country with a minimum amount of interference in their ability to sell guns in conformance with other provisions of the law.

I think this is a really important piece of legislation, and I welcome the opportunity to work with the Senator. Hopefully, we will have it acted on as well as the other provisions that are before the Senate dealing with the massive movement of weapons from State to State. In my own State of Massachusetts, about 80 percent of the weapons that are used in crimes of violence are imported. As good as we have, in terms of the local and State control, we are not able to control it and deal with the issues of providing security to our people in our State.

But I thank the Senator and welcome the chance to join with him and look forward to working with him on the legislation.

By Mr. ROCKEFELLER (for himself, Mr. MACK, Mr. FRIST, Mr. MOYNIHAN, Mr. KENNEDY, Mr. ABRAHAM, Mr. KERREY, Mr. CRAIG, Mr. WELLSTONE, Mr. COCHRAN, Ms. MIKULSKI, Mr. CAMPBELL, Mr. LEAHY, Mr. JEFFORDS, Mrs. HUTCHISON, Mr. HOLLINGS, Mr. FAIRCLOTH, and Mr. BINGAMAN.

S. 381. A bill to establish a demonstration project to study and provide coverage of routine patient care costs for Medicare beneficiaries with cancer who are enrolled in an approved clinical trail program; to the Committee on Finance.

THE MEDICARE CANCER CLINICAL TRIAL COVERAGE ACT OF 1997

Mr. ROCKEFELLER. Mr. President, I am very pleased to be reintroducing a modest but important bill that would establish a demonstration project to assure Medicare beneficiaries with cancer that Medicare will cover their routine patient costs when part of a clinical research trial. I am especially proud to have Senator MACK joining me again as my key cosponsor. It is a privilege to work with Senator MACK, who knows the anguish of fighting cancer only too well. And, we are especially glad to be joined by so many of our colleagues, including Senators FRIST, MOYNIHAN, KENNEDY, ABRAHAM, KERREY, CRAIG, WELLSTONE, COCHRAN, MIKULSKI, CAMPBELL, LEAHY, JEFFORDS, HUTCHISON, HOLLINGS, and FAIRCLOTH.

Mr. President, cancer is the second leading cause of death in the United States. Medicare beneficiaries account for more than half of all cancer diagnoses, and 60 percent of all cancer deaths. Over 12,000 new cases of cancer will be diagnosed this year in my own State of West Virginia.

Access to clinical trials is especially important in the field of cancer. With today's rapid discoveries of new cancer therapies and the lack of effective treatments for some cancers, peer-reviewed clinical trials often provide cancer patients the best available care. Given differences in biological responses according to age, research is needed on the particular effects of cancer and cancer treatments on those age 65 and older. Our legislation will promote that vital research. At the same time, it will provide the Health Care Financing Administration with the information it needs on whether coverage for experimental therapies and treatments should be eventually extended to the entire Medicare population. In the long run, the coverage of patient care costs in clinical trials will save the health care delivery system millions of dollars by telling us at the earliest possible time which medical interventions work and which do not.

Our legislation is an effort to give Medicare beneficiaries the security and decency of knowing that if they are diagnosed with cancer, their treatment options will be determined by whatever therapy they and their doctor decide will give them the best shot of beating the disease. These life and death decisions should not be guided by what may or may not be paid for by the Medicare Program.

Currently, Medicare's payment policies are unclear and, as a result, unpredictable. There is anecdotal evidence that Medicare, in fact, usually pays for the routine patient care costs associated with clinical research trials. But when denials do happen, they tend to be arbitrary and random. This unpredictability discourages Medicare patients from enrolling in a clinical trial, even when it may medically be their best treatment option.

Three winners of the Nobel Prize in Medicine and Physiology have written me and Senator MACK in support of our legislation. They wrote, ''clinical trials represent the standard of care and are often the best hope for a successful treatment outcome. Only by supporting clinical research will we be able to advance the state of medical knowledge and learn more quickly which medical interventions are effective and which are not.''

