



February 17, 2009

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The Honorable Bettye Davis, Chair
Senate Health and Social Services Committee
Alaska State Capitol, Room 30
Juneau, AK 99801-1182

RE: SB 10 (Davis)--Support

Dear Chair Davis,

On behalf of the members of AARP in Alaska, we encourage you and your colleagues on the Senate Health and Social Services Committee to support SB 10, authored by you.

SB 10 would require insurance programs, including Medicaid, to provide coverage for cancer victims undergoing clinical trials just as they would if the individual was not in the trial.

Most of our significant advances in cancer treatment that have become standard procedures began as clinical trials.

It makes no sense not to offer health insurance coverage for procedures that may be still considered experimental but offer some hope for the cancer victim. We purchase insurance (or the State provides it through Medicaid) so that we can have help with the costs that accompany a threatening disease. SB 10 is one of those bills that AARP believes makes sense, especially to a cancer victim and his/her family.

AARP recommends an "AYE" vote on SB 10.

Should you have any questions about our position, please feel free to contact me (586-3637) or Patrick Luby, AARP Advocacy Director (907-762-3314).

Thank you for your consideration.

Sincerely,

Marie Darlin, Coordinator
AARP Capital City Task Force
415 Willoughby Avenue, Apt. 506
Juneau, AK 99801
586-3637 (voice)
463-3580 (fax)

CC: Vice-Chair Joe Paskvan
Senator Joe Thomas

Senator Fred Dyson
Senator Johnny Ellis



American Society of Clinical Oncology

February 17, 2009

The Honorable Bettye Davis
Alaska State Senator
District K
Capitol Building Room 30
Juneau, AK 99801-1182

Dear Senator Davis:

The Denali Oncology Group and American Society of Clinical Oncology are pleased to offer support for your legislation to require insurance coverage for people who participate in clinical trials. Our organizations represent physicians specializing in cancer treatment and clinical research, and clinical research is a vital mission of our membership.


Clinical trials are critically important because they offer the promise of new cancer treatments. As you know from personal experience, they also provide an essential, state-of-the-art treatment option for current cancer patients. Therefore, insurance coverage of the routine patient care costs associated with clinical trials is vital for cancer patients.

For many people with cancer, participation in a clinical trial is often their best treatment option. Yet, as you know, many third-party payers take the position that routine patient care costs should be denied to anyone who enrolls in such trials. We believe such policy deprives beneficiaries of the value of their health insurance, wrongly restricts their treatment options, and inhibits medical progress against serious and life-threatening diseases. DOG and ASCO believe that insurers should cover all routine care costs for patients who are enrolled in cancer clinical trials. Your legislation is the key to making this happen.

DOG and ASCO applaud your leadership in pursuing legislation that provides this essential element of quality cancer care. We are eager to work with you to ensure passage. Please do not hesitate to contact Suanna Bruinooge, ASCO's Director of Research Policy, at 571-483-1613 or suanna.bruinooge@asco.org, or Dr. Mary Stewart at mstewartonc@yahoo.com or 907-279-3155.

Sincerely,

Mary Stewart, MD
President, Denali Oncology Group


Joseph S. Bailes, MD
Chair, ASCO Government Relations Council



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American Society of Clinical Oncology Statement In Support of Insurance Coverage for Clinical Trials

With more than 26,000 members worldwide, ASCO is the leading medical society for physicians involved in cancer treatment and research. Engagement in clinical research is a vital mission of ASCO members. Unfortunately, many cancer patients have limited curative treatment options and enrollment in a clinical trial may offer hope for a response to a new drug or other intervention. Oncologists want their patients to consider enrolling in clinical trials, not only because of potential treatment benefits for the individual patient but also because it is through these trials that general progress against cancer is achieved. Patients are usually eager to participate if given the opportunity. ASCO considers the opportunity to participate in cancer clinical trials as an essential element of quality cancer care.

