITION.—

(i) IN GENERAL.—The term ''high-risk condition'' means, with respect to a chemoprevention drug, chemoprevention device, or chemoprevention food, a medical condition that—

(I) has been diagnosed in individuals who have not been diagnosed with cancer or who do not currently have progressive, life-threatening cancer; and

(II) unless treated, could develop into progressive and life-threatening cancer.

(ii) DETERMINATION.—Determinations under this subparagraph with respect to any drug, device, or food shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug or food under section 582 of the Federal Food, Drug, and Cosmetic Act is made.

(E) QUALIFIED TESTING.—The term ''qualified testing'' means—

(i) human clinical testing—

(I) which is carried out under an exemption for a chemoprevention drug under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)); and

(II) which occurs after the date such drug is designated under section 582 of such Act (as added by subsection (a)) and before the date on which an application with respect to such drug is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) or under section 351 of the Public Health Service Act (42 U.S.C. 292); and

(ii) preclinical testing involving a drug is designated under such section 582 and before the date on which an application with respect to such drug is submitted under such section 505(b) or under such section 351.

(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2008 through 2010.

(c) STUDIES.—

(1) MEDICAL DEVICES OR MEDICAL FOOD FOR HIGH RISK CONDITIONS.—The Secretary of Health and Human Services shall conduct a study to determine whether the application of subchapter G of chapter V of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) to medical devices or medical foods for the high-risk condition for which such devices or foods are designated, or to both, is needed to encourage the development of such devices and foods. The Secretary shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate not later than 1 year after the date of the enactment of this Act.

(2) CHEMOPREVENTION PRODUCTS.—The Director of the Institute of Medicine shall conduct a study to measure the quality and quantity of chemoprevention products resulting from the application of subpart G of chapter V of the Federal

Food, Drug, and Cosmetic Act to drugs, medical devices, and medical foods for which such drugs, devices, and foods are designated, or to all.

(d) CHEMOPREVENTION PRODUCTS BOARD.—Part A of title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

"SEC. 229. CHEMOPREVENTION PRODUCTS BOARD.

''(a) IN GENERAL.—There is established in the Department of Health and Human Services a board for the development of chemoprevention drugs (including biologics) and devices (including diagnostic products), to be known as the Chemoprevention Products Board (referred to in this section as the 'Board'). The Board shall be comprised of the Assistant Secretary for Health of the Department of Health and Human Services and representatives, selected by the Secretary, of the Food and Drug Administration, the National Institutes Health, the Centers for Disease Control and Prevention, and any other Federal department or agency which the Secretary determines has activities relating to chemoprevention drugs and devices. The Assistant Secretary for Health shall chair the Board.

''(b) DEFINITIONS.—In this section:

''(1) CHEMOPREVENTION DEVICE.—The term 'chemoprevention device' has the meaning given such

term in section 582 of the Federal Food, Drug, and Cosmetic Act.

''(2) CHEMOPREVENTION DRUG.—The term 'chemoprevention drug' has the meaning given such term in section 582 of the Federal Food, Drug, and Cosmetic Act.

''(3) HIGH-RISK CONDITION.—The term 'high-risk condition' has the meaning given such term in section 582 of the Federal Food, Drug, and Cosmetic Act.

''(c) FUNCTION.—The function of the Board shall be to promote the development of chemoprevention drugs and devices and the coordination among Federal, other public, and private agencies in carrying out their respective functions relating to the development of such articles for such drugs to treat high-risk conditions.

''(d) DUTIES.—In the case of chemoprevention drugs, the Board shall—

''(1) evaluate—

''(A) the effect of subchapter G of chapter V of the Federal Food, Drug, and Cosmetic Act on the development of such drugs; and

''(B) the implementation of such subchapter; and

''(2) evaluate the activities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration for the development of such drugs for high-risk conditions;

''(3) assure appropriate coordination among the Food and Drug Administration, the National Institutes of Health, the Alcohol, Drug Abuse, and Mental Health Administration, and the Centers for Disease Control and Prevention in the carrying out of their respective functions relating to the development of drugs for high-risk conditions to assure that the activities of each agency are complementary;

''(4) assure appropriate coordination among all interested Federal agencies, manufacturers, and organizations representing patients, in their activities relating to such drugs;

