WISCONSIN STATE LEGISLATURE
COMMITTEE HEARING RECORDS

2005-06
(session year)

Assembly
(Assembly, Senate or Joint)

Committee on Insurance (AC-In)

File Naming Example:

Record of Comm. Proceedings ... RCP

- 05hr_AC-Ed_RCP_pt01a
- 05hr_AC-Ed_RCP_pt01b
- 05hr_AC-Ed_RCP_pt02

COMMITTEE NOTICES ...

- *Committee Hearings ... CH* (Public Hearing Announcements)
- **

- *Committee Reports ... CR*
- **

- *Executive Sessions ... ES*
- **

- *Record of Comm. Proceedings ... RCP*
- **

INFORMATION COLLECTED BY COMMITTEE CLERK FOR AND AGAINST PROPOSAL

- *Appointments ... Appt*
- **

Name:

- *Clearinghouse Rules ... CRule*
- **

- *Hearing Records ... HR* (bills and resolutions)
- **05hr_ab0617_AC-In_pt02**

- *Miscellaneous ... Misc*
- **

J. A. Stewart MD 8/31/05

SENATE BILL 288

Wednesday, Aug. 31
Room 201 S.E.

Thank you Chairperson Roessler and members of the committee.

I'm Jim Stewart, I work as a Medical Oncologist here in Madison at the Cancer Center and have practiced as a cancer clinician for 25 years. I personally, and UW Health as an organization strongly support this bill because of the benefit to Wisconsin's 26,000 residents who will be diagnosed with cancer this year. I also believe that passage of this bill will help control cancer care costs, not increase them. In the past 25 years I've treated thousands patients and been involved in many clinical trials. Clinical trials have two objectives. They are designed to both treat the patient and to learn how to make the treatment better. Today we are seeing a revolution in cancer care. We are seeing the application in the clinic of lessons learned in the basic science laboratories over the the last 30 years. Understanding how cancer works is leading to more effective treatments.

Patients are energized and come to clinic more than ever having done homework about their disease and armed with good questions and ideas about their plan of care. Cancer for most is no longer an unspoken diagnosis as it was only 30 years ago. However my excitement is diminished by the reality of what I see in cancer care as

you know, a large and very expensive area of health care. Let me explain by reviewing some history.

Twenty five to 30 years ago surgical and radiation treatments dominated cancer care. Chemotherapy was avoided by many patients, some surgeons advised patients to not get chemotherapy, we did not have good nausea control, there was much risk for infection and the chemotherapy treatments all too often were ineffective. For patients with colon, breast, lung, pancreas and prostate cancer if there was metastatic disease it was not considered curable. Oncologists in cancer centers and a few in community settings were dissatisfied with this, certainly patients were, and in concert with the National Cancer Institute developed systems of care called clinical trials that provide cancer patients with access to the newest options for cancer treatment and at the same time study the ongoing treatment plans and compare them to new ones, always trying to make treatments more effective and less toxic. Today in the US and (we should all be proud to note) particularly throughout Wisconsin there is an outstanding network of oncology nurses and doctors trained to deliver care in the context of a clinical trial. Cancer Clinical trials are part of treatment plans for patients in 30 Wisconsin communities. In Green Bay and Milwaukee, Madison and LaCrosse, Marshfield and Rhinelander patients have the opportunity to receive their cancer treatment as part of a clinical trial.

Where is the problem then? In one generation, in just the few decades I've described, some progress has of course been made,

and certainly there has been dramatic growth in the number of oncologists and cancer clinics, in the number of drugs available, an extraordinary increase in cancer care costs and what is perhaps most striking to me a dramatic increase in the willingness of patients and clinicians to use expensive and often still too toxic treatments that all too often don't work. Yet for most patients with metastatic colon, breast, lung, pancreas or prostate cancer there is still no curable treatment. The average survival in pancreas cancer is less then a year with only 3% of patients living to 5 years. For lung cancer only 12% of patients live 5 years. Yet we have in all cancer clinics routine use of expensive therapy that is considered "standard" yet doesn't work well. This standard herapy that is given outside of a trial setting is readily paid for by HMO's and other insurance plans. In fact we have become too content with these standards and too quick to label poor treatment as standard. The dissatisfaction with ineffective treatment that stimulated things 25 years ago is too often absent in our doctors and surprisingly in those who manage the money that pays for these treatments.

