

110TH CONGRESS
1ST SESSION

S. _____

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

Mrs. FEINSTEIN (for herself and Mr. BROWNBACK) introduced the following bill; which was read twice and referred to the Committee on

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “National Cancer Act of 2007”.

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

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

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

- Sec. 101. Sense of the Senate concerning investments in cancer research funding.
- Sec. 102. Sense of the Senate concerning investments in cancer research to develop targeted drugs.
- Sec. 103. Expansion of cancer-related research, prevention, detection, treatment, and survivorship programs.
- Sec. 104. National Institute for Environmental Health Sciences.
- Sec. 105. National Center on Minority Health and Health Disparities.
- Sec. 106. Comprehensive cancer control plans.
- Sec. 107. Lung cancer early detection demonstration project.
- Sec. 108. Colorectal cancer screening.
- Sec. 109. National program of cancer registries.
- Sec. 110. Other transactions authority.

TITLE II—EXPANDING ACCESS TO CANCER DRUGS AND
TREATMENT

- Sec. 201. Drugs to prevent cancer.
- Sec. 202. Compassionate access to investigational drugs and devices.
- Sec. 203. Oncology Drugs Advisory Committee.
- Sec. 204. Technical amendment.

TITLE III—PAYMENTS FOR CANCER-RELATED SERVICES AND
PRODUCTS

- Sec. 301. Coordinating cancer care for patients.
- Sec. 302. Elimination of optional exclusion from medicaid prescription drug coverage for tobacco cessation medications.

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.
- Sec. 402. MedPac report on payments for specimen collection.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Cancer killed 6,700,000 people around the
4 world in 2002 and this figure is expected to rise to
5 10,100,000 in 2020.

6 (2) In 2007, an estimated 1,444,920 new can-
7 cer cases will be diagnosed in the United States.

8 More than 1,000,000 cases of skin cancer are also

1 expected to be diagnosed this year. Cancer accounts
2 for one in every four deaths, and about 559,650
3 Americans are expected to die from cancer this year.
4 Approximately 40 percent of all Americans in the
5 United States will be diagnosed with cancer at some
6 point in their lives, 1 of every 2 men and 1 of every
7 3 women.

8 (3) The National Institutes of Health estimated
9 the overall cost of cancer for 2006 at
10 \$206,300,000,000.

11 (4) Cancer can strike at any age, but it remains
12 largely a disease of aging. As the American popu-
13 lation ages, the number of cancer cases will rise. It
14 is estimated that between 2000 and 2010, the num-
15 ber of cancer diagnoses will increase by 20 percent
16 based on this change in population dynamics and no
17 change in cancer risk. With such increases in the in-
18 cidence of cancer, not only will costs continue to
19 grow, but there will be a serious shortage of individ-
20 uals in the workforce to provide cancer care, particu-
21 larly in long-term care settings.

22 (5) Since 1971, when the National Cancer Act
23 was enacted, and the “War on Cancer” was de-
24 clared, the science of cancer has advanced dramati-
25 cally. The revolution in molecular and cellular biol-

1 ogy and advances in technology have created unprec-
2 edented opportunities for understanding cancer and
3 the role of genetics, environmental risk factors, and
4 lifestyle factors in relation to cancer.

5 (6) Since 1971, mortality rates for some can-
6 cers have decreased, while such rates for other can-
7 cers remain high. The United States has seen the
8 number of cancer deaths drop for 2 consecutive
9 years, despite an older and larger population. This
10 success is largely due to reductions in smoking prev-
11 alence over the past several decades, improvements
12 in cancer screening rates, and the use of increasingly
13 effective treatment regimens.

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

22 (8) The quality of cancer care is uneven across
23 the Nation. Many cancer patients do not receive op-
24 timal care.

1 (9) Cancer is the chief cause of death by dis-
2 ease in children between the ages of 1 and 14. Each
3 year, 14,000 children and adolescents are diagnosed
4 with cancer. However, while nearly every childhood
5 cancer diagnosis 20 years ago was fatal, today ap-
6 proximately 80 percent of children diagnosed with
7 cancer survive at least 5 years.

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

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

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

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

4 (13) Approximately 10,500,000 cancer sur-
5 vivors are living in the United States. These sur-
6 vivors may experience physical, psychological, social
7 and economic effects as a result of cancer and its
8 treatment.

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

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

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

1 (17) New translational research centers focused
2 on cancer are needed to provide the preclinical and
3 early clinical trial support required to advance sci-
4 entific discoveries into new drugs and technologies to
5 prevent, detect, treat, and diagnose cancer.

6 (18) The number of medical researchers is de-
7 clining, a decrease which will negatively affect the
8 prevention, detection, and treatment of cancer.

9 (19) Since 1971, the conduct of research has
10 involved more collaboration between public and pri-
11 vate sectors and more multidisciplinary approaches.
12 The biotechnology pharmaceutical and device indus-
13 tries have grown and provided a broad array of pre-
14 vention, detection, and treatment approaches and
15 scientific opportunities for cancer patients, pro-
16 viders, and researchers.

17 (20) In May 2001, Gleevec, the first in what is
18 expected to be a number of targeted cancer treat-
19 ments, was approved for use by the Food and Drug
20 Administration. It appeared to be effective in stop-
21 ping the growth of deadly Chronic Myeloid Leu-
22 kemia cells within 3 months of use. In 2002, Gleevec
23 showed ability to stop growth of gastrointestinal
24 stromal tumors. Trials have now demonstrated that

1 89 percent of CML patients taking Gleevec are alive
2 5 years after diagnosis.

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

6 (22) In 2006, the Food and Drug Administra-
7 tion approved the first vaccine to prevent the two
8 strains of Human Papillomavirus (HPV) responsible
9 for 70 percent of cervical cancer cases.

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

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

1 **TITLE I—EXPANSION OF CAN-**
2 **CER-RELATED RESEARCH,**
3 **PREVENTION, DETECTION,**
4 **AND TREATMENT PROGRAMS**

5 **SEC. 101. SENSE OF THE SENATE CONCERNING INVEST-**
6 **MENTS IN CANCER RESEARCH FUNDING.**

7 It is the sense of the Senate that—

8 (1) past investments in cancer research have re-
9 sulted in better health, an improved quality of life,
10 and new discoveries; and

11 (2) to build on, and sustain, the progress made
12 between 1998 and 2003 during which Congress dou-
13 bled the budget at the National Institutes of Health,
14 the National Cancer Institute requires continued
15 Federal investment, as outlined in the National Can-
16 cer Institute Directors Bypass Budget: The Nation's
17 Investment in Cancer, to achieve a balanced research
18 portfolio and to develop more targeted, more effec-
19 tive therapies or drugs and other cancer treatments
20 and to address those rare, deadly cancers lacking ef-
21 fective early detection tests or treatments for a wide
22 range of cancers, commensurable with the National
23 Cancer Institute bypass budget.

