107TH CONGRESS
2D SESSION

S. 2955

To improve data collection and dissemination, treatment, and research relating to cancer, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 18, 2002

Mr. BROWNBACK (for himself and Mr. GREGG) 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 improve data collection and dissemination, treatment, and research relating to 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.

This Act may be cited as the ''National Cancer Act of 2002''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) In 2002 an estimated 1,284,900 Americans will have been diagnosed with some form of cancer.

(2) In 2002 an estimated 555,500 Americans will die of cancer.

(3) In 2001 the National Institutes of Health estimated the overall cost of cancer at $156,700,000,000.

(4) The National Cancer Institute estimates that with the expected growth and aging of the United States population, expenditures for cancer treatment will nearly double over the next decade, rising to just under $100,000,000,000.

(5) In 2000, 62.6 percent of women over the age of 50 had received a mammogram in the preceding year. In 2002 an estimated 205,000 Americans will be newly diagnosed with breast cancer, and 40,000 will die of the disease.

(6) In 2000, 89 percent of women between the ages of 18 and 44 have received a pap test in the preceding 3 years. In 2002, an estimated 13,000 women will be newly diagnosed with cancer of the uterine cervix, and 4,100 women will die of the disease.

(7) In 1999, only 19.1 percent of adults 50 and older had received the recommended annual colon cancer screening within the preceding year, and only 32.2 percent had received a colonoscopy or

sigmoidoscopy in the preceding 5 years. In 2002, an estimated 148,300 Americans will be diagnosed with cancer of the colon and rectum and 56,600 will die of the disease.

(8) Older Americans are the most likely to be diagnosed with cancer. In order to ensure high quality cancer care for our Nation's seniors, medicare reimbursements must reflect the true cost of treatment in every treatment setting. Medicare payments should accurately reflect the cost of drug and biologics as well as the cost of administering drugs and supportive care and therapies.

(9) Despite an aging population, the rates of new cancer cases and deaths declined in the United States between 1990 and 1997.

(10) Despite an aging population, death rates for the 4 most common cancer sites—lung, colorectal, breast, and prostate continue to drop.

(11) Despite an aging population, 1997 marked the first time the total number of cancer deaths did not rise from the previous year.

(12) In May 2001, Gleevec, the first in what is expected to be a number of cancer treatments which rely on molecular targeting, was approved for use by the Food and Drug Administration. Gleevec appears

to be effective in stopping the growth of deadly Chronic Myeloid Leukemia cells within 3 months of use.

SEC. 3. SENSE OF THE SENATE.

It is the sense of the Senate that the United States is at a point in history in which we must take the proper steps to reach the goal of making cancer survivorship the rule and cancer deaths rare by the year 2015.

TITLE I—PUBLIC HEALTH PROVISIONS

SEC. 101. NATIONAL PROGRAM OF CANCER REGISTRIES.

(a) STRATEGIC PLAN.—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.

''(a) STRATEGIC PLAN.—

''(1) IN GENERAL.—The Secretary shall develop a plan 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 can share information to ensure more comprehensive cancer data.

''(2) REPORT.—Not later than 1 year after the date of enactment of this section, the Secretary shall submit to the appropriate committees of Congress a report—

''(A) outlining the capabilities and data collected by the State cancer registries funded with grants under section 399B;

''(B) outlining the capabilities and data collected by the Surveillance, Epidemiology, and End Results program of the National Cancer Institute; and

''(C) containing the plan described in paragraph (1).

''(b) PREPARING CANCER REGISTRIES FOR THE FUTURE.—

''(1) IN GENERAL.—The Secretary shall enter into a contract with the General Accounting Office for the completion of a study and report identifying specific indicators that State cancer registries should maintain and disseminate in order to ensure maximum usefulness for patients, advocates, health care providers, and researchers.