Unfortunately, participation in clinical trials is significantly deterred by the prospect that insurance coverage may be withheld on the ground that treatment provided in trials is "experimental" or "investigational." This position has been effectively discarded by the federal Medicare program, as well as by the Department of Defense health care system, and by many states. ASCO strongly supports state and federal efforts to ensure that patients enrolled in clinical trials receive coverage for the routine health care costs that would be covered if they did not participate on a trial. It is a basic issue of fairness, and it will help ensure that we continue to improve treatment options for cancer patients and learn about this devastating group of diseases.

What is a Clinical Trial?

Clinical trials are research studies involving people. Clinical trials are designed to evaluate whether a new treatment is safe, effective, and better than the current standard of care. These interventions can include new drugs, new combinations of existing therapies, new approaches to radiation therapy or surgery, new methods of treatment, complementary or alternative therapies, and new prevention methods. Cancer clinical trials are designed to compare an investigational therapy with the standard treatment regimen being used at the time. Placebo-controlled clinical trials in cancer research are rare, but are used when there is no effective, standard treatment available.

Cancer clinical trials have led to scientific advances that have increased doctors' understanding of how and why tumors develop and grow. The knowledge gained has helped scientists and doctors develop new ideas on how



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to slow, halt, and even prevent the development of the disease. Clinical trials are the most reliable route to definitive answers and are the only accepted scientific method to determine if a new treatment works better than the current standard of care.

Clinical trials undergo rigorous review prior to opening and involve regular oversight during and after a trial to protect the safety and rights of the participants involved. Each clinical trial follows a set of rules called a protocol. A protocol describes inclusion and exclusion criteria; the schedule of tests, procedures, medications, and doses; and the length of the study. While in a clinical trial, participants are seen regularly by the research staff to monitor their health and determine the safety and effectiveness of the treatment.

Precedents for Clinical Trials Coverage

For more than two decades, the cancer community has expressed its concerns about the negative impact of restrictions on coverage of clinical trials by third-party payers, both public and private. Such restrictions are harmful not only to individual patients but also to overall progress against cancer. In 1999, public authorities began to respond favorably to these arguments and to reform their coverage policies with respect to clinical trials.

Pursuant to a negotiated agreement between the National Cancer Institute (NCI) and the Department of Defense (DoD), the DoD's TRICARE health care plan commenced coverage of NCI-sponsored clinical trials in 1999. The original agreement, began as a pilot project, was made a permanent benefit in March 2008, accompanied by a DoD press release describing it as "a long successful project between the NCI and DoD."

In 2000, the Medicare program took a more expansive approach to clinical trial coverage. In an Executive Memorandum, President Clinton instructed Medicare officials to adopt a clinical trials policy covering not just cancer trials but all diseases and all phases. To implement the policy, the Centers for Medicare & Medicaid Services (then the Health Care Financing Administration) published a National Coverage Determination in September 2000.

State governments have also been active in ensuring coverage of clinical trials by private insurance plans under their control. Almost half of the states throughout the U.S. enjoy coverage of clinical trials, either through legislation



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or through voluntary consensus agreements with insurers, and more are considering such requirements.

Impact of Policy Changes on Clinical Trial Participation

One of the nation's leading cooperative research groups, the Southwest Oncology Group (SWOG), has conducted studies that underscore the impact of the Medicare coverage policy on clinical trial participation among the elderly. In 1999, SWOG published a study finding significant underrepresentation of the elderly in cancer clinical trials.¹ The study found that, whereas 63% of cancer patients were Medicare eligible, seniors were only 25% of those patients participating in SWOG clinical trials during the period 1993-1996. Following the Medicare coverage policy in 2000, a second SWOG study found there was a significant increase in participation among Medicare beneficiaries, with seniors representing 38% of SWOG trial participants in the period 2001-2003.²

Cost of Clinical Trials Coverage

While there have been no definitive studies of the cost consequences of clinical trial coverage, there have been a series of articles finding that participation in clinical trials "did not result in substantial increases in the direct costs of medical care,"³ that "[c]linical protocols may add relatively little to that cost,"⁴ and that "additional costs of an open reimbursement policy for government-sponsored cancer clinical trials appear minimal."⁵ And with almost eight years of experience with the 2000 Medicare coverage policy, there is no evidence of increased cost to the program.