The clinical trials process should be considered standard mainstream cancer care. All trials involve treatment for cancer that is given with therapeutic intent. It is part of the patient's treatment. Often it is the best treatment choice. All trials undergo extensive review for safety by Institutional Review Boards at the local hospital/clinic level and many studies receive multiple levels of review with national review as well. This is a federal requirement for clinical research done not only

in cancer but other diseases, whether at a university or community hospital.

Now for one of the most important points of this bill that is before you. This bill does not mandate new coverage by insurers. The bill asks for uniformity among payors with regard to the routine care costs of treatment whether or not the patient is part of a clinical trial. It does not require payment for the research costs. It is clear that insurers will already pay for chemotherapy for a patient with lung cancer. They routinely pay for doctor visits, x-rays to see if the cancer is shrinking or progressing, the nurses time for administering the treatment and so on...costs that would be expected for any treatment. Yet if the patient elects to get treatment in the context of a well designed, well reviewed clinical trial where research costs will be covered by the sponsor of the clinical trial and we will learn something that will lead to better treatment the insurance company will many times say no....we don't participate in experimental treatment, we don't support clinical trials....even if routine standard treatment is expected to yield minimal benefit.

Passage of this bill will encourage rather than discourage treatment in a clinical trial setting and I would argue that both in the short and long run this will actually save the insurer dollars. Often overall costs to insurers are less because the research funding agency, be it the NCI or industry supply the drug being used. Costs should not be more because the funding agency pays for the research costs associated with the trial.

For those concerned about potential increased "routine" costs because a study setting is involved it is important to know that the IRB review process requires that testing done just for research be identified and excluded from routine costs. This prevents the insurer from paying for excess doctor visits or excess imaging tests that might be needed to answer a research question but are not part of routine care. In addition, insurers will have their subscribers participating in a highly audited system of care (because clinical trials based care is extensively reviewed), a system of care with greater uniformity of practice across the doctors and clinic sites, and they will have outcome data that is difficult to get otherwise. Some insurers I speak with think this is an excellent setting for treatment.

Some critics of the bill are concerned that treatment on a trial is too experimental. There is a history of labeling studies as phase I, 2, 3 and so on depending on how far developed the treatment is. Traditionally phase I trials were the earliest testing of new drugs in a variety of cancers with phase 2 focusing in on a specific cancer, and phase 3 type trials being a comparison of treatments. Currently there are many hundreds of drugs and strategies that are good candidates for testing in cancer trials. In fact there are too many to test (remember we are seeing the payoff from the laboratory research of the last 30 years) so that even in the earliest phases of this evaluation only the very best candidates make it into the clinic. We are seeing, because of this, some phase I trials such as in kidney cancer with 30-40% tumor response rates. These are much higher responses than the standard and dramatically expensive interferon

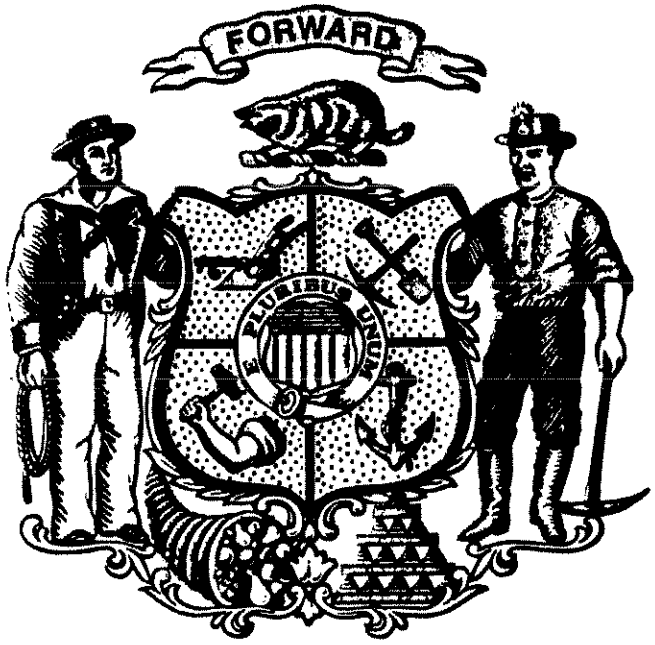
that has been used in kidney cancer for years. My view of this phase language is that it is antiquated and in many of the newer studies the lines are blurred. Some trials cross phase lines and increasingly trials are not even labeled by phase. In any case all of these trials are used with therapeutic intent and from a patients perspective they are reasonable treatment options often their best medical option.