''(2) CONTENTS.—The study and report described in paragraph (1) shall—

''(A) examine studies conducted by the National Cancer Institute and the American Society of Clinical Oncology;

''(B) describe the hardware and software needed to collect and disseminate necessary registry data; and

''(C) examine strategies registries may take to ensure data collection from the greatest number of health care facilities possible.

''(3) REPORT.—Not later than 6 months after the date of enactment of this section the Secretary shall submit to Congress a report containing the results of the General Accounting Office study authorized under this section.''.

SEC. 102. ENHANCING EXISTING SCREENING EFFORTS.

(a) GRANT AND CONTRACT AUTHORITY OF STATES.—Section 1501(b)(2) of the Public Health Service Act (42 U.S.C. 300k(b)(2)) is amended to read as follows:

''(2) CERTAIN APPLICATIONS.—

''(A) STRATEGIES FOR COLORECTAL CANCER SCREENING.—If any entity submits an application to a State to receive an award of a grant or contract pursuant to paragraph (1) that includes strategies for colorectal cancer screening and outreach, the State may give pri-

ority to the application submitted by that entity in any case in which the State determines that the quality of such application is equivalent to the quality of the application submitted by the other entities.

''(B) WOMEN DIAGNOSED WITH CANCER.—If any entity submits an application to a State to receive an award of a grant or contract pursuant to paragraph (1) that includes strategies for the provision of treatment for uninsured women diagnosed with cancer discovered in the course of the screening, the State may give priority to the application submitted by that entity in any case in which the State determines that the quality of such application is equivalent to the quality of the application submitted by the other entities.''.

(b) BREAST AND CERVICAL CANCER PROGRAM.—Section 1510(a) of the Public Health Service Act (42 U.S.C. 300n–5(a)) is amended by striking ''for each of the fiscal years 1995 through 2003.'' and inserting ''for each of the fiscal years 2003 through 2007.''.

(c) REPORT ON THE COMPREHENSIVE COLORECTAL CANCER INITIATIVE.—Not later than 6 months after the date of enactment of this Act, the Director of the Centers

for Disease Control and Prevention shall submit to the appropriate committees of Congress a report containing—

(1) an assessment of the success of the Comprehensive Colorectal Cancer Initiative (within the Centers for Disease Control and Prevention) in—

(A) increasing public awareness of colorectal cancer;

(B) increasing awareness of screening guidelines among health care providers;

(C) monitoring national colorectal cancer screening rates;

(D) promoting increased patient-provider communication about colorectal cancer screening;

(E) supporting quantitative and qualitative research efforts; and

(F) providing funding to State programs to implement colorectal cancer priorities.

(2) recommendations about the resources needed by the Centers for Disease Control and Prevention in order to improve the areas described in paragraph (1).

SEC. 103. ENHANCE PAIN MANAGEMENT AND PALLIATIVE CARE FOR CANCER PATIENTS.

(a) PATIENT EDUCATION PROGRAM.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399O. PAIN MANAGEMENT AND PALLIATIVE CARE PROGRAM GRANTS AND STUDY.

''(a) GRANTS AUTHORIZED.—The Secretary is authorized to award grants to eligible entities to implement programs to educate patients and their families about the availability of effective medical techniques to reduce and prevent pain and suffering for those with cancer. Such programs shall focus on the entire course of cancer treatment and care.

''(b) APPLICATION.—An eligible entity desiring a grant under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

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

(b) PRACTITIONER EDUCATION PROGRAM.—Section 414 of the Public Health Service Act (42 U.S.C. 285a–3) is amended by adding at the end the following:

''(d) REQUIREMENT.—A center described under subsection (a) shall maintain a program for disseminating to

patients and research participants, as well as their caregivers, the latest information about pain and symptom management and palliative care in order to receive funding under this section.''.