''(5) with the consent of the sponsor of a chemoprevention drug exempt under section 505(i) of the Federal Food, Drug, and Cosmetic Act or regulations issued under such section, inform physicians and the public respecting the availability of such drug for the high-risk condition for which it is designated under section 582 of such Act and inform physicians and the public respecting the availability of drugs approved under section 505(c) of

such Act or licensed under section 351 of this Act for chemoprevention;

''(6) seek business entities and others to undertake the sponsorship of chemoprevention drugs, seek investigators to facilitate the development of such drugs, and seek business entities to participate in the distribution of such drugs;

''(7) reorganize and incentivize collaborative efforts between public and private entities and efforts by individuals seeking the development of chemoprevention drugs in developing such drugs; and

''(8) promote healthy competition to support the steady movement of chemoprevention products through the research and development process.

''(e) CONSULTATION.—The Board shall consult with interested persons respecting the activities of the Board under this section and as part of such consultation shall provide the opportunity for the submission of oral views.

''(f) ANNUAL REPORT.—

''(1) IN GENERAL.—Not later than June 1 of each year, the Board shall submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual re-

port, that, with respect to the preceding calendar year—

"(A) identifies the drugs which have been designated under section 582 of the Federal Food, Drug, and Cosmetic Act as chemoprevention drugs;

"(B) describes the activities of the Board; and

"(C) contains the results of the evaluations carried out by the Board.

"(2) ADDITIONAL INFORMATION FOR INCLUSION IN ANNUAL REPORT.—

"(A) RESEARCH ACTIVITIES.—The Director of the National Institutes of Health and the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration shall submit to the Board for inclusion in the annual report under paragraph (1) a report on the chemoprevention research activities of the Institutes of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration.

"(B) EFFECT OF PROVISIONS.—The Secretary shall submit to the Board for inclusion in the annual report under paragraph (1) a re-

port on the program of assistance under section ____(c) of the National Cancer Act of 2007 for the development of chemoprevention drugs.''.

(e) SENSE OF THE SENATE ON CHEMOPREVENTION DRUGS.—It is the sense of the Senate that—

(1) adequate chemoprevention drugs have not been developed;

(2) there is reason to believe that promising chemoprevention drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and to provide incentives to develop such drugs; and

(3) it is in the public interest to provide such changes and incentives for the development of chemoprevention drugs.

SEC. 202. COMPASSIONATE ACCESS TO INVESTIGATIONAL DRUGS AND DEVICES.

(a) IN GENERAL.—Section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amended by adding at the end the following:

''(f) ONCOLOGIC COMPASSIONATE ACCESS PROGRAM.—Acting under the existing expanded access program, the Secretary shall establish a new program to expand access to investigational treatments for individuals diagnosed with cancer who have exhausted all treatment

options approved by Secretary for the condition or disease for which the patient is a reasonable candidate, and have unsuccessfully sought treatment, or obtained treatment that was not effective, with an investigational drug, biological product, or device for which such individual is a reasonable candidate. In carrying out this compassionate access program, the Secretary shall publish and broadly disseminate written guidance to health care providers and organizations representative of patients diagnosed with cancer that—

''(1) describes such compassionate access programs for investigational drugs, biological products, and devices intended to treat cancer;

''(2) facilitates the provision of investigational drugs and devices to seriously ill cancer patients without unreasonable delay by recognizing that the use of available investigational products for treatment is the responsibility of the physician and the patient; and

''(3) facilitates the contribution of safety and efficacy data of investigational treatments from participants in such compassionate access program.

''(g) IMPLEMENTATION OF COMPASSIONATE ACCESS PROGRAMS.—

''(1) TRAINING OF PERSONNEL.—Not later than 90 days after the date of enactment of this subsection, the Secretary shall implement training programs at the Food and Drug Administration with respect to existing expanded access program established under this section.

''(2) POLICIES, REGULATIONS, AND GUIDANCE.—The Secretary shall establish policies, regulations, and guidance designed to most directly benefit seriously ill cancer patients.''.

(b) DEVELOPMENT OF SURROGATE ENDPOINTS AND BIOMARKERS.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561 (21 U.S.C. 360bbb) the following:

''SEC. 561A. DEVELOPMENT OF SURROGATE ENDPOINTS AND BIOMARKERS.