We have wonderful health care systems in Wisconsin. UW Health and the Comprehensive Cancer Center are certainly important components of Wisconsin's cancer care systems and I hope you are as proud of our Cancer Center as I am. But we have a well established and geographically wide cancer clinical trials network that is independent of UW. Both Marshfield and Green Bay have NCI support from independent grants that fuel their clinical trials programs. The Medical College is extremely active in cancer trials. So it is important to note that this is not a bill centered on UW Madison activities. It is centered on the people of Wisconsin who have or will develop cancer. Nationally, in terms of statewide cancer clinical trials legislation or agreements we are not ahead of the curve. Over 20 states have programs that prevent discrimination against a patient with cancer just because they choose to receive treatment in a clinical trials setting. It is also important to note that Medicare approved such coverage several years ago.

As an aside if this bill is passed I think it offers opportunity for the cancer clinical community to work together with insurers to reduce costs both in and outside of the trial setting. We don't do that often

enough. Another important history lesson is the 1990's when high dose chemotherapy and bone marrow transplant became a community standard for breast cancer. The ongoing trials to test the value of transplant were not being supported by insurers but this treatment strategy became common via litigation. When the trials were finally done and showed that the transplant based treatment was not an advance the use of transplant in breast cancer stopped in a few months. Think of the unnecessary toxicity and millions of dollars that could have been saved if the right trials had been done first.

I don't want a repeat of that story and so would strongly support this bill to help make trials treatment part of mainstream cancer care.


FORWARD

Stoll, Joanna

From: JudyMHO@aol.com
Sent: Monday, October 31, 2005 11:38 AM
To: Rep.LehmanJ
Subject: AB 617/SB 288 Hearing Thursday, Nov. 3

Dear John,

The Cancer Patient Protection Bill, AB 617, will be coming before your committee on insurance this Thursday. As you know, I am a cancer patient with Multiple Myeloma, an incurable cancer. Clinical trials are where the newest drugs and combinations of drugs are studied. This bill only relates to requiring coverage for extra health costs in a clinical trial if the same costs would have been covered for standard cancer treatment. Currently, 22 other states offer such coverage and studies show minimal increases in coverage cost when such a law is enacted.

Please stress the importance of this bill to your colleagues on the committee. Thanks

Sincerely,

Judy

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Racine, WI 53402
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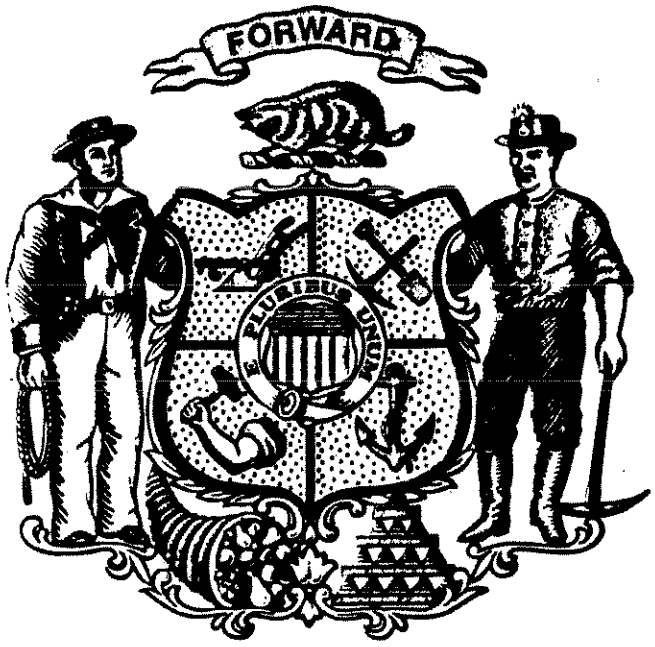
Rep.Lehmanj@legis.state.wi.us