1 **SEC. 102. SENSE OF THE SENATE CONCERNING INVEST-**
2 **MENTS IN CANCER RESEARCH TO DEVELOP**
3 **TARGETED DRUGS.**

4 (a) FINDINGS.—The Senate finds that—

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

8 (2) as a normal cell becomes malignant, its sig-
9 nature changes and this change becomes a signal of
10 the presence of cancer; and

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

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

20 **SEC. 103. EXPANSION OF CANCER-RELATED RESEARCH,**
21 **PREVENTION, DETECTION, TREATMENT, AND**
22 **SURVIVORSHIP PROGRAMS.**

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

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

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

3 and

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

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

7 **“SEC. 417E. STUDY AND STRATEGIC PLANS.**

8 “(a) IN GENERAL.—Not later than 6 months after
9 the date of enactment of the National Cancer Act of 2007,
10 the Institute shall prepare a progress report on the goal
11 of reducing death and suffering from cancer in the next
12 10 years, that identifies unmet needs, recommends
13 progress goals and benchmarks, recommends pro-
14 grammatic restructuring, and recommends a level of fund-
15 ing necessary in the following areas:

16 “(1) Understanding the causes of cancer.

17 “(2) Research regarding cancer prevention.

18 “(3) Improving early detection and diagnosis of
19 cancer.

20 “(4) Developing effective and efficient cancer
21 treatments.

22 “(5) Understanding the factors that influence
23 patient outcomes.

24 “(6) Improving the quality of cancer care.

1 “(b) DUTIES OF DIRECTOR.—In carrying out the
2 program under subsection (a), the Director of the Insti-
3 tute shall—

4 “(1) award grants and facilitate the process to
5 award grants to public or nonprofit private entities
6 to conduct research to develop a molecularly-ori-
7 ented, knowledge-based approach to cancer drug dis-
8 covery and development; and

9 “(2) not later than 6 months after the date of
10 enactment of the National Cancer Act of 2007, de-
11 velop and implement a strategic plan for intensifying
12 and expanding research conducted to increase the
13 number of cancer treatments available that are low
14 toxicity, high efficacy agents, and in particular, re-
15 search to develop treatments that selectively target
16 malignant or cancerous cells.

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

20 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
21 is authorized to be appropriated to carry out this section,
22 such sums as may be necessary for each of fiscal years
23 2008 through 2011.

1 **“SEC. 417E-2. CLINICAL TRIALS.**

2 “(a) IN GENERAL.—For the purpose of enhancing
3 patient access to clinical trials and investigational thera-
4 pies for the treatment or prevention of cancer, the Na-
5 tional Cancer Institute shall establish an education pro-
6 gram that provides patients and providers with—

7 “(1) information about how to access and use
8 the National Cancer Institute clinical trials database
9 online;

10 “(2) information about the Food and Drug Ad-
11 ministration process for approving the use of drugs
12 and biologics for a single patient;

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

16 “(4) recommendations regarding logistical sup-
17 port and sources of funding for patients support
18 costs.

19 “(b) INFORMATION DISSEMINATION.—In carrying
20 out such information dissemination described under this
21 section, the Director of the Institute shall regularly pro-
22 vide information to cancer care providers, professional and
23 patient organizations, including community-based organi-
24 zations, and patients to increase provider participation
25 and patient enrollment in clinical trials.

1 “(c) DIVERSITY ASSURANCE.—The Director of the
2 Institute shall require that all research grant applications
3 include assurances that the applicant will actively recruit
4 a diverse patient population, including disparity popu-
5 lations, to participate in trials, when such recruitment is
6 medically appropriate.

7 “(d) SENSE OF THE SENATE ON A CENTRAL INSTI-
8 TUTIONAL REVIEW BOARD.—It is the sense of the Senate
9 that—

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

16 “(2) the National Cancer Institute should be
17 commended for its work in centralizing the institu-
18 tional review board process and should continue to
19 recommend and support meaningful reform of the
20 existing Central Institutional Review Board Initia-
21 tive; and

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

1 **“SEC. 417E-3. CANCER CARE RESEARCHERS.**

2 “(a) SUPPLY OF CANCER RESEARCHERS.—In order
3 to ensure a sufficient number of researchers who are
4 trained in the prevention, early detection, diagnosis, cure,
5 and treatment of cancer in future fiscal years, the Director
6 of the Institute, in coordination with the Secretary of Vet-
7 erans Affairs and the National Institute of Nursing Re-
8 search, shall conduct a study as described in section 417E-
9 4 for the purpose of recommending activities to promote
10 training and education for health care professionals and
11 institutions supporting cancer research.

12 “(b) LOAN REPAYMENT.—

13 “(1) IN GENERAL.—The Director of the Insti-
14 tute shall establish a program of entering into con-
15 tracts with qualified health professionals under
16 which such health professionals agree to engage in
17 cancer prevention research in consideration of the
18 Federal Government agreeing to repay, for each year
19 of engaging in such research, not more than
20 \$35,000 of the principal and interest of the edu-
21 cational loans of such health professionals.

22 “(2) SERVICE PROVISIONS.—The provisions of
23 sections 338B, 338C, and 338E shall, except as in-
24 consistent with paragraph (1), apply to the program
25 established in such paragraph to the same extent
26 and in the same manner as such provisions apply to

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

4 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
5 is authorized to be appropriated to carry out this section,
6 such sums as may be necessary for each of fiscal years
7 2008 through 2011.

8 **“SEC. 417E-4. CANCER CARE WORKFORCE.**

9 “(a) IN GENERAL.—

10 “(1) STUDY.—The Secretary shall conduct a
11 study on the current and future cancer care work-
12 force needs in the following areas:

13 “(A) Cancer research.

14 “(B) Care and treatment of cancer pa-
15 tients and survivors.

16 “(C) Quality of life, symptom manage-
17 ment, and pain management.

18 “(D) Early detection and diagnosis.

19 “(E) Cancer prevention.

20 “(F) Genetic testing, counseling, and eth-
21 ical considerations related to such testing.

22 “(G) Diversity and appropriate care for
23 disparity populations.

24 “(H) Palliative and end-of-life care.

1 “(2) REPORT.—Not later than 1 year after the
2 date of enactment of the National Cancer Act of
3 2007, the Secretary shall submit to Congress a re-
4 port that describes the findings of the study con-
5 ducted under subsection (a).

6 “(b) PROGRAM.—

7 “(1) ESTABLISHMENT.—The Secretary shall
8 issue programmatic recommendations and establish
9 a program to carry out activities based on the re-
10 sults of the study conducted under subsection (a).

11 “(2) RECOMMENDATIONS.—The programmatic
12 recommendations described in paragraph (1) shall—

13 “(A) set annual and long-term training
14 goals to assure an adequate cancer care work-
15 force;

16 “(B) prepare and implement a plan to as-
17 sist to cancer healthcare professions with the
18 most severe shortages, under which awards will
19 be made under this section to eligible individ-
20 uals to increase cancer care workforce training
21 for individuals to become cancer care providers,
22 which may include such individuals who make a
23 commitment to serve in underserved commu-
24 nities or areas with disproportionately high can-
25 cer incidence or mortality and for health profes-

1 sions for which there are anticipated shortages;
2 and

3 “(C) be coordinated with existing programs
4 to prevent duplication.