''The Secretary shall—

''(1) establish a program to encourage the development of surrogate endpoints and biomarkers, which shall include medical images, that are reasonably likely to predict—

''(A) clinical benefit for cancer-related conditions for which there exist significant unmet medical needs; and

''(B) individual risk for cancer-related conditions for which there exist unmet medical needs;

''(2) request the Institute of Medicine to undertake a study to identify validated surrogate endpoints and biomarkers, which shall include medical images, and recommend research to validate such surrogate endpoints and biomarkers, that may support approvals for products intended for the treatment of cancer;

''(3) request the Institute of Medicine to undertake a study to evaluate the practicality of expanding the use of large, community-based simple trials designed to identify product safety and efficacy in a larger and more representative patient population of individuals diagnosed with cancer prior to approving the product for widespread use; and

''(4) make available to the public a list of drugs, biological products, and devices that are being investigated for cancer and that are in no earlier than the Phase II stage of clinical trials.''.

(c) CONFORMING AMENDMENT.—Section 561(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(c)) is amended by striking the heading and insert-

ing ''COMPASSIONATE ACCESS TO INVESTIGATIONAL DRUGS AND DEVICES FOR CANCER PATIENTS.—''.

SEC. 203. ONCOLOGY DRUGS ADVISORY COMMITTEE.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 566. MEMBERSHIP OF ONCOLOGY DRUGS ADVISORY COMMITTEE.

''Membership of the Oncology Drugs Advisory Committee of the Food and Drug Administration shall consist of no less than 2 patient representatives who are voting members of the committee.''.

SEC. 204. TECHNICAL 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''.

TITLE III—PAYMENTS FOR CANCER-RELATED SERVICES AND PRODUCTS

SEC. 301. COORDINATING CANCER CARE FOR PATIENTS.

(a) 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:

''CANCER COVERAGE REQUIREMENTS

''SEC. 1849. (a) IN GENERAL.—The following provisions shall apply to a participating cancer care coordinator treating an individual who has been diagnosed with cancer and who is covered under the insurance program established under this part.

''(b) DEFINITIONS.—In this section:

''(1) CANCER CARE COORDINATOR.—

''(A) IN GENERAL.—The term 'cancer care coordinator' means, with respect to items or services provided under the coverage related to the treatment of cancer, a lead managing physician, nurse practitioner with an oncology certification (as provided by a nationally accredited organization), or registered nurse (as provided by a nationally accredited organization) that is designated at the time of cancer diagnosis by the provider, 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 individual among all providers who provide items or services to the individual, and who otherwise meet the requirements of this paragraph.

''(B) RESPONSIBILITIES.—A designee under subparagraph (A) shall be responsible for the overall coordination and management of the medical, nursing, and other health services provided to the individual during the period in which the individual is undergoing treatment for such cancer.

''(C) COORDINATION AND MANAGEMENT.—

''(i) IN GENERAL.—The overall coordination and management under subparagraph (A) shall include the development of a plan of care that—

''(I) details, to the greatest extent practicable, all aspects of the care to be provided to the individual, with respect to the treatment of such cancer, including any curative treatment and comprehensive symptom management (such as palliative care) involved;

''(II) is furnished in written form to the individual in person within a period specified by the Secretary that is as soon as practicable after the date

on which the individual is so diagnosed;

''(III) is furnished in a form that is appropriate for use by disparity populations, to the extent practicable; and

''(IV) is in accordance with standards determined by the Secretary to be appropriate;

''(ii) COVERED INDIVIDUAL.—With respect to an individual for whom the plan of care has been developed under clause (i), such plan shall be revised as necessary to account for any substantial change in the condition of the individual, if such revision—

''(I) is in accordance with subclauses (I) and (III) of such clause; and

''(II) is furnished in written form to the individual within a period specified by the Secretary that is as soon as practicable after the date of such revision.

"(iii) FOLLOW-UP PLAN.—With respect to an individual who has completed the primary treatment for cancer, as defined by the Secretary (such as completion of chemotherapy or radiation treatment), the development of a follow-up cancer care plan that—

"(I) describes the elements of the primary treatment, including symptom management, furnished to such individual;

"(II) provides recommendations for the subsequent care of the individual with respect to the cancer involved;

"(III) is furnished in written form to the individual in person within a period specified by the Secretary that is as soon as practicable after the completion of such primary treatment;

"(IV) is furnished in a form that is appropriate for use by disparity populations to the extent practicable; and

"(V) is in accordance with standards determined by the Secretary to be appropriate.