Mr. President, our legislation is very targeted to give older Americans their best shot at fighting cancer. This bill does not create a new benefit. It merely ensures that patients enrolled in clinical studies receive Medicare coverage for the same type of routine patient care costs, such as hospital and physician fees, that would be covered outside of a trial setting. We are not asking Medicare to pay for the cost of research. These expenses will still be covered by trial sponsors, including pharmaceutical companies.

In establishing a demonstration project, this bill will also provide valuable information about the costs and benefits of providing coverage for clinical trials for other life threatening diseases. We started with cancer first because cancer is a major affliction of Medicare beneficiaries. In addition, there is a well-established national cancer clinical trial system to deliver this patient care.

Mr. President, this is the year to enact this bill into law. This proposal is a key Medicare reform to include in the action expected in the upcoming budget process that will deal with Medicare spending and policy.

Mr. President, I ask unanimous consent that additional material be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 381

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 ''Medicare Cancer Clinical Trial Coverage Act of 1997''.

SEC. 2. MEDICARE CANCER PATIENT DEMONSTRATION PROJECT.

(A) ESTABLISHMENT.—Not later than January 1, 1998, the Secretary of Health and Human Services (in this Act referred to as the ''Secretary'') shall establish a demonstration project which provides for payment under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) of routine patient care costs—

(1) which are provided to an individual diagnosed with cancer and enrolled in the medicare program under such title as part of the individual's participation in an approved clinical trial program; and

(2) which are not otherwise eligible for payment under such title for individuals who are entitled to benefits under such title.

(b) APPLICATION.—The beneficiary cost sharing provisions under the medicare program, such as deductibles, coinsurance, and copayment amounts, shall apply to any individual participating in a demonstration project conducted under this Act.

(c) APPROVED CLINICAL TRIAL PROGRAM.—For purposes of this Act, the term ''approved clinical trial program'' means a clinical trial program which is approved by—

(1) the National Institutes of Health;

(2) a National Institutes of Health cooperative group or a National Institutes of Health center;

(3) the Food and Drug Administration (in the form of an investigational new drug or device exemption);

(4) the Department of Veterans Affairs;

(5) the Department of Defense; or

(6) a qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(d) ROUTINE PATIENT CARE COSTS.—

(1) IN GENERAL.—for purposes of this Act, ''routine patient care costs'' shall include the costs associated with the provision of items and services that—

(A) would otherwise be covered under the medicare program if such items and services were not provided in connection with an approved clinical trial program; and

(B) are furnished according to the design of an approved clinical trial program.

(2) EXCLUSION.—For purposes of this Act, ''routine patient care costs'' shall not include the costs associated with the provision of—

(A) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

(B) any item or service supplied without charge by the sponsor of the approved clinical trial program.

SEC. 3. STUDY, REPORT, AND TERMINATION.

(a) STUDY.—The Secretary shall study the impact on the medicare program under title

XVIII of the Social Security Act of covering routine patient care costs for individuals with a diagnosis of cancer and other diagnoses, who are entitled to benefits under such title and who are enrolled in an approved clinical trial program.

(b) REPORT TO CONGRESS.—Not later than January 1, 2002, the Secretary shall submit a report to Congress that contains a statement regarding—

(1) any incremental cost to the medicare program under title XVIII of the Social Security Act resulting from the provisions of this Act; and

(2) a projection of expenditures under the medicare program if coverage of routine patient care costs in an approved clinical trial program were extended to individuals entitled to benefits under the medicare program who have a diagnosis other than cancer.

(c) TERMINATION.—The provisions of this Act shall not apply after December 31, 2002.

MEDICARE CANCER CLINICAL TRIAL COVERAGE ACT OF 1997

CURRENT LAW

Medicare's policy regarding coverage of clinical trials is unclear. Medicare carriers occasionally deny coverage of physician services or hospital charges on the grounds that they have been provided in the context of a clinical trial. Patients or physicians may be at risk for the cost of items or services that are normally covered by Medicare if they choose to enroll in a clinical trial, even though such trials are regarded as the standard of care for treatment of cancer.