Conclusion

In light of the experience described above, we heartily support efforts to ensure that health plans and all insurers provide coverage for the routine costs

¹ Hutchins et al., "Underrepresentation of Patients 65 Years of Age or Older in Cancer-Treatment Trials," *N Engl J Med* 341: 2061-2067 (1999).

² Unger et al., "Impact of the Year 2000 Medicare Policy Change on Older Patient Enrollment to Cancer Clinical Trials," *J Clin Oncol* 24:141-144 (2006).

³ Fireman et al., "Cost of Care for Patients in Cancer Clinical Trials," *J Natl Cancer Inst* 92:136-142 (2000).

⁴ Wager et al., "Incremental Costs of Enrolling Cancer Patients in Clinical Trials: a Population-Based Study," *J. Natl. Cancer Inst* 91:847-853 (1999).

⁵ Goldman et al., "Incremental Treatment Costs in National Cancer Institute-Sponsored Clinical Trials," 289:2970-2977 (2003).



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associated with clinical trials participation. ASCO members strive to ensure access to the best treatment options for their cancer patients, and this requires that health insurers offer clinical trials coverage. We think it is clear that best cancer care and best health care coverage require access to high quality cancer clinical trials.

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Making a world of difference in cancer care



*American Association
for Cancer Research*



Association of
American Cancer Institutes



American Society of Clinical Oncology

December 1, 2008

Kevin J. Cullen, MD
Director, University of Maryland
Marlene and Stewart Greenebaum Cancer Center
22 South Greene Street
Baltimore, MD 21201

Dear Dr. Cullen:

This letter is written in follow-up to our recent discussions about Medicare coverage of routine patient care costs for beneficiaries participating in phase I cancer clinical trials. As the world's leading professional and scientific organizations representing oncology cancer care professionals, we write to affirm our position that phase I cancer clinical trials are the essential gateway for advancement of new cancer treatments—and a vital component of our cancer treatment armamentarium.

It is the view of the undersigned organizations that the current Medicare National Coverage Determination (NCD) (310.1) for Routine Costs in Clinical Trials explicitly includes coverage of phase I cancer clinical trials and that these trials should be covered.

Requirements for Medicare Coverage

The NCD lays out three basic requirements for Medicare coverage:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The NCD also requires that clinical trials covered under the policy have seven "desirable characteristics."

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

The policy also states that certain trials “are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage.” Trials that are automatically deemed include:

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.”

Phase 1 Cancer Clinical Trials Have Therapeutic Intent

The National Cancer Institute’s (NCI) Investigator Handbook is instructive as to the therapeutic intent of a Phase I trial. That handbook includes the following information about phase 1 cancer clinical trials (emphasis added):

Phase 1 trials determine a safe dose for Phase 2 trials and define acute effects on normal tissues. In addition, these trials examine the agent's pharmacology and may reveal evidence of antitumor activity. **Therapeutic intent is always present in Phase 1 trials**; indeed, anticancer agents are not tested in patients unless preclinical activity studies have already demonstrated evidence of significant activity in laboratory models.¹

The Food and Drug Administration (FDA) has also adopted a definition of phase 1 trials that is consistent with the NCI’s definition. FDA states that phase 1 studies “are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to **gain early evidence of effectiveness**.” This early evidence of effectiveness is the grounding for therapeutic intent – both in the choice of oncologists and patients to enroll in the trial, and as one of the aims of the trial.

Although the scientific goals of a phase 1 trial are to determine the toxic effects, pharmacologic behavior, and recommended doses for future study of a new agent, there is always a strong preclinical

¹ Available on the NCI website at <http://ctep.cancer.gov/handbook/index.html>

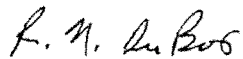
rationale for bringing the drug into the clinic with the expectation of positive clinical outcomes for some patients.² In fact, Institutional Review Boards would not permit the administration of potentially toxic treatments to patients unless there was some reasonable prospect of antitumor effect.³ It is also important to note that phase 1 oncology treatment trials are **never** done in healthy volunteers because of the potential toxicities associated with the treatments under investigation.