State Representative
John Lehman


FORWARD
E PLURIBUS UNUM

WISCONSIN
BREAST CANCER
COALITION

November 1, 2005

To: The Assembly Committee on Insurance
Re: AB 617 – Cancer Patient Protection Bill

Dear Chairperson Nischke and Committee Members:

The Wisconsin Breast Cancer Coalition would like to express our support for Assembly Bill 617, The Cancer Patient Protection Bill. The WBCC is a statewide, grassroots nonprofit organization. Clinical trials are of particular importance to us because we know that even with good research being conducted, we still need a mechanism for getting that research from the lab to the patients who need it. The intermediate step that is needed is the clinical trials process.

Unfortunately, barriers to participation in trials result in less than 5% of adult cancer patients joining clinical trials. One of those barriers is not having coverage for routine care costs covered by an insurer while participating in a trial.

There are thousands of cancer patients in Wisconsin whose best, and possibly last, hope for cutting edge treatment might be found in a clinical trial. There are even more of us who are waiting for solid, evidence-based research to provide hope for the future – because cancer in one form or another is something virtually all of us can count on being touched by. If we do not work to remove barriers to participation in trials, low accrual rates may impede the progress of good research.

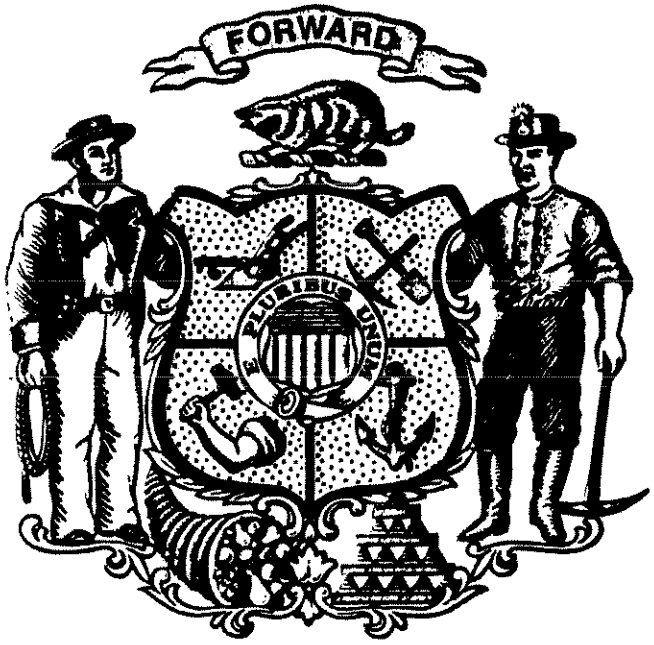
The WBCC works to provide education about the process to cancer patients and their families. We try to remove any barriers related to misunderstandings or myths about what happens in a clinical trial. We cannot, however, do anything about insurance coverage.

The system must be set up in a way that all stake holders – patients, health care providers, health insurers, pharmaceutical companies, advocacy groups, and the government – are invested in the same outcome: finding the best diagnostic procedures and treatments for cancer. This should be the goal for all of us.

We encourage your support of AB 617. Thank you for your consideration.