PROPOSED CHANGE

The Secretary of HHS would be required to conduct a demonstration project, beginning no later than January 1, 1998, which would study the feasibility of covering patient costs for beneficiaries diagnosed with cancer and enrolled in certain approved clinical trials. Eligibility for coverage would be dependent on approval of the trial design by one of several high quality peer-review organizations, including the National Institutes of Health, the Food and Drug Administration, the Department of Defense, and the Department of Veterans Affairs. No later than January 1, 2002, the Secretary would be required to report to Congress concerning any incremental costs of such coverage and the advisability of covering other diagnoses under the same circumstances. The demonstration project would sunset on December 31, 2002.

Supported by: National Coalition for Cancer Survivorship; Candlelighters Childhood Cancer Foundation; Cancer Care, Inc.; National Alliance of Breast Cancer Organizations (NABCO); US TOO International; Y-ME National Breast Cancer Organization; American Cancer Society; American Society of Clinical Oncology; American Society of Pediatric Hematology/Oncology; Association of American Cancer Institutes; Association of Community Cancer Centers; Cancer Research Foundation of America; North American Brain Tumor Coalition; Leukemia Society of America; National Breast Cancer Coalition; National Childhood Cancer Foundation; National Coalition for Cancer Research; Oncology Nursing Society; Prostate Cancer Support-group Network; and Society of Surgical Oncology.

Mr. MACK. Mr. President, I am pleased to join Senator ROCKEFELLER today as we introduce legislation to provide Medicare patients fighting cancer with coverage of benefits when they participate in approved clinical trials.

Under current law, Medicare will not generally pay for the costs of patient care if they are participating in clinical trials. Beneficiaries are denied access to clinical trials of promising new therapies because Medicare deems these therapies experimental, and therefore not qualified for coverage. This means cancer patients who are Medicare beneficiaries essentially have two choices when they have exhausted all traditional cancer therapies—either pay the costs of participating in a clinical trial themselves, or go without additional treatment. For all but the most wealthy beneficiaries, it is too cost-prohibitive to take part in a clinical trial.

Clinical trials are one of the most effective ways the Federal Government has of determining which treatments are most effective. Yet, researchers have told me they have difficulty accruing the required number of patients to participate in the trials they are conducting. Researchers have identified noncoverage by Medicare and private insurers as one of the primary reasons why patients do not participate in clinical trials. At a time when American researchers are making such tremendous progress in cancer genetics and cancer biology, it is essential that this knowledge be translated into new therapies through well-designed clinical trials. This legislation will help enhance our research efforts by facilitating broad patient participation in important cancer clinical trials.

Our legislation is limited to only the highest-quality clinical trials. Only those trials which have undergone the rigors of peer-review will be considered. These include trials approved by the National Institutes of Health [NIH], the Food and Drug Administration, the Department of Veterans Affairs, the Department of Defense, or organizations which are approved by the NIH, such as the American Cancer Society.

Like most of my colleagues, I am very reluctant to introduce legislation to expand Medicare at a time when the report of the Board of Trustees of Social Security and Medicare clearly shows that Medicare is going broke. My support of such legislation is conditional upon the added benefit providing a clear and needed service at no significant cost to taxpayers.

The legislation we introduce today does not add to Medicare's basic benefit package, but merely provides coverage for routine patient costs which Medicare is already obligated to reimburse when provided outside a clinical trial. Medicare will not be responsible for paying for research or new pharmaceutical products. In addition, Medicare beneficiaries will still be responsible for meeting deductibles and copayment requirements traditionally required by Medicare. Because these beneficiaries are cancer patients, they are already receiving, or will receive in the future, many of the medical services covered by this legislation.

Finally, this is a true demonstration program. In 2002, the Secretary of Health and Human Services must submit a report to Congress detailing any cost increases to the Medicare program and provide projects for future expenditures, if the program continues. Congress can then decide, based upon these data and any hearings which may take place, whether to enact legislation to make coverage of cancer clinical trials permanent.

Therefore, I am convinced this legislation meets my two criteria for expanding Medicare. First, there is an indisputable urgent need for this benefit and, second, I believe it will not add significantly to the costs of the Medicare system. In fact, the information we learn from these clinical trials may provide us with more cost-effective means of treating cancer patients.