5 “(c) **ELIGIBILITY.**—To be eligible to receive assist-
6 ance under this section, an individual shall submit an ap-
7 plication to the Secretary at such time, in such manner,
8 and containing such information as the Secretary reason-
9 ably requires. In such application, such individual shall
10 demonstrate the intent to seek training to obtain a certifi-
11 cate, license, or postsecondary degree as the Secretary
12 provides in the report under subsection (a), or in the case
13 of licensed health care professionals, the intent to seek
14 professional development to upgrade skills and knowledge
15 or to obtain specialized knowledge according to criteria de-
16 veloped by the Secretary.

17 “(d) **USE OF FUNDS.**—The use of funds by a recipi-
18 ent of assistance under this section shall be deemed by
19 the Secretary and reported to Congress not later than 1
20 year after the issuance of the report under subsection (a).

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

1 **“SEC. 417F-5. CANCER SURVIVORSHIP.**

2 “(a) IN GENERAL.—The Secretary, acting through
3 the Director of the National Cancer Institute, shall con-
4 duct a study of the unique health challenges associated
5 with cancer survivorship and carry out projects and inter-
6 ventions to improve the long-term health status of cancer
7 survivors. Such projects shall be carried out directly or
8 through the awarding of grants or contracts.

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

11 “(1) the coordination of a partnership between
12 the National Cancer Institute and the Centers for
13 Disease Control and Prevention to assess the unique
14 challenges associated with cancer survivorship and
15 the enhancement of cancer related surveillance sys-
16 tems to track the status of cancer survivors and de-
17 termine whether cancer survivors are at-risk for
18 other chronic and disabling conditions;

19 “(2) the development of a national cancer survi-
20 vorship action plan, in partnership with health orga-
21 nizations focused on cancer survivorship, including
22 further support for the Childhood Cancer Survivors
23 Study, to be carried out in coordination with the
24 State-based comprehensive cancer control program
25 of the Centers for Disease Control and Prevention
26 to—

1 “(A) develop unique and innovative post-
2 treatment programs, services, and demonstra-
3 tions designed to support and advance cancer
4 survivorship through—

5 “(i) promotion of physical activity and
6 healthy lifestyles;

7 “(ii) educational outreach programs
8 for health care providers;

9 “(iii) support for innovative programs
10 to improve the quality of life among cancer
11 survivors;

12 “(iv) home and community-based
13 interventions;

14 “(v) peer support and mentor pro-
15 grams;

16 “(vi) public awareness and outreach
17 campaigns; and

18 “(vii) information dissemination to in-
19 form health care providers and cancer sur-
20 vivors of their health care options and
21 available survivorship programs; and

22 “(B) develop unique cancer survivorship
23 demonstration programs designed to address
24 the needs of underserved populations, including

1 minorities, children, and individuals residing in
2 rural areas.

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

7 “(d) REPORT TO CONGRESS.—Not later than Octo-
8 ber 1, 2008, the Secretary shall submit to Congress a re-
9 port describing the results of the study conducted under
10 subsection (a), and as applicable, the strategies developed
11 under such subsection.

12 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
13 is authorized to be appropriated to carry out this section,
14 such sums as may be necessary for each of fiscal years
15 2008 through 2011.

16 **“SEC. 417G-6. MONITORING AND EVALUATING CANCER**
17 **CARE IN CANCER SURVIVORSHIP.**

18 “(a) IN GENERAL.—The Secretary, acting through
19 the Director of the Institute and the Director of the Na-
20 tional Cancer Institute, shall make grants to eligible enti-
21 ties for the purpose of enabling such entities to develop,
22 monitor, and evaluate information concerning quality can-
23 cer care in cancer survivorship.

1 “(b) ELIGIBLE ENTITIES.—An entity shall be eligible
2 for a grant under this section for a fiscal year if such enti-
3 ty—

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

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

13 “(c) CONTRACTING AUTHORITY.—In carrying the
14 purpose described in subsection (a), an eligible entity may
15 expend a grant under such subsection to enter into con-
16 tracts with academic institutions, cancer centers, and
17 other entities, when determined appropriate by the Sec-
18 retary.

19 “(d) APPLICATION.—To be eligible for a grant under
20 subsection (a), an eligible entity shall submit to the Sec-
21 retary an application at such time, in such manner, and
22 containing such agreements, assurances, and information
23 as the Secretary determines to be necessary to carry out
24 this section.

1 “(e) AUTHORITY OF SECRETARY REGARDING USE OF
2 GRANT FUNDS.—The Secretary shall determine the ap-
3 propriate uses of grant funds under subsection (a) to
4 achieve the purpose described in such subsection.

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

9 **“SEC. 417E-7. CANCER CARE GUIDELINES.**

10 “The National Cancer Institute shall regularly con-
11 vene cancer experts, cancer care providers, practicing
12 oncologists, patients, representatives of disparity popu-
13 lations, and other relevant experts and organizations, in-
14 cluding representatives of the Agency for Healthcare Re-
15 search and Quality, the Health Resources Administration,
16 and the Centers for Disease Control and Prevention, to
17 coordinate the development and regularly update—

18 “(1) consensus protocols and guidelines for op-
19 timal cancer treatments and prevention, including
20 palliation, symptom management, and end-of-life
21 care; and

22 “(2) guidelines for providing patients with mul-
23 tidisciplinary consultation before treatment is initi-
24 ated to provide overall coordination and management

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

3 **“SEC. 417E-8. OTHER ACTIVITIES TO IMPROVE OUTCOMES**
4 **OF CANCER CARE.**

5 “(a) IN GENERAL.—

6 “(1) RESEARCH.—The Director of the Insti-
7 tute, in consultation with the entities described in
8 section 417E-8, shall conduct and support research
9 and other activities to build an evidence base regard-
10 ing effective clinical and organizational intervention
11 strategies to improve the quality and outcomes of
12 cancer care, and access to such care, at all stages
13 of the health care continuum.

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

21 “(b) SPECIFIC REQUIREMENTS.—The Director of the
22 Institute shall—

23 “(1) ensure the targeted dissemination of the
24 most current scientific evidence in appropriate for-
25 mats for use by organizations representing cancer

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

5 “(2) develop effective strategies to facilitate pa-
6 tient communication with health care providers re-
7 garding such protocols and guidelines and to ensure
8 overall coordination and management of cancer care
9 by providers.

10 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
11 is authorized to be appropriated to carry out this section
12 such sums as may be necessary for each of fiscal years
13 2007 through 2011.”.

14 **SEC. 104. NATIONAL INSTITUTE FOR ENVIRONMENTAL**
15 **HEALTH SCIENCES.**

16 (a) IN GENERAL.—Not later than 6 months after the
17 date of enactment of this Act, the Director of the National
18 Institute for Environmental Health Sciences shall, in co-
19 ordination with the National Cancer Institute, prepare
20 and submit to the Secretary of Health and Human Serv-
21 ices a strategic plan that identifies the unmet needs,
22 progress goals and benchmarks, and the level of funding
23 necessary for research on environmental risk factors for
24 cancer and gene-environment interactions.