Sincerely,

Dawn Anderson
Chairperson, State Policy
WI Breast Cancer Coalition
(414) 332-6179


FORWARD

11/2/2005

Testimony of Charles L Bennett MD PhD
Professor of Medicine, Northwestern University
Co-Program Director for Cancer Control for the
Robert H Lurie Comprehensive Cancer Center of Northwestern University
Associate Director,
Veterans Affairs MidWest Center for Health Services and Policy Research

Chairman. I am pleased to testify before your committee regarding Wisconsin clinical trials bill - AB 617/SB 288. The bill requires healthcare insurance to provide coverage for healthcare services administered in a cancer clinical trial if the service would be covered if administered in a traditional treatment regimen. The bill was introduced by Representatives Gunderson, Davis, Wasserman, Albers, Ballweg, Benedict, Berceau, Bies, Boyle, Fields, Gronemus, Hahn, Hines, Kaufert, Krawczyk, Kreibich, Lehman, Lothian, Molepske, Montgomery, Musser, Nelson, Ott, Pettis, Sheridan, Steinbrink, Townsend, Van Akkeren, Van Roy, Vos and Vruwink; and is cosponsored by Senators Stepp, Roessler, Brown, Darling, Erpenbach, Hansen, Kanavas, A. Lasee, Lassa, Olsen, Risser, Wirch and Zien. AB 617 was referred to the Assembly Committee on Insurance. SB 288 was referred to the Senate Committee on Health. A public hearing was held on SB 288 on August 31, 2005.

I am a practicing hematologist/oncologist at the Robert H Lurie Comprehensive Cancer Center of Northwestern University and the Chicago VA Hospital and a Professor of Medicine with tenure at Northwestern University. The Robert H Lurie Comprehensive Cancer Center of Northwestern University is the only National Cancer Institute designated comprehensive cancer center in Illinois. I have a PhD in the field of Public Policy from the RAND Corporation, granted in 1991 and presented to me by Henry Kissinger. I am also the immediate past Chairman of the Health Services Research Committee of the American Society of Clinical Oncology. I will read to you my testimony regarding costs of clinical trials and submit in writing the testimony as well as several related supporting documents. I would like to make several points.

First, the medical care costs for patients enrolled on phase II and phase III cancer trials is about the same as that for patients who receive costs outside of the clinical trial setting. I base this statement in part on data I have reported in an August 2000 paper published in the Journal of Clinical Oncology. That study was a pilot effort that included detailed assessment of total direct medical charges for 6 months of care for 35 case patients with cancer who received care on phase II clinical trials and for 35 matched controls who received care at Northwestern University, Fox Chase, the Moffit Cancer Center, Tulane Cancer Center, and the University of Pittsburgh. Matching was based on age, sex, disease, stage, and treatment period. Total mean charges for treatment from the time of study enrollment through 6 months were similar: $57,542 for clinical trial patients and $63,721 for control patients (in $1998).

Second, in a follow-up paper that I published in December 2001 in the Journal of Clinical Oncology, I updated the findings in the literature on this subject. I was able to identify five pilot studies which provided information on phase II/phase III clinical trials matched with controls on standard care. A variety of economic methodologies were used in these studies, which were conducted by myself as well as oncologists and economists at Memorial Sloan Kettering Cancer Center, Kaiser Permanente, the Mayo Clinic, and the Group Health Cooperative in Seattle. Four of these studies based their findings on costs, and one used charges. At 6 months follow-up, mean costs/charges for clinical trial versus control patients were between 10% lower to 23% higher; at 12 months, the difference was reported as 10% and 14% higher in two studies; at 24 months, the difference was 20% greater; and at 60 months, the mean difference was only 1%. The studies included 377 patients on phase II and phase III clinical trials. Control groups included patients with the same diagnosis and tumor stage and similar comorbidity levels who received similar treatments in the setting of standard cancer care. The payment systems included two fee-for-service, two managed care, and one Medicare programs. In the manuscript which I will submit with my testimony, I review the methodologic differences among the studies.

Third, my former colleagues at the RAND Corporate validated our findings. In a study sponsored by the National Cancer Institute, these investigators evaluated the costs of 750 individuals enrolled onto phase II/phase III clinical trials from multiple community and tertiary care cancer centers and 750 matched controls. The study found essentially the same results as in the six prior studies. All of the studies taken together indicate that the patient care costs for individuals with cancer who participate in phase II or phase III trials is at most 10% to 20% greater than the costs of similar patients who receive cancer care outside of the clinical trial setting. I would stress that these findings reflect the committed efforts of clinical trialists to design studies which do not include extraneous tests or assessments. This was rarely the case 10 or 15 years ago. The studies also include the costs of complications of therapy. Medical complications for cancer patients occur in the setting of routine clinical care and clinical trials, and generally relate to side effects of the general types of treatment- radiation, surgery, and chemotherapy- and would often occur in the setting outside of a clinical trial.