(c) ELEVATING THE IMPORTANCE OF PAIN AND SYMPTOM MANAGEMENT THROUGHOUT THE NATION'S CANCER PROGRAMS.—

(1) NATIONAL CANCER PROGRAM.—Section 411 of the Public Health Service Act (42 U.S.C. 285a) is amended—

(A) by striking ''of (1) an expanded'' and inserting the following: ''of—

''(1) an expanded''; and

(B) by striking ''carcinogens'' and all that follows and inserting the following:

''(2) pain and symptom management for cancer patients; and

''(3) the other programs and activities of the Institute.''.

(2) CANCER CONTROL PROGRAMS.—Section 412(2) of the Public Health Service Act (42 U.S.C. 285a–1(2)) is amended—

(A) in subparagraph (A), by striking ''and'' at the end; and

(B) by adding at the end the following:

''(C) appropriate methods of pain and symptom management for individuals with cancer, including end-of-life care, and''.

(3) SPECIAL AUTHORITIES OF THE DIRECTOR.—Section 413(a)(2) of the Public Health Service Act (42 U.S.C. 285a–2(a)(2)) is amended—

(A) in subparagraph (D) by striking ''and'' at the end;

(B) in subparagraph (E) by striking the period and inserting ''; and''; and

(C) by adding at the end the following:

''(F) assess and improve pain and symptom management of cancer throughout the course of treatment.''.

(4) BREAST AND GYNECOLOGICAL CANCERS.—Section 417 of the Public Health Service Act (42 U.S.C. 285a–6) is amended—

(A) in subsection (c)(1)—

(i) in subparagraph (D), by striking ''and'' at the end;

(ii) in subparagraph (E), by striking the period and inserting ''; and''; and

(iii) by inserting after subparagraph (E) the following:

''(F) basic, clinical, and applied research concerning pain and symptom management.''; and

(B) in subsection (d)—

(i) in paragraph (4), by striking ''and'' at the end;

(ii) in paragraph (5), by striking the period and inserting ''and;''; and

(iii) by adding at the end the following:

''(6) basic, clinical, and applied research concerning pain and symptom management.''.

(5) PROSTATE CANCER.—Section 417A(c)(1) of the Public Health Service Act (42 U.S.C. 285a–7(c)(1)) is amended—

(A) in subparagraph (F), by striking ''and'' at the end;

(B) in subparagraph (G), by striking the period and inserting ''; and''; and

(C) by inserting after subparagraph (G) the following:

''(H) basic and clinical research concerning pain and symptom management.''.

SEC. 104. SURVIVORSHIP RESEARCH PROGRAM.

(a) IN GENERAL.—Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following:

"SEC. 417E. SURVIVORSHIP RESEARCH PROGRAM.

''(a) ESTABLISHMENT.—There is established, within the Institute, an Office on Cancer Survivorship (in this section referred to as the 'Office'), which may be headed by an Associate Director, to implement and direct the expansion and coordination of the activities of the Institute with respect to cancer survivorship research.

''(b) COLLABORATION AMONG AGENCIES.—In carrying out the activities described in subsection (a), the Office shall collaborate with other institutes, centers, and offices within the National Institutes of Health that are determined appropriate by the Office.

''(c) REPORT.—Not later than 1 year after the date of enactment of this section, the Secretary shall prepare and submit to the appropriate committees of Congress a report providing a description of the survivorship activities of the Office and strategies for future activities.''.

(b) FUNDING.—Section 417B(d)(2) of the Public Health Service Act (42 U.S.C. 285a–8(d)(2)) is amended—

(1) in subparagraph (B), by striking ''and'' after the semicolon;

(2) in subparagraph (C), by striking ''each subsequent fiscal year.'' and inserting ''each fiscal year through 2002; and''; and

(3) by adding at the end the following:

''(D) 11.5 percent, in the case of fiscal year 2003 and 13 percent, in the case of fiscal year 2004 and each subsequent fiscal year, of which not less than 1.5 percent in fiscal year 2003, 2 percent in fiscal year 2004, and 3 percent in fiscal year 2005 and each subsequent fiscal year shall be for the Office on Survivorship under section 417E.''.