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

4 **SEC. 105. NATIONAL CENTER ON MINORITY HEALTH AND**
5 **HEALTH DISPARITIES.**

6 Not later than 6 months after the date of enactment
7 of this Act, the Director of the National Cancer Institute,
8 in coordination with the National Center on Minority
9 Health and Health Disparities, shall prepare a strategic
10 plan that identifies progress goals, benchmarks, and need-
11 ed resources for research on disparities in cancer treat-
12 ment, control, and prevention.

13 **SEC. 106. COMPREHENSIVE CANCER CONTROL PLANS.**

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

16 (1) in the first sentence, by inserting “, for sur-
17 vivorship,” after “treatment of cancer”;

18 (2) in paragraph (1)(B), by striking “cancer
19 patients” and all that follows and inserting the fol-
20 lowing: “cancer patients, families of cancer patients,
21 and cancer survivors, and”; and

22 (3) in paragraph (3), by inserting “and con-
23 cerning cancer survivorship programs,” after “con-
24 trol of cancer”.

1 **SEC. 107. LUNG CANCER EARLY DETECTION AND RE-**
2 **SEARCH DEMONSTRATION PROJECT.**

3 Title XV of the Public Health Service Act (42 U.S.C.
4 300k et seq.) is amended by adding at the end the fol-
5 lowing:

6 **“SEC. 1511. LUNG CANCER EARLY DETECTION AND RE-**
7 **SEARCH DEMONSTRATION PROJECT.**

8 “(a) IN GENERAL.—The Secretary, acting through
9 the Director of the Centers for Disease Control and Pre-
10 vention, shall award not less than 10 competitive grants
11 to public and non-profit private entities to enable such en-
12 tities to establish demonstration programs pursuant to the
13 general authority under title III to carry out lung cancer
14 early detection and research activities using Computer To-
15 mography (CT) scanning within a high risk population
16 utilizing the comprehensive protocol that encompasses pre-
17 diagnosis and post-diagnosis, that was developed under
18 the best published clinical practices, and that was estab-
19 lished by the multi-institutional, multi-disciplinary re-
20 search program initiated in the year 1993. Such dem-
21 onstration programs shall continue and enhance the re-
22 search initiated by such protocol into all aspects of early
23 detection and disease management, the incorporation of
24 technological advances in imaging and the development of
25 computer assisted diagnostic tools, and shall include the
26 provision of appropriate referral and case management for

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

6 “(b) REQUIREMENTS.—

7 “(1) IN GENERAL.—To be eligible for a grant
8 under this section, an entity shall agree to adopt the
9 protocol as defined in subsection (a) for the selection
10 of participants in the program funded under the
11 grant, the scanning equipment used in such pro-
12 gram, the personnel involved in the scanning and di-
13 agnoses provided under such program, the method of
14 diagnosing used in the program, the scans utilized
15 under the program, and the follow-up procedures
16 used under such program.

17 “(2) COLLECTION OF IMAGING DATA.—To be
18 eligible for a grant under this section, an entity shall
19 agree to collect, transmit, and preserve imaging data
20 as required under the protocol as defined in sub-
21 section (a). Prior to such collection, transmission,
22 and preservation of imaging data, patient consent
23 shall be obtained from participating entities as de-
24 fined by subsection (a).

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

8 “(A) under any State compensation pro-
9 gram, under an insurance policy, or under any
10 Federal or State health benefits program; or

11 “(B) by an entity that provides health
12 service on a prepaid basis.

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

15 “(A) establish such fiscal control and fund
16 accounting procedures as may be necessary to
17 ensure proper disbursement of, and accounting for,
18 amounts received under this section; and

19 “(B) provide agreed upon annual reports
20 to the Secretary or the Comptroller General of
21 the United States for the purposes of auditing
22 the expenditures of the entity.

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

1 to the Secretary such reports as the Secretary deems
2 appropriate.

3 “(c) DEFINITION.—In this section, the term ‘high
4 risk population’ means those individuals over the age of
5 50 with a smoking history of 20 pack years or a family
6 history of lung cancer, or those individuals whose occupa-
7 tion or military service exposed them to asbestos, Agent
8 Orange and other herbicides, beryllium, radon, nuclear
9 fuels or waste, or other lung cancer carcinogens.

10 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
11 is authorized to be appropriated to carry out this section
12 such sums as may be necessary for each of the fiscal years
13 2007 through 2011.”.

14 **SEC. 108. COLORECTAL CANCER SCREENING.**

15 Title XV of the Public Health Service Act (42 U.S.C.
16 300k et seq.), as amended by section 106, is further
17 amended by adding at the end the following:

18 **“SEC. 1512. COLORECTAL CANCER SCREENING DEM-**
19 **ONSTRATION PROJECT.**

20 “(a) IN GENERAL.—The Secretary, acting through
21 the Director of the Centers for Disease Control and Pre-
22 vention, shall award competitive grants to public and non-
23 profit private entities to enable such entities to establish
24 demonstration programs pursuant to the general authority

1 of title III to carry out colorectal screening activities in-
2 cluding—

3 “(1) screening asymptomatic individuals for
4 colorectal cancer as a preventive health measure ac-
5 cording to scientific evidence-based screening guide-
6 lines;

7 “(2) providing the full continuum of cancer care
8 for individuals screened pursuant to this section and
9 to ensure the appropriate follow-up services for ab-
10 normal tests, diagnostic and therapeutic services,
11 and treatment for detected cancers, subject to the
12 requirements of subsection (c)(2);

13 “(3) activities to improve the education, train-
14 ing, and skills of health professionals (including al-
15 lied health professionals) in the detection and con-
16 trol of colorectal cancer;

17 “(4) activities to evaluate the programs under
18 this section through appropriate surveillance or pro-
19 gram monitoring activities;

20 “(5) the development and dissemination of find-
21 ings derived through such evaluations through public
22 and professional education; and

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

1 “(b) USE OF CERTAIN STANDARDS UNDER MEDI-
2 CARE PROGRAM.—A grant may be awarded under sub-
3 section (a) only if the applicant involved agrees that—

4 “(1) screenings under subsection (a)(1) will be
5 carried out as preventive health measures in accord-
6 ance with evidence-based screening procedures as
7 specified in section 1861(pp)(1) of the Social Secu-
8 rity Act;

9 “(2) an individual will be considered high risk
10 for purposes of subsection (a)(1)(B)(ii) only if the
11 individual is high risk within the meaning of section
12 1861(pp)(2) of such Act; and

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

19 “(c) REQUIREMENTS.—

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

24 “(A) individual who is at least 50 years of
25 age; or

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

5 “(2) RELATIONSHIP TO ITEMS AND SERVICES
6 UNDER OTHER PROGRAMS.—To be eligible for a
7 grant under subsection (a), an entity shall agree
8 that grant funds will not be expended to make pay-
9 ments for any item or service to the extent that pay-
10 ment has been made, or can reasonably be expected
11 to be made, with respect to such item or service—

12 “(A) under any State compensation pro-
13 gram, under an insurance policy, or under any
14 Federal or State health benefits program; or

15 “(B) by an entity that provides health
16 service on a prepaid basis.