"(iv) REVISIONS TO FOLLOW UP PLAN.—With respect to an individual for whom a follow-up cancer care plan has been developed under clause (iii), the revision of such plan as necessary to account for any substantial change in the condition of the individual, if such revision—

"(I) is in accordance with subclauses (I), (II), and (IV) of such clause; and

"(II) is furnished in written form to the individual within a period specified by the Secretary that is as soon as practicable after the date of such revision.

"(D) STANDARDS.—The Secretary shall establish standards to carry out this paragraph in consultation with appropriate organizations that represent providers of services related to cancer treatment and organizations representing survivors of cancer. Such standards shall include standards for determining the

need and frequency for revisions of the plans of care and follow-up plans based on changes in the condition of the individual and standards for the communication of the plan to the patient.

''(2) INDIVIDUAL.—The term 'individual' means a person 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 by adding at the end the following new paragraph:

''(5) In the case of physician or nursing services furnished to an individual under this section who receives care for such cancer, there shall be paid to the cancer care coordinator of that individual during the period in which that individual is undergoing treatment for such cancer 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. 302. ELIMINATION OF OPTIONAL EXCLUSION FROM MEDICAID PRESCRIPTION DRUG COVERAGE FOR TOBACCO CESSATION MEDICATIONS.

(a) IN GENERAL.—Section 1927(d)(2) of the Social Security Act (42 U.S.C. 1396r–8(d)(2)) is amended—

(1) by striking subparagraph (E);

(2) by redesignating subparagraphs (F) through (K) as subparagraphs (E) through (J), respectively; and

(3) in subparagraph (F) (as redesignated by paragraph (2)), by inserting before the period at the end the following: ‘‘, other than agents approved by the Food and Drug Administration for purposes of promoting, and when used to promote, tobacco cessation’’.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to services furnished on or after the date of enactment of this Act.

TITLE IV—PROMOTING BIOSPECIMEN COLLECTION TO ACCELERATE THE GENOMIC MAPPING OF THE MOST LETHAL CANCERS

SEC. 401. ADOPTION OF NATIONAL CANCER INSTITUTE GUIDELINES FOR BIOREPOSITORIES.

(a) IN GENERAL.—A biorepository may adopt the First-Generation Guidelines for NCI-Supported Biospecimen Resources, published by the National Cancer Institute of the National Institutes of Health on November 21, 2006 (or any successor guidelines), for the collection of biospecimens and any accompanying data.

(b) DEFINITIONS.—For purposes of this section:

(1) BIOREPOSITORY.—The term ''biorepository'' means a collection of biological materials (which may include tissues, biomolecules, body fluids, and medical imaging) derived from patients, stored under specifically-defined conditions, and accessed for the purpose of scientific research or patient care.

(2) BIOSPECIMEN.—The term ''biospecimen'' means any material or medical images of material that is biologically-derived, such as blood, tissue, and urine, and used for diagnosis and analysis.

SEC. 402. MEDPAC REPORT ON PAYMENTS FOR SPECIMEN COLLECTION.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Medicare Payment Assessment Commission shall submit to Congress a report (in this section referred to as the ''report'') on approaches to developing a payment system within Medicare for the collection and storage of cancer and related tissues for use in research involving the application of genomic or proteomic technologies.

(b) REPORT DETAILS.—

(1) IN GENERAL.—The report shall include recommendations on the following:

(A) Potential billing code systems for the collection, storage, and pathological definition of cancer and related tissues.

(B) Potential payment systems for the collection, storage, and pathological definition of cancer and related tissues.

(C) The feasibility of expanding the recommended payment system to cover tissue collection, storage, and pathological definition for research on conditions unrelated to cancer.

(2) PAYMENT SYSTEMS.—Proposed payment systems referred to in paragraph (1)(B) shall consider the following factors:

(A) Numbers and types of cancer tissues collected for the purpose of research involving the application of genomic or proteomic technologies.

(B) Professional time required for pathologists, surgeons, other experts to collect these tissues for post-genomics research.

(C) Specific annotation of collected tissue required beyond normal diagnostic needs currently in practice.

(D) Numbers of tissues collected on government sponsored clinical trials and method of coverage for the collection of these tissues.

(E) The cost of maintenance of such highly annotated resources.

(F) The cost of overseeing the standards needed to ensure that the tissues collected for molecular oncology research, including the certification and oversight by a qualified professional body.

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