As I have mentioned to my colleagues before, many members of my family have battled cancer. As a family, we have worked extensively with numerous cancer organizations. As a Senator, I have met with thousands of cancer patients throughout Florida and the rest of the United States. They have told me how important it is that patients themselves, not the Government, be responsible for making treatment decisions with their physicians. Patients desperately want to participate in clinical trials when traditional therapies are no longer beneficial. The legislation which Senator ROCKEFELLER and I introduce today, which has the enthusiastic support of cancer patient, physician, nurse, and research organizations, will empower cancer patients with more treatment choices in a cost-effective manner.

I want to commend Senator JOHN ROCKEFELLER for his leadership in bringing this issue to the forefront. Senator ROCKEFELLER has always been there for cancer patients, as evidenced by his landmark 1993 legislation which provided Medicare coverage of anticancer drugs. We've worked together on cancer issues on several occasions over the years, and it's always a pleasure to work with him.

Mr. President, our legislation would provide cancer patients who are Medicare participants with an additional choice at a time when a clinical trial may be their best, or only, hope for survival. I therefore urge my colleagues to cosponsor the Medicare Cancer Clinical Trial Program Coverage Act of 1997.

ADDITIONAL COSPONSORS

S. 61

At the request of Mr. LOTT, the names of the Senator from Utah [Mr. HATCH], the Senator from Kentucky [Mr. FORD], the Senator from Illinois [Ms. MOSELEY-BRAUN], and the Senator from Virginia [Mr. ROBB] were added as cosponsors of S. 61, a bill to amend title 46, United States Code, to extend eligibility for veterans' burial benefits, funeral benefits, and related benefits for veterans of certain service in the U.S. merchant marine during World War II.

S. 66

At the request of Mr. HATCH, the name of the Senator from Ohio [Mr. DEWINE] was added as a cosponsor of S. 66, a bill to amend the Internal Revenue Code of 1986 to encourage capital formation through reductions in taxes on capital gains, and for other purposes.

S. 202

At the request of Mr. LOTT, the names of the Senator from Alabama [Mr. SESSIONS], the Senator from Texas [Mrs. HUTCHISON], and the Senator from New York [Mr. D'AMATO] were added as cosponsors of S. 202, a bill to amend title II of the Social Security Act to eliminate the earnings test for individuals who have attained retirement age.

S. 211

At the request of Mrs. MURRAY, her name was added as a cosponsor of S. 211, a bill to amend title 38, United States Code, to extend the period of time for the manifestation of chronic disabilities due to undiagnosed symptoms in veterans who served in the Persian Gulf war in order for those disabilities to be compensable by the Secretary of Veterans Affairs.

S. 224

At the request of Mr. WARNER, the name of the Senator from Texas [Mrs. HUTCHISON] was added as a cosponsor of S. 224, a bill to amend title 10, United States Code, to permit covered beneficiaries under the military health care system who are also entitled to medicare to enroll in the Federal Employees Health Benefits program, and for other purposes.

S. 260

At the request of Mr. ABRAHAM, the name of the Senator from Nebraska [Mr. HAGEL] was added as a cosponsor of S. 260, a bill to amend the Controlled Substances Act with respect to penalties for crimes involving cocaine, and for other purposes.

S. 263

At the request of Mr. MCCONNELL, the name of the Senator from Illinois [Ms. MOSELEY-BRAUN] was added as a cosponsor of S. 263, a bill to prohibit the import, export, sale, purchase, possession, transportation, acquisition, and receipt of bear viscera or products that contain or claim to contain bear viscera, and for other purposes.

S. 306

At the request of Mr. FORD, the name of the Senator from Florida [Mr. GRAHAM] was added as a cosponsor of S. 306, a bill to amend the Internal Revenue Code of 1986 to provide a decrease in the maximum rate of tax on capital gains which is based on the length of time the taxpayer held the capital asset.

S. 347

At the request of Mr. CLELAND, the name of the Senator from Maryland [Ms. MIKULSKI] was added as a cosponsor of S. 347, a bill to designate the Federal building located at 100 Alabama Street NW, in Altanta, GA, as the ''Sam Nunn Federal Center.''