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

20 “(A) establish such fiscal control and fund
21 accounting procedures as may be necessary to
22 ensure proper disbursement of, and accounting for,
23 amounts received under this section; and

24 “(B) provide agreed upon annual reports
25 to the Secretary or the Comptroller General of

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

3 “(4) REPORTS.—To be eligible for a grant
4 under subsection (a), an entity shall agree to submit
5 to the Secretary such reports as the Secretary deter-
6 mines appropriate.

7 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
8 is authorized to be appropriated to carry out this section,
9 such sums as may be necessary for each of the fiscal years
10 2007 through 2011.”.

11 **SEC. 109. NATIONAL PROGRAM OF CANCER REGISTRIES.**

12 Part M of title III of the Public Health Service Act
13 (42 U.S.C. 280e et seq.) is amended by inserting after
14 section 399B the following:

15 **“SEC. 399B-1. ENHANCING CANCER REGISTRIES AND PRE-**
16 **PARING FOR THE FUTURE.**

17 “Not later than 1 year after the date of enactment
18 of the National Cancer Act of 2007 the Secretary shall
19 develop a plan and submit a report to Congress that out-
20 lines strategies by which the State cancer registries funded
21 with grants under section 399B and the Surveillance, Epi-
22 demiology, and End Results program of the National Can-
23 cer Institute (in this section referred to as the ‘SEER pro-
24 gram’) can share information to ensure more comprehen-

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

3 “(1) standardize data between State cancer reg-
4 istries and the SEER program;

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

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

10 “(4) maximize the use of State registry data
11 and data from the SEER program in State and re-
12 gional public health planning processes; and

13 “(5) promote the use of data to—

14 “(A) improve the health status of cancer
15 survivors; and

16 “(B) research quality of cancer care and
17 access to that care.

18 **“SEC. 399B-2. NATIONAL CHILDHOOD CANCER REGISTRY.**

19 “(a) IN GENERAL.—The Director of the National In-
20 stitute of Health (in this section referred to as the ‘Direc-
21 tor’) shall, through the awarding of a grant to, or contract
22 or cooperative agreement with, support the existing Na-
23 tional Cancer Institute-designated multi-center national
24 infrastructure for collaborative pediatric cancer research
25 to support a national population-based childhood cancer

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

3 “(1) formalize the consent process by which pe-
4 diatric cancer patients enroll on to a clinical trial or
5 receive treatment within the multi-center infrastruc-
6 ture;

7 “(2) conduct non-therapeutic studies, monitor
8 and evaluate the incidence, survival rate, and long-
9 term health outcomes of childhood cancer patients,
10 develop information concerning best practices in pe-
11 diatric cancer care; and

12 “(3) evaluate the quality of pediatric cancer
13 care, and monitor long-term pediatric cancer survi-
14 vorship.

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

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

22 **SEC. 110. OTHER TRANSACTIONS AUTHORITY.**

23 Section 402(i) of the Public Health Service Act (42
24 U.S.C. 282(i)) is amended by adding at the end the fol-
25 lowing:

1 “(4) Notwithstanding any other provision of law, the
2 Director of the National Cancer Institute may use
3 amounts appropriated under section 417B(a) to enter into
4 transactions (other than contracts, cooperative agree-
5 ments, or grants) to carry out research in support of the
6 development of advanced technologies leading to the expe-
7 dited delivery of clinical products to benefit the cancer pa-
8 tient.”.

9 **TITLE II—EXPANDING ACCESS**
10 **TO CANCER DRUGS AND**
11 **TREATMENT**

12 **SEC. 201. DRUGS TO PREVENT CANCER.**

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

16 **“Subtitle G—Chemoprevention**
17 **Drugs**

18 **“SEC. 581. RECOMMENDATIONS FOR INVESTIGATIONS OF**
19 **CHEMOPREVENTION DRUGS.**

20 “(a) IN GENERAL.—The sponsor of a
21 chemoprevention drug in the States may request the Sec-
22 retary to provide written recommendations for the nonclin-
23 ical and clinical investigations which must be conducted
24 with the drug before—

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

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

7 If the Secretary has reason to believe that a drug for
8 which a request is made under this section is a
9 chemoprevention drug, the Secretary shall provide the per-
10 son making the request written recommendations for the
11 nonclinical and clinical investigations which the Secretary
12 believes, on the basis of information available to the Sec-
13 retary at the time of the request under this section, would
14 be necessary for approval under section 505 or licensing
15 under section 351 of the Public Health Service Act of such
16 chemoprevention drug for the high-risk condition that
17 such drug is designed to treat.

18 “(b) REGULATIONS.—The Secretary shall by regula-
19 tion promulgate procedures for the implementation of sub-
20 section (a).

21 **“SEC. 582. DESIGNATION OF CHEMOPREVENTION DRUGS.**

22 “(a) DESIGNATION.—

23 “(1) IN GENERAL.—The manufacturer or the
24 sponsor of a drug may request the Secretary to des-
25 ignate the drug as a chemoprevention drug. A re-

1 quest for designation of a drug shall be made before
2 the submission of an application under section
3 505(b) for the drug or the submission of an applica-
4 tion for licensing of the drug under section 351 of
5 the Public Health Service Act. If the Secretary finds
6 that a drug for which a request is submitted under
7 this subsection is a chemoprevention drug that is
8 being or will be investigated for a high-risk condition
9 and—

10 “(A) if an application for such drug is ap-
11 proved under section 505; or

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

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

23 “(2) DEFINITIONS.—In this subtitle:

1 “(A) CHEMOPREVENTION DRUG.—The
2 term ‘chemoprevention drug’ means a drug de-
3 signed to treat a high-risk condition.

4 “(B) HIGH-RISK CONDITION.—The term
5 ‘high-risk condition’ means a medical condition
6 that—

7 “(i) has been diagnosed in individuals
8 who have not been diagnosed with cancer
9 or who do not currently have progressive,
10 life-threatening cancer; and

11 “(ii) unless treated, could develop into
12 progressive and life-threatening cancer

13 “(C) DETERMINATION.—Determinations
14 under subparagraphs (A) and (B) with respect
15 to any drug shall be made on the basis of the
16 facts and circumstances as of the date the re-
17 quest for designation of the drug under this
18 subsection is made.

19 “(b) CONDITIONS OF DESIGNATION.—A designation
20 of a drug under subsection (a) shall be subject to the con-
21 dition that—

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

1 the Secretary of any discontinuance of the produc-
2 tion of the drug at least 1 year before discontinu-
3 ance; and

4 “(2) if an application has not been approved for
5 the drug under section 505(b) or a license has not
6 been issued for the drug under section 351 of the
7 Public Health Service Act and if preclinical inves-
8 tigations or investigations under section 505(i) are
9 being conducted with the drug, the manufacturer or
10 sponsor of the drug will notify the Secretary of any
11 decision to discontinue active pursuit of approval of
12 an application under section 505(b) or approval of
13 a license under section 351 of the Public Health
14 Service Act.

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

18 “(d) REGULATIONS.—The Secretary shall by regula-
19 tion promulgate procedures for the implementation of sub-
20 section (a).