Additionally, many of the NCI phase 1 trials involve agents that are already approved for the treatment of one type of cancer and are being studied in a different type of cancer, or in combination with other treatments. As a result, we have some evidence of therapeutic effectiveness that provides solid grounding on which to base therapeutic intent. Indeed, an analysis of 12,000 individuals who participated in 460 NCI-funded phase 1 trials done in 2005 found that 10.6% of patients experienced an objective response. This number increased to 17.8% of patients when one drug included in the trial regimen was already FDA-approved.⁴

Furthermore, our growing knowledge of the molecular basis of cancer is allowing us to increasingly develop treatments that are targeted to particular molecular pathways and personalized to specific patient populations. These types of agents will provide a "high pretreatment probability of achieving both an objective response and more subjective clinical benefit" for the trial participants.⁵

To bring about these exciting new developments in cancer treatment, clinical trials participation is required. It is particularly important in the Medicare-aged population not only because of the increased incidence of cancer in the elderly and but also to develop our understanding of how treatments work in this population. Both the NCI and FDA definitions demonstrate that phase 1 oncology trials meet the requirements for Medicare coverage, including therapeutic intent, and should be covered.

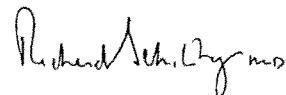
Sincerely,



Raymond N. DuBois, MD, PhD
President
American Association for
Cancer Research



Edward J. Benz, Jr., MD
President
Association of American
Cancer Institutes



Richard L. Schilsky, MD
President
American Society of
Clinical Oncology

² ASCO: Critical role of phase 1 clinical trials in cancer treatment. *J Clin Oncol* 15:853-859, 1997.

³ Kodish E, Stocking C, Ratain MJ, et al: Ethical issues in phase I oncology research: A comparison of investigators and IRB chairpersons. *J Clin Oncol* 10:1810-1816, 1992.

⁴ Horstmann E, McCabe MS, Grochow L, et al: Risks and benefits of phase 1 oncology trials, 1991 through 2002. *New Engl J Med* 352:895-905, 2005.

⁵ Markman M: Further evidence of clinical benefits associated with participation in phase 1 oncology trials. *B J Cancer* 98:1021-1022, 2008.



Alaska

January 20, 2009

The Honorable Bettye Davis
Alaska State Senate
State Capitol Building
Juneau, Alaska 99801-1182

RE: Senate Bill 10

Dear Senator Davis,

On behalf of the National Federation of Independent Business/Alaska, I wish to express our opposition to Senate Bill 10. The National Federation of Independent Business is the largest small-business advocacy group in the Alaska.

Health-care costs have been the No. 1 issue facing small-business owners since 1986, and those concerns are growing, according to NFIB's members. As health-care costs go through the roof, small-business owners have very few choices when selecting insurance coverage for their employees. The tipping point is here, and small businesses are begging for solutions to rising health-care costs, lack of access and other issues.

For many small employers in Alaska insurance premiums for small groups or single coverage have increased by more than 82 percent since 2000, a jaw-dropping statistic. This is completely unsustainable over the long-term. Much of the increase is driven by the additions to coverage by state mandates

Unfortunately, SB10 mandates specified coverage of medical care coverage during specified clinical trials that may not fit employee's needs but for which small employers providing health insurance bear the cost. Increased mandates force employers to consider whether they can afford to continue coverage or are forced

The Honorable Betty Davis

January 20, 2009

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by increased prices to eliminate health insurance for their employees. Mandates prevent small employers from providing affordable insurance programs tailored to its specific work force.

SB 10 is discriminatory against small employers as the mandate applies to those who provide coverage regulated by state insurance statutes, but not programs offered by the state and other governmental entities or large employers who typically offer ERISA programs. Thus it creates a less fair business environment for small employers.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dennis L. DeWitt", with a stylized flourish at the end.