TITLE II—RESEARCH PROVISIONS

SEC. 201. NATIONAL CANCER INSTITUTE.

(a) OTHER TRANSACTIONS AUTHORITY.—Subpart 1 of Part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following:

''SEC. 417D. OTHER TRANSACTIONS AUTHORITY.

''Notwithstanding any other provision of this subpart, the Director of the National Cancer Institute may co-fund grant projects with private entities for any purpose described in this subpart.''.

(b) NCI REPORT TO CONGRESS ON THE BYPASS BUDGET.—Section 413 of the Public Health Service Act (42 U.S.C. 285a–2) is amended—

(1) in subsection (b), by striking paragraph (9) and inserting the following:

''(9) notwithstanding section 405(a), shall prepare and submit, directly to the President for review and transmittal to the Committee on the Budget of the Senate and the Committee on the Budget of the House of Representatives, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Institute program, after reasonable opportunity for comment by the Secretary, the Director of NIH, the Institute's advisory council, and the National Cancer Advisory Board.''; and

(2) by adding at the end the following:

''(c) The National Cancer Advisory Board shall accept comments on the budget described in subsection (b)(9) from nongovernment organizations and shall compile significant suggestions into a report for the Director of the Institute pursuant to subsection (b)(9). The Director of the Institute shall respond, as appropriate, to such suggestions prior to submitting such budget.''.

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

(1) the current procedure of sending 1 clinical trial through multiple local internal 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 life saving treatment to cancer patients;

(2) the National Cancer Institute should be commended for its work in centralizing the internal review board process; and

(3) the research community should continue to streamline the internal review board process in order to bring life saving treatments to patients as quickly as possible.

(d) PATIENT AND PROVIDER OUTREACH OPPORTUNITIES WITH EXPERIMENTAL THERAPIES.—For the purpose of enhancing patient access to experimental therapies, the National Cancer Institute shall conduct the following activities:

(1) Integrate, to the maximum extent practicable, trials being conducted by private manufacturers into the National Cancer Institute's clinical trials online database. Such integration may require

specific awareness-raising and outreach activities by the National Cancer Institute to private industry.

(2) Establish an education program which provides patients and providers with—

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

(B) information about the Food and Drug Administration process for approving the use of drugs and biologics for a single patient.

TITLE III—MEDICARE PROVISIONS

SEC. 301. SENSE OF THE SENATE REGARDING REIMBURSEMENT FOR ITEMS AND SERVICES USED IN THE COURSE OF CANCER THERAPY.

It is the sense of the Senate that—

(1) the medicare program under title XVIII of the Social Security Act should neither over-reimburse nor under-reimburse for the cost of drugs and biologicals used in the course of cancer therapy;

(2) the medicare program should neither over-reimburse nor under-reimburse for the skilled nursing services, supplies, and equipment that are essential to the delivery of high quality cancer care; and

(3) the goal of any change to medicare reimbursement policy for cancer care should be in the interest of ensuring that medicare beneficiaries with cancer have access to the highest quality care in the greatest number of health care facilities available.

SEC. 302. SENSE OF THE SENATE REGARDING PAYMENT RATE FOR DRUGS AND BIOLOGICALS UNDER THE MEDICARE HOSPITAL OUTPATIENT DEPARTMENT PROSPECTIVE PAYMENT SYSTEM.

(a) FINDINGS.—The Senate finds the following:

(1) Payments for drugs and biologicals under the medicare hospital outpatient department prospective payment system under section 1833(t) of the Social Security Act (42 U.S.C. 1395*l*(t)) should be based on all of the costs of delivering outpatient pharmacy therapy (involving the drug or biological) in the outpatient hospital setting, including acquisition, storage, handling, processing, quality control, disposal, and pharmacy overhead costs.