21 **“SEC. 583. PROTECTION FOR CHEMOPREVENTION DRUGS.**

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

24 “(1) approves an application filed pursuant to
25 section 505(b); or

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

14 “(b) OTHER APPLICATION APPROVAL.—If an appli-
15 cation filed pursuant to section 505(b) is approved for a
16 drug designated as a chemoprevention drug under section
17 582 or if a license is issued under section 351 of the Public
18 Health Service Act for such a drug, the Secretary may,
19 during the 7-year period beginning on the date of the ap-
20 plication approval or of the issuance of the license, approve
21 another application under section 505(b) or issue a license
22 under section 351 of the Public Health Service Act, for
23 such drug for the high-risk condition that such drug is
24 designated for a person who is not the holder of such ap-
25 proved application or of such license if—

1 “(1) the Secretary finds, after providing the
2 holder notice and opportunity for the submission of
3 views, that in such period the holder of the approved
4 application or of the license cannot assure the avail-
5 ability of sufficient quantities of the drug to meet
6 the needs of persons with such high-risk condition
7 for which the drug was designated; or

8 “(2) such holder provides the Secretary in writ-
9 ing the consent of such holder for the approval of
10 other applications or the issuance of other licenses
11 before the expiration of such 7-year period.

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

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

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

6 “(2)(A) if the drug is the subject of—

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

11 “(ii) a listed patent for which a certifi-
12 cation has been submitted under subsections
13 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section
14 505,

15 the period during which an application may not
16 be approved under section 505(c)(3) or section
17 505(j)(5)(B) shall be extended by a period of
18 seven years after the date the patent expires
19 (including any patent extensions); or

20 “(B) if the drug is the subject of a listed patent
21 for which a certification has been submitted under
22 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-
23 tion 505, and in the patent infringement litigation
24 resulting from the certification the court determines
25 that the patent is valid and would be infringed, the

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

6 “(3) with respect to a drug that is so des-
7 ignated that is also subject to market exclusivity ex-
8 tension under section 505A, the extension of the pe-
9 riods described under paragraphs (1) and (2) of this
10 subsection shall be increased by six months in ac-
11 cordance with such section 505A.

12 **“SEC. 584. OPEN PROTOCOLS FOR INVESTIGATIONS OF**
13 **CHEMOPREVENTION DRUGS.**

14 “If a drug is designated under section 582 as a
15 chemoprevention drug and if notice of a claimed exemption
16 under section 505(i) or regulations issued thereunder is
17 filed for such drug, the Secretary shall encourage the
18 sponsor of such drug to design protocols for clinical inves-
19 tigations of the drug which may be conducted under the
20 exemption to permit the addition to the investigations of
21 persons with the high-risk condition for which such drug
22 was designated.”.

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

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

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

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

9 (C) defraying the costs of developing
10 chemoprevention foods.

11 (2) DEFINITIONS.—For purposes of this sub-
12 section:

13 (A) CHEMOPREVENTION DEVICE.—The
14 term “chemoprevention device” means a device
15 to be approved to treat a high-risk condition.

16 (B) CHEMOPREVENTION DRUG.—The term
17 “chemoprevention drug” means a drug designed
18 to treat a high-risk condition.

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

1 based on recognized scientific principles, are es-
2 tablished by medical evaluation.

3 (D) HIGH-RISK CONDITION.—

4 (i) IN GENERAL.—The term “high-
5 risk condition” means, with respect to a
6 chemoprevention drug, chemoprevention
7 device, or chemoprevention food, a medical
8 condition that—

9 (I) has been diagnosed in individ-
10 uals who have not been diagnosed
11 with cancer or who do not currently
12 have progressive, life-threatening can-
13 cer; and

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

17 (ii) DETERMINATION.—Determina-
18 tions under this subparagraph with respect
19 to any drug, device, or food shall be made
20 on the basis of the facts and circumstances
21 as of the date the request for designation
22 of the drug or food under section 582 of
23 the Federal Food, Drug, and Cosmetic Act
24 is made.

1 (E) QUALIFIED TESTING.—The term
2 “qualified testing” means—

3 (i) human clinical testing—

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

9 (II) which occurs after the date
10 such drug is designated under section
11 582 of such Act (as added by sub-
12 section (a)) and before the date on
13 which an application with respect to
14 such drug is submitted under section
15 505(b) of such Act (21 U.S.C.
16 355(b)) or under section 351 of the
17 Public Health Service Act (42 U.S.C.
18 292); and

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

1 (3) AUTHORIZATION OF APPROPRIATIONS.—

2 There is authorized to be appropriated to carry out
3 this section such sums as may be necessary for each
4 of fiscal years 2008 through 2010.

5 (c) STUDIES.—

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

21 (2) CHEMOPREVENTION PRODUCTS.—The Di-
22 rector of the Institute of Medicine shall conduct a
23 study to measure the quality and quantity of
24 chemoprevention products resulting from the appli-
25 cation of subpart G of chapter V of the Federal

1 Food, Drug, and Cosmetic Act to drugs, medical de-
2 vices, and medical foods for which such drugs, de-
3 vices, and foods are designated, or to all.

4 (d) CHEMOPREVENTION PRODUCTS BOARD.—Part A
5 of title II of the Public Health Service Act (42 U.S.C.
6 202 et seq.) is amended by adding at the end the fol-
7 lowing:

8 **“SEC. 229. CHEMOPREVENTION PRODUCTS BOARD.**

9 “(a) IN GENERAL.—There is established in the De-
10 partment of Health and Human Services a board for the
11 development of chemoprevention drugs (including bio-
12 logics) and devices (including diagnostic products), to be
13 known as the Chemoprevention Products Board (referred
14 to in this section as the ‘Board’). The Board shall be com-
15 prised of the Assistant Secretary for Health of the Depart-
16 ment of Health and Human Services and representatives,
17 selected by the Secretary, of the Food and Drug Adminis-
18 tration, the National Institutes Health, the Centers for
19 Disease Control and Prevention, and any other Federal
20 department or agency which the Secretary determines has
21 activities relating to chemoprevention drugs and devices.
22 The Assistant Secretary for Health shall chair the Board.

23 “(b) DEFINITIONS.—In this section:

24 “(1) CHEMOPREVENTION DEVICE.—The term
25 ‘chemoprevention device’ has the meaning given such

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

3 “(2) CHEMOPREVENTION DRUG.—The term
4 ‘chemoprevention drug’ has the meaning given such
5 term in section 582 of the Federal Food, Drug, and
6 Cosmetic Act.

7 “(3) HIGH-RISK CONDITION.—The term ‘high-
8 risk condition’ has the meaning given such term in
9 section 582 of the Federal Food, Drug, and Cos-
10 metic Act.

11 “(c) FUNCTION.—The function of the Board shall be
12 to promote the development of chemoprevention drugs and
13 devices and the coordination among Federal, other public,
14 and private agencies in carrying out their respective func-
15 tions relating to the development of such articles for such
16 drugs to treat high-risk conditions.