Dennis L. DeWitt
Alaska State Director

Jeanne E. Anderson, MD
Katmai Oncology Group, LLC
3851 Piper Street, Suite U340
Anchorage, AK 99508-4627

I am Jeanne Anderson, a Medical Oncologist in practice in Anchorage. On behalf of Alaska cancer physicians and patients, I thank the members of the Labor and Commerce Committee members for considering this bill. It is predicted that 2,650 Alaskans will be diagnosed with cancer in 2008. In the 1970's, only 50% of cancer patients lived 5 years after diagnosis. In 2008, 66% are predicted to survive 5 years. We all know that many Alaskans die of cancer every day and that improvements are desperately needed. The cancer physicians in Alaska are committed to providing the best care possible to our patients, to relieve suffering and reduce death from cancer. In caring for our patients, we often turn to clinical trial as providing the best treatment for our patients. A clinical trial is a formal, scientific way to test whether a new treatment is safe, effective, and superior to existing treatments. The physicians and hospitals in Alaska support clinical trials and there are over 50 trials open in this state for our cancer patients. However, only a small number of our patients enroll on these clinical trials, approximately 40 per year. There are many reasons why enrollment is low. These reasons include lack of knowledge or interest on the part of the patient or physician, lack of availability of an appropriate trial for the patient, and (relevant to this bill) lack of insurance coverage or fear by the patient they will lose coverage if enrolled on a study. Passage of this bill will clearly remove an important barrier to access of a clinical trial. It will result in Alaska physicians providing improved care for our patients, reducing the burden of cancer in our population, and facilitating patients to stay in Alaska for state-of-the-art care.

POSITION PAPER ON HEALTH PLAN COVERAGE FOR PATIENT CARE COSTS IN CANCER CLINICAL TRIALS

Sponsored by the Denali Oncology Group, the Alaska State Affiliate of the American Society of
Clinical Oncology

February 14, 2009

BACKGROUND:

1. Clinical trials for cancer patients provide state-of-the-art treatment for patients with life-threatening diseases. Cancer patients and their physicians typically look to clinical trials as an option when the investigational treatment offers as much or more benefit than standard treatment.
2. Currently, in Alaska, health plans can exclude coverage for routine patient care costs while a patient with cancer is enrolled on a clinical trial.
3. Since 2000, Medicare has provided coverage for beneficiaries for routine costs associated with cancer clinical trial enrollment. Results have shown increased enrollment, while no increase in cost has been identified.
4. Twenty-four states in the United States plus the District of Columbia have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care a patient receives while participating in a clinical trial.
5. Some health plans mistakenly think that money is saved by excluding care when patients participate in clinical trials. However, if not enrolled on a clinical trial, these patients will continue to receive conventional therapy. Studies have shown that there are not significant differences in cost of care for patients enrolled on clinical trials compared with patients on conventional therapy.
6. Results of clinical trials lead to more rational use of cancer treatment and more successful outcomes, resulting in short-term and long-term cost savings.

PROPOSED LEGISLATION:

We propose that the Senate and House of the State of Alaska pass a bill requiring that all health care plans, including Medicaid, cover routine patient care costs for patients enrolled in all phases of clinical trials, including prevention, detection, treatment and palliation (supportive care) of cancer.

BENEFITS:

1. Passage of this bill will remove an important barrier to the participation of patients in cancer clinical trials. It will result in physicians more often recommending patient participation and in patients having greater desire to enroll in clinical trials.
2. Greater participation by Alaskans in cancer clinical trials will result in improved care of our patients in the short- and long-term, improved doctor-patient relationship, increased patient satisfaction with treatment, and increased retention of patients in Alaska for their cancer care.
3. Alaska will be in the forefront in making meaningful progress in providing care for cancer and other life threatening conditions.

REFERENCES:

1. States That Require Health Plans to Cover Patient Care Costs in Clinical Trials
<http://www.cancer.gov/clinicaltrials/learning/laws-about-clinical-trial-costs>
2. Clinical Trials and Insurance Coverage - A Resource Guide
<http://www.cancer.gov/clinicaltrials/learning/insurance-coverage/page1>
3. Coverage of Routine Patient Care Costs in Clinical Trials Position Statement
http://www.asco.org/asco/downloads/patient_care_costs_3.05.pdf
4. American Society of Clinical Oncology Response to CMS Town Hall Meeting "The Effect of Coverage and Payment on Clinical Research Study Participation and Retention" September 10, 2007
5. Harris Interactive. *Health Care News*. Vol 1, Issue 3. January 22, 2001.
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9. Bennett CL, et al: Evaluating the financial impact of clinical trials in oncology: results from a pilot study from the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project. *Journal of Clinical Oncology*. 18:2805-2810, 2000.
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11. Wagner JL, et al: Incremental costs of enrolling cancer patients in clinical trials: a population-based study. *Journal of the National Cancer Institute*. 91:847-853, 1999.
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April 2, 2008

Testimony to Support SB280

To

Senate Labor & Commerce Committee,

I am a medical oncologist-hematologist practicing in Anchorage.