(2) The payment rates proposed by the Centers for Medicare & Medicaid Services, in the ''Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates and Changes to Payment Suspension for Unified Cost Report''; Proposed Rule, 67 Fed.

Reg, 52092 et seq. (August 9, 2002), for most drugs and biologicals are based only on the estimated acquisition cost of the drug or biological and do not reflect other related costs.

(3) The methodology used by the Centers for Medicare & Medicaid Services to estimate such acquisition costs is flawed because the methodology—

(A) derives such estimates from what hospitals charged for individual products on patient bills without appropriate adjustment for hospital charging practices; and

(B) relies on data that are several years old.

(4) The methodology described in paragraph (3) substantially underestimates the acquisition costs of newer, more expensive drugs and biologicals and this underestimation disproportionately affects drugs and biologicals used to treat cancer.

(5) Medicare beneficiary access may be jeopardized in the outpatient hospital setting for those drugs and biologicals for which medicare program payments are substantially below the costs of delivery.

(6) The payment rates proposed for most drugs and biologicals under the medicare hospital out-

patient department prospective payment system for calendar year 2003 are less than the payment rates established for such drugs and biologicals in 2002, with the payment reductions exceeding 30 percent in most cases.

(7) The methodology used to develop the payment rates in 2003 described in paragraph (6) produces erratic and unreliable results, including—

(A) the payment rate for 1 product increasing 700 percent and the rates for many others exceeding 100 percent of their average wholesale price (AWP); and

(B) the payment rates for 9 drugs and biologicals used in cancer therapy experiencing rate reductions of between 50 and 90 percent.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that the Administrator of the Centers for Medicare & Medicaid Services should address the consequences of the proposed payments rates for drugs and biologicals in 2003 under the medicare hospital outpatient department prospective payment system under section 1833(t) of the Social Security Act (42 U.S.C. 1395*l*(t)) by either—

(1) revising the payment rates for drugs and biologicals under such system; or

(2) suspending the proposed rule establishing such payment rates and extending the period of data collection for the purposes of establishing a more rational payment structure for drugs and biologicals under such system in the future.

SEC. 303. SENSE OF THE SENATE REGARDING COVERING PALLIATIVE CARE THROUGHOUT CANCER TREATMENT.

(a) FINDINGS.—The Senate finds the following:

(1) Serious chronic pain is one of the most widespread public health problems in the American adult population.

(2) Because so few federal research dollars are devoted to pain there are no exact figures, however, best estimates indicate that up to 75,000,000 Americans suffer serious pain annually, 50,000,000 enduring serious chronic pain (pain lasting six months or longer), and 25,000,000 experiencing acute pain (from injuries, accidents, surgeries, etc.).

(3) The medicare and medicaid programs pay for pain medication when administered as part of routine acute, skilled nursing, hospice, or other specialized health care benefits, such as doctor-administered infusion medication.

(4) Without coverage for self-administered prescription drugs to alleviate pain, many of the approximately 1,500 people that die from cancer each day and the more than 9,000,000 cancer survivors may need to live without appropriate access to adequate pain care.

(b) SENSE OF THE SENATE.—It is the Sense of the Senate that—

(1) patients experiencing pain should be identified at the earliest detection of discomfort to best treat the condition before the pain becomes prohibitive and debilitating;

(2) early treatment of pain will improve clinical outcomes, quality of care and comfort, and ultimately improve the quality of life for cancer patients;

(3) medicare beneficiaries experiencing pain, even at the end of life, are frequently under-treated for pain and other symptoms associated with cancer, in part because of the lack of an outpatient prescription drug benefit under the medicare program;

(4) the medicare program's approach to reimbursement for those patients with intense pain should be modified to ensure access to technologies

and therapies for cancer pain patients well in advance of qualifying for hospice care; and

(5) each head of an agency that is responsible for the operation a federal health care program should—

(A) review coverage under the program for effective pain prevention and management services, including outpatient prescription medications; and

(B) submit to the Senate a report on such review by not later than December 31, 2003.