S. 348

At the request of Mr. MCCONNELL, the name of the Senator from North Carolina [Mr. HELMS] was added as a cosponsor of S. 348, a bill to amend title I of the Omnibus Crime Control and Safe Streets Act of 1968 to encourage States to enact a Law Enforcement Officers' Bill of Rights, to provide standards and protection for the conduct of internal police investigations, and for other purposes.

NOTICE OF HEARING

COMMITTEE ON ENERGY AND NATURAL RESOURCES, SUBCOMMITTEE ON NATIONAL PARKS, HISTORIC PRESERVATION, AND RECREATION

Mr. THOMAS: Mr. President, I would like to announce for the public that an oversight hearing has been scheduled before the Subcommittee on Parks, Historic Preservation, and Recreation.

The hearing, which will take place over 2 days, will be held on Thursday, March 13, 1997 and Thursday, March 20, 1997.Each session will begin at 2 p.m. in room SD–366 of the Dirksen Senate Office Building in Washington, DC.

The purpose of this oversight hearing is to address the future of the National Park System and to identify and discuss needs, requirements, and innovative programs that will insure Park Service will continue to meet its many responsibilities well into the next century.

Because of the limited time available for the hearing, witnesses may testify by invitation only. However, those wishing to submit written testimony for the hearing record should send two copies of their testimony to the Subcommittee on Parks, Historic Preservation and Recreation, Committee on Energy and Natural Resources, U.S. Senate, 304 Dirksen Senate Office Building, Washington, DC. 20510–6150.

For further information, please contact Jim O'Toole of the subcommittee staff at (202) 224–5161.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON ARMED SERVICES

Mr. BROWNBACK. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet on Thursday, February 27, 1997, at 9:30 a.m. in open session, to receive testimony concerning the Department of Defense actions pertaining to the Persian Gulf illness.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. BROWNBACK. Mr. President, I ask unanimous consent that the Senate Committee on Commerce, Science, and Transportation be authorized to meet on February 27, 1997, at 10 a.m. on TV Violence.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FINANCE

Mr. BROWNBACK. Mr. President, the Finance Committee requests unanimous consent to conduct a hearing on Thursday, February 27, 1997, beginning at 11 a.m. in room 215 Dirksen.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON INDIAN AFFAIRS

Mr. BROWNBACK. Mr. President, I ask unanimous consent that the Senate Committee on Indian Affairs be authorized to meet during the session of the Senate on Thursday, February 27, 1997 at 9:30 a.m. to approve the committee's letter to the Committee on the Budget concerning the committee's budget views and estimates for fiscal year 1998 for Indian programs. The meeting will be held in room 485 of the Russell Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON LABOR AND HUMAN RESOURCES

Mr. BROWNBACK. Mr. President, I ask unanimous consent that the Committee on Labor and Human Resources be authorized to meet for a hearing on Reauthorization of Higher Education Act during the session of the Senate on Thursday, February 27, 1997, at 10 a.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON SMALL BUSINESS

Mr. BROWNBACK. Mr. President, I ask unanimous consent that the Committee on Small Business be authorized to meet during the session of the Senate for a hearing on S. 208, the HUBZone Act of 1997 on Thursday, February 27, 1997, which will begin at 9:30 a.m. in room 428A of the Russell Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON HEALTH CARE

Mr. BROWNBACK. Mr. President, the Finance Committee Subcommittee on Health Care requests unanimous consent to conduct a hearing on Thursday, February 27, 1997, beginning at 2 p.m. in room SD–215.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON INTERNATIONAL RELATIONS

Mr. BROWNBACK. Mr. President, I ask unanimous consent that the Subcommittee on International Relations of the Committee on Foreign Relations be authorized to meet during the session of the Senate on Thursday, February 27, 1997, at 11 a.m. to hold a hearing.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON STRATEGIC FORCES

Mr. BROWNBACK. Mr. President, I ask unanimous consent that the Subcommittee on Strategic Forces of the Committee on Armed Services be authorized to meet at 2 p.m. on Thursday, February 27, 1997 to receive testimony on ballistic missile defense programs in review of the Defense authorization request for fiscal year 1998 and the future years defense program.