17 “(d) DUTIES.—In the case of chemoprevention drugs,
18 the Board shall—

19 “(1) evaluate—

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

23 “(B) the implementation of such sub-
24 chapter; and

1 “(2) evaluate the activities of the National In-
2 stitutes of Health and the Alcohol, Drug Abuse, and
3 Mental Health Administration for the development
4 of such drugs for high-risk conditions;

5 “(3) assure appropriate coordination among the
6 Food and Drug Administration, the National Insti-
7 tutes of Health, the Alcohol, Drug Abuse, and Men-
8 tal Health Administration, and the Centers for Dis-
9 ease Control and Prevention in the carrying out of
10 their respective functions relating to the development
11 of drugs for high-risk conditions to assure that the
12 activities of each agency are complementary;

13 “(4) assure appropriate coordination among all
14 interested Federal agencies, manufacturers, and or-
15 ganizations representing patients, in their activities
16 relating to such drugs;

17 “(5) with the consent of the sponsor of a
18 chemoprevention drug exempt under section 505(i)
19 of the Federal Food, Drug, and Cosmetic Act or
20 regulations issued under such section, inform physi-
21 cians and the public respecting the availability of
22 such drug for the high-risk condition for which it is
23 designated under section 582 of such Act and in-
24 form physicians and the public respecting the avail-
25 ability of drugs approved under section 505(c) of

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

3 “(6) seek business entities and others to under-
4 take the sponsorship of chemoprevention drugs, seek
5 investigators to facilitate the development of such
6 drugs, and seek business entities to participate in
7 the distribution of such drugs;

8 “(7) reorganize and incentivize collaborative ef-
9 forts between public and private entities and efforts
10 by individuals seeking the development of
11 chemoprevention drugs in developing such drugs;
12 and

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

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

20 “(f) ANNUAL REPORT.—

21 “(1) IN GENERAL.—Not later than June 1 of
22 each year, the Board shall submit to the Committee
23 on Health, Education, Labor and Pensions of the
24 Senate and the Committee on Energy and Com-
25 merce of the House of Representatives an annual re-

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

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

7 “(B) describes the activities of the Board;
8 and

9 “(C) contains the results of the evaluations
10 carried out by the Board.

11 “(2) ADDITIONAL INFORMATION FOR INCLU-
12 SION IN ANNUAL REPORT.—

13 “(A) RESEARCH ACTIVITIES.—The Direc-
14 tor of the National Institutes of Health and the
15 Administrator of the Alcohol, Drug Abuse, and
16 Mental Health Administration shall submit to
17 the Board for inclusion in the annual report
18 under paragraph (1) a report on the
19 chemoprevention research activities of the Insti-
20 tutes of the National Institutes of Health and
21 the Alcohol, Drug Abuse, and Mental Health
22 Administration.

23 “(B) EFFECT OF PROVISIONS.—The Sec-
24 retary shall submit to the Board for inclusion
25 in the annual report under paragraph (1) a re-

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

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

6 (1) adequate chemoprevention drugs have not
7 been developed;

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

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

16 **SEC. 202. COMPASSIONATE ACCESS TO INVESTIGATIONAL**
17 **DRUGS AND DEVICES.**

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

21 “(f) ONCOLOGIC COMPASSIONATE ACCESS PRO-
22 GRAM.—Acting under the existing expanded access pro-
23 gram, the Secretary shall establish a new program to ex-
24 pand access to investigational treatments for individuals
25 diagnosed with cancer who have exhausted all treatment

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

11 “(1) describes such compassionate access pro-
12 grams for investigational drugs, biological products,
13 and devices intended to treat cancer;

14 “(2) facilitates the provision of investigational
15 drugs and devices to seriously ill cancer patients
16 without unreasonable delay by recognizing that the
17 use of available investigational products for treat-
18 ment is the responsibility of the physician and the
19 patient; and

20 “(3) facilitates the contribution of safety and
21 efficacy data of investigational treatments from par-
22 ticipants in such compassionate access program.

23 “(g) IMPLEMENTATION OF COMPASSIONATE ACCESS
24 PROGRAMS.—

1 “(B) individual risk for cancer-related con-
2 ditions for which there exist unmet medical
3 needs;

4 “(2) request the Institute of Medicine to under-
5 take a study to identify validated surrogate
6 endpoints and biomarkers, which shall include med-
7 ical images, and recommend research to validate
8 such surrogate endpoints and biomarkers, that may
9 support approvals for products intended for the
10 treatment of cancer;

11 “(3) request the Institute of Medicine to under-
12 take a study to evaluate the practicality of expand-
13 ing the use of large, community-based simple trials
14 designed to identify product safety and efficacy in a
15 larger and more representative patient population of
16 individuals diagnosed with cancer prior to approving
17 the product for widespread use; and

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

22 (c) CONFORMING AMENDMENT.—Section 561(c) of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 360bbb(c)) is amended by striking the heading and insert-

1 ing “COMPASSIONATE ACCESS TO INVESTIGATIONAL
2 DRUGS AND DEVICES FOR CANCER PATIENTS.—”.

3 **SEC. 203. ONCOLOGY DRUGS ADVISORY COMMITTEE.**

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

7 **“SEC. 566. MEMBERSHIP OF ONCOLOGY DRUGS ADVISORY
8 COMMITTEE.**

9 “Membership of the Oncology Drugs Advisory Com-
10 mittee of the Food and Drug Administration shall consist
11 of no less than 2 patient representatives who are voting
12 members of the committee.”.

13 **SEC. 204. TECHNICAL AMENDMENT.**

14 Section 526(a)(2) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 360bb(a)(2)) is amended by in-
16 serting “or targets and mechanisms of pathogenesis of dis-
17 eases” after “disease or condition”.

18 **TITLE III—PAYMENTS FOR CAN-
19 CER-RELATED SERVICES AND
20 PRODUCTS**

21 **SEC. 301. COORDINATING CANCER CARE FOR PATIENTS.**

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

1 “CANCER COVERAGE REQUIREMENTS

2 “SEC. 1849. (a) IN GENERAL.—The following provi-
3 sions shall apply to a participating cancer care coordinator
4 treating an individuals who has been diagnosed with can-
5 cer and who is covered under the insurance program es-
6 tablished under this part.

7 “(b) DEFINITIONS.—In this section:

8 “(1) CANCER CARE COORDINATOR.—

9 “(A) IN GENERAL.—The term ‘cancer care
10 coordinator’ means, with respect to items or
11 services provided under the coverage related to
12 the treatment of cancer, a lead managing physi-
13 cian, nurse practitioner with an oncology certifi-
14 cation (as provided by a nationally accredited
15 organization), or registered nurse (as provided
16 by a nationally accredited organization) that is
17 designated at the time of cancer diagnosis by
18 the provider, in consultation with the partici-
19 pant or beneficiary, and other providers in-
20 volved to provide for the overall coordination
21 and management of the cancer care of the indi-
22 vidual among all providers who provide items or
23 services to the individual, and who otherwise
24 meet the requirements of this paragraph.

1 “(B) RESPONSIBILITIES.—A designee
2 under subparagraph (A) shall be responsible for
3 the overall coordination and management of the
4 medical, nursing, and other health services pro-
5 vided to the individual during the period in
6 which the individual is undergoing treatment
7 for such cancer.