SEC. 304. SENSE OF THE SENATE REGARDING IMPROVING THE COVERAGE OF HOSPICE CARE.

(a) FINDINGS.—The Senate finds the following:

(1) While 23 percent of the medicare beneficiaries who died in 2000 received hospice care, 60 percent of medicare beneficiaries who died in 2000 of cancer received hospice care.

(2) By the time medicare hospice patients are exposed to a variety of pain management tools, it is often too late and the cancer has progressed beyond the point of lucid patient decision-making.

(3) The medicare hospice reimbursement structure contains built-in disincentives to providing palliative therapies that have high early costs, even

when these therapies may become cost-effective after a certain period of time. Small hospices in particular are often unable to cover the costs of these treatments to palliate symptoms.

(4) Median lengths of stay in a hospice care program decreased from 26 days in 1992 to 19 days in 1998.

(5) In 2001, ½ the patients in hospice care programs were there for 3 weeks or less.

(6) A recent study of hospice patients found that 33 percent of patients die within 7 days of receiving hospice care.

(7) Because of the requirement under the medicare program that patients receive no curative therapy while receiving hospice care, the medicare hospice reimbursement structure contains built-in disincentives to entering hospice care programs and receiving palliative therapies that could extend life and improve the quality of life for terminal patients.

(8) Recent studies published by Harvard University and Medicare Payment Advisory Commission have suggested that medicare might have the ability to provide improved coverage for cancer pain patients and realize a cost savings by modifying exist-

ing policy to create and utilize an outlier payment system.

(9) At the present time, the medicare program will reimburse physicians for consulting with patients about end-of-life care. In practice, however, it is often a registered nurse or social worker who provides patients with end-of life-care. These services are complex, sensitive and time consuming.

(10) Registered nurses and medical social workers with an expertise in palliative or hospice care are qualified to perform end-of-life services and are able to make home visits when necessary. Their services should be reimbursed under the medicare program.

(11) A payment source is needed for patients who require palliative care and who are terminally ill but do not meet the medicare hospice criteria or who still want to receive aggressive treatment.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that the Administrator of the Centers for Medicare & Medicaid Services should—

(1) restructure the hospice benefit under the medicare program for high cost outliers;

(2) increase medicare hospice care reimbursement for short stays;

(3) provide for reimbursement under the medicare program for nurses and social workers with expertise in hospice care for consultations and home visits provided to terminally ill patients who, for a variety of reasons, may not have elected access the hospice benefit;

(4) create a payment source for palliative care for terminally ill patients who do not elect hospice care or do not meet the medicare hospice benefit criteria;

(5) improve the medicare hospice benefit through approaches such as—

(A) increasing the reimbursement on the day of admission and the day of death, to offset the cost of late referrals;

(B) increasing the reimbursement rate for the last 7 days a patient spends on the benefit; and

(C) using a case-mix reimbursement rate rather than the flat-rate, four-category per diem benefit.

SEC. 305. SENSE OF THE SENATE REGARDING THE COVERAGE OF ALL TREATMENTS FOR CANCER PATIENTS.

(a) FINDINGS.—The Senate finds the following:

(1) While cancer treatments are often treated within the setting of a health care facility, many of the latest treatment advances afford patients the opportunity to treat themselves at home.

(2) The medicare program often does not provide for reimbursement for the most efficient and effective treatments based on the fact that the treatments are self-injectable or taken orally.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) medicare patients should have access to the best treatment available;

(2) the lack of reimbursement for certain treatments can serve as a disincentive for researchers to investigate more efficient and effective treatments for elderly cancer patients; and

(3) in the event that a comprehensive outpatient prescription drug benefit under the medicare program is not enacted into law during the 107th Congress, the Senate should consider a targeted outpatient prescription medication benefit under the medicare program for cancer patients.

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