Hence I am involved in caring for many, many patients with cancer, which are oftentimes deadly.

As yet, many cancers do not have curative treatments. One of the options I offer to all my patients is to consider treatment under clinical trials- scientifically conducted studies by approved medical organizations to try & improve cancer care.

Unfortunately, due to Insurers denying coverage for routine medical care when patients enter clinical trials, patients very obviously & naturally, decline to participate in clinical trials.

In my opinion, this state of affairs is a major handicap for patients/ individuals in Alaska to receive State of Art Care for Cancer & related problems in Alaska.

Just to give you an example, Herceptin is now used in early breast cancer treatment as the women with breast cancer who participated proved its efficacy in a clinical trial. This trial included at least 2 women in Alaska.

I wholeheartedly support SB280 & sincerely hope your committee members will too for all of our sakes.

Sincerely,

Latha Subramanian MD, FACP



National Surgical Adjuvant Breast and Bowel Project

PARTNERS IN CANCER RESEARCH

Norman Wolmark, MD
Chairman

Operations Center

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Clinical Coordinating Division
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TESTIMONY OF D. LAWRENCE WICKERHAM, MD, ASSOCIATE CHAIRMAN OF THE NSABP, CONCERNING SB280

I am Dr. Lawrence Wickerham, the Associate Chairman of the National Surgical Adjuvant Breast and Bowel Project (NSABP), which is one of the National Cancer Institute's Cooperative Trials Groups.

The NSABP conducts large phase III studies that compare standard treatments with newer innovative therapies in patients with early stage breast or colorectal cancer. The group's mission is to improve the survival and quality of life of these patients. 2008 is the 50th anniversary of the NSABP and over those years we have entered over 130,000 individuals into our trials. Today we have 200 participating centers and 300 satellite centers located throughout the U.S., Canada, Puerto Rico, and Ireland, and we do have centers in Alaska.

Results of previous NSABP studies have had a major impact in improving the care of both breast and bowel cancer. The results of our breast cancer studies have eliminated the use of true radical mastectomies, demonstrated that lumpectomy is an effective alternative, and we have shown that adjuvant treatment (treatment after surgery) can improve survival. Adjuvant therapy for breast cancer includes chemotherapy, hormonal therapy, and newer targeted treatments.

Figures from the American Cancer Society demonstrate that the mortality rate from breast cancer in the U.S. has declined for over a decade. This improvement is thought to be the result of screening mammograms to detect the disease and improvements in treatment. These improvements in care come primarily from clinical

D. Lawrence Wickerham, MD

trials like those conducted by the NSABP. The more patients that enter these studies, the more quickly we get results and the faster we can improve care. Unfortunately, for a variety of reasons, less than 5% of cancer patients choose to enter clinical trials. Cost is a major barrier.

Requiring health care insurers to cover the standard of care costs for individuals participating in cancer clinical trials would remove one significant barrier to increasing participation. Any research trial includes two general categories of costs: 1) research costs – expenses that the patient would not routinely incur if he or she was not a part of the trial (extra lab tests, x-rays, etc.), and 2) standard of care costs – expenses that would occur whether or not the patient entered the trial.

NSABP studies routinely identify the non-standard of care components. We provide the drug(s) being studied and typically provide additional non-federal funding to help defray the costs of trial participation, including the cost of non-standard of care items. The goal is to minimize any additional costs to the patient, improve trial participation and improve cancer care in general.

I and the NSABP strongly urge you to enact this bill so that cancer patients in Alaska can have improved access to state-of-the-art research studies like those available to patients in other states.

Thank you for listening to my testimony and I would be pleased to try to answer your questions.