8 “(C) COORDINATION AND MANAGEMENT.—

9 “(i) IN GENERAL.—The overall co-
10 ordination and management under sub-
11 paragraph (A) shall include the develop-
12 ment of a plan of care that—

13 “(I) details, to the greatest ex-
14 tent practicable, all aspects of the
15 care to be provided to the individual,
16 with respect to the treatment of such
17 cancer, including any curative treat-
18 ment and comprehensive symptom
19 management (such as palliative care)
20 involved;

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

1 on which the individual is so diag-
2 nosed;

3 “(III) is furnished in a form that
4 is appropriate for use by disparity
5 populations, to the extent practicable;
6 and

7 “(IV) is in accordance with
8 standards determined by the Sec-
9 retary to be appropriate;

10 “(ii) COVERED INDIVIDUAL.—With re-
11 spect to an individual for whom the plan of
12 care has been developed under clause (i),
13 such plan shall be revised as necessary to
14 account for any substantial change in the
15 condition of the individual, if such revi-
16 sion—

17 “(I) is in accordance with sub-
18 clauses (I) and (III) of such clause;
19 and

20 “(II) is furnished in written form
21 to the individual within a period speci-
22 fied by the Secretary that is as soon
23 as practicable after the date of such
24 revision.

1 “(iii) FOLLOW-UP PLAN.—With re-
2 spect to an individual who has completed
3 the primary treatment for cancer, as de-
4 fined by the Secretary (such as completion
5 of chemotherapy or radiation treatment),
6 the development of a follow-up cancer care
7 plan that—

8 “(I) describes the elements of the
9 primary treatment, including symp-
10 tom management, furnished to such
11 individual;

12 “(II) provides recommendations
13 for the subsequent care of the indi-
14 vidual with respect to the cancer in-
15 volved;

16 “(III) is furnished in written
17 form to the individual in person with-
18 in a period specified by the Secretary
19 that is as soon as practicable after the
20 completion of such primary treatment;

21 “(IV) is furnished in a form that
22 is appropriate for use by disparity
23 populations to the extent practicable;
24 and

1 “(V) is in accordance with stand-
2 ards determined by the Secretary to
3 be appropriate.

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

11 “(I) is in accordance with sub-
12 clauses (I), (II), and (IV) of such
13 clause; and

14 “(II) is furnished in written form
15 to the individual within a period speci-
16 fied by the Secretary that is as soon
17 as practicable after the date of such
18 revision.

19 “(D) STANDARDS.—The Secretary shall
20 establish standards to carry out this paragraph
21 in consultation with appropriate organizations
22 that represent providers of services related to
23 cancer treatment and organizations rep-
24 resenting survivors of cancer. Such standards
25 shall include standards for determining the

1 need and frequency for revisions of the plans of
2 care and follow-up plans based on changes in
3 the condition of the individual and standards
4 for the communication of the plan to the pa-
5 tient.

6 “(2) INDIVIDUAL.—The term ‘individual’ means
7 a person who has been diagnosed with cancer and
8 who is covered under the insurance program estab-
9 lished under this part.”.

10 (b) ADDITIONAL PAYMENT.—Section 1833(m) of the
11 Social Security Act (42 U.S.C. 1395 l(m)) is amended by
12 adding at the end the following new paragraph:

13 “(5) In the case of physician or nursing services
14 furnished to an individual under this section who re-
15 ceives care for such cancer, there shall be paid to the
16 cancer care coordinator of that individual during the
17 period in which that individual is undergoing treat-
18 ment for such cancer from the Federal Supple-
19 mentary Medical Insurance Trust Fund, a separate
20 and additional payment amount for the services
21 under this part in addition to any amount otherwise
22 paid under this part.”.

1 **SEC. 302. ELIMINATION OF OPTIONAL EXCLUSION FROM**
2 **MEDICAID PRESCRIPTION DRUG COVERAGE**
3 **FOR TOBACCO CESSATION MEDICATIONS.**

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

6 (1) by striking subparagraph (E);

7 (2) by redesignating subparagraphs (F)
8 through (K) as subparagraphs (E) through (J), re-
9 spectively; and

10 (3) in subparagraph (F) (as redesignated by
11 paragraph (2)), by inserting before the period at the
12 end the following: “, other than agents approved by
13 the Food and Drug Administration for purposes of
14 promoting, and when used to promote, tobacco ces-
15 sation”.

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

1 **TITLE IV—PROMOTING BIO-**
2 **SPECIMEN COLLECTION TO**
3 **ACCELERATE THE GENOMIC**
4 **MAPPING OF THE MOST LE-**
5 **THAL CANCERS**

6 **SEC. 401. ADOPTION OF NATIONAL CANCER INSTITUTE**
7 **GUIDELINES FOR BIOREPOSITORIES.**

8 (a) IN GENERAL.—A biorepository may adopt the
9 First-Generation Guidelines for NCI-Supported Biospeci-
10 men Resources, published by the National Cancer Insti-
11 tute of the National Institutes of Health on November 21,
12 2006 (or any successor guidelines), for the collection of
13 biospecimens and any accompanying data.

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

15 (1) BIOREPOSITORY.—The term “bioreposi-
16 tory” means a collection of biological materials
17 (which may include tissues, biomolecules, body
18 fluids, and medical imaging) derived from patients,
19 stored under specifically-defined conditions, and
20 accessed for the purpose of scientific research or pa-
21 tient care.

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

1 **SEC. 402. MEDPAC REPORT ON PAYMENTS FOR SPECIMEN**
2 **COLLECTION.**

3 (a) IN GENERAL.—Not later than 1 year after the
4 date of enactment of this Act, the Medicare Payment As-
5 sessment Commission shall submit to Congress a report
6 (in this section referred to as the “report”) on approaches
7 to developing a payment system within Medicare for the
8 collection and storage of cancer and related tissues for use
9 in research involving the application of genomic or
10 proteomic technologies.

11 (b) REPORT DETAILS.—

12 (1) IN GENERAL.—The report shall include rec-
13 ommendations on the following:

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

17 (B) Potential payment systems for the col-
18 lection, storage, and pathological definition of
19 cancer and related tissues.

20 (C) The feasibility of expanding the rec-
21 ommended payment system to cover tissue col-
22 lection, storage, and pathological definition for
23 research on conditions unrelated to cancer.

24 (2) PAYMENT SYSTEMS.—Proposed payment
25 systems referred to in paragraph (1)(B) shall con-
26 sider the following factors:

1 (A) Numbers and types of cancer tissues
2 collected for the purpose of research involving
3 the application of genomic or proteomic tech-
4 nologies.

5 (B) Professional time required for patholo-
6 gists, surgeons, other experts to collect these
7 tissues for post-genomics research.

8 (C) Specific annotation of collected tissue
9 required beyond normal diagnostic needs cur-
10 rently in practice.

11 (D) Numbers of tissues collected on gov-
12 ernment sponsored clinical trials and method of
13 coverage for the collection of these tissues.

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

16 (F) The cost of overseeing the standards
17 needed to ensure that the tissues collected for
18 molecular oncology research, including the cer-
19 tification and oversight by a qualified profes-
20 sional body.