Fourth, former President, Bill Clinton, in 2000 issued a memorandum stating that Medicare was authorized to cover the costs of cancer clinical trials. This decision was based on the study findings which I have outlined, an Institute of Medicine report recommending Medicare coverage of routine patient costs on clinical trials, and a growing body of state legislation and voluntary initiatives from private insurers. The Final National Coverage Determination extended the definition of qualified clinical trials beyond those funded or conducted by government bodies to trials such as those which were funded by the NIH, the Centers for Disease Control and Prevention, the Agency for Health Research and Quality, CMS, the DOD, and the VA; trials supported by centers or cooperative groups that are funded by these organizations; and trials conducted under an IND from the FDA. As of October 2005, 22 states have passed laws mandating coverage of patient care costs associated with cancer clinical trials. At the end of the last decade, several large private insurers agreed to reimburse for medical care that occurs with

clinical trials. These insurers included the New Jersey Association of Health Plans, Ohio Med, United Healthcare, and the Mayo Health Plan. The New Jersey Association of Health Plans agreement is unique in that it represents the first instance for which all private insurers in a single state voluntarily agreed to provide cancer clinical trial coverage. Insurers in Michigan and Minnesota have followed the New Jersey example by encouraging collaborative task forces to work with private insurers to voluntarily pursue clinical trial coverage.

Fifth, with respect to patient safety, clinical trials are a real buy. Only 1% to 10% of serious adverse drug reactions are reported by physicians to the FDA or other sources in the setting of routine cancer care. In contrast, 100% of all serious adverse events are reported by clinicians for cancer patients who receive care in clinical trials. This is especially important for cancer treatments, because accelerated FDA approval is limited to cancer and HIV. In information that has been accepted for an oral presentation at the American Society of Clinical Oncology's national conference in May in Chicago, I have reviewed the findings for 24 potentially fatal Adverse Drug Reactions associated with 21 oncology drugs which were identified post-FDA approval in the years 2000 to 2002. Deaths from the ADR were reported for as many as 44 individuals. Of note, for this drug, irinotecan, use of the drug in thousands of individuals outside of the clinical trial setting had not identified the same fatal ADR. I also reported important findings for thalidomide, a drug with a tragic history which has had a resurgence for multiple myeloma and other cancers. This illness is an important one- Geraldine Ferrara, the former vice-presidential candidate, for one has benefited from this drug. Thalidomide was used for 17,000 cancer patients in 2005, with each patient being registered on a program that addressed its safety. However, it was only because of clinician involvment in clinical trials that I was able to identify a large number of blood clots in the lungs and a 25% rate of this potentially fatal complication.

In summary, I would like to thank the Committee for allowing me to testify today on this important legislation. As a physician and policy researcher, there is no more important issue today than clinical trials for cancer patients. On a personal basis, I personally took care of my grandfather who died of metastatic bladder cancer. The overwhelming majority of pediatric cancer patients receive care in the setting of clinical trials and the largest breakthroughs in oncology have been for these individuals. In contrast, exciting new cancer therapies such as Gleevec for leukemia made their way into clinical practice because of clinical trials and have now saved tens of thousands of lives in the country and thousands of lives here in Wisconsin. Fewer than 5% of adult cancer patients participate in clinical trials. A Harris poll found that 60% of cancer patients who were aware of clinical trials and elected not to participate (representing 71% of all cancer patients) cited concerns about insurance denial as a primary barrier to participation. I strongly urge your committee to support legislation requiring insurance companies to provide coverage for patient care costs associated with cancer clinical trials. It adds little, if anything, to the overall treatment costs, it has an added and previously unrecognized benefit of dramatically improving patient safety, and it is the right thing to do. I will leave with the committee my written remarks and several additional supporting pieces of evidence for their review. Thank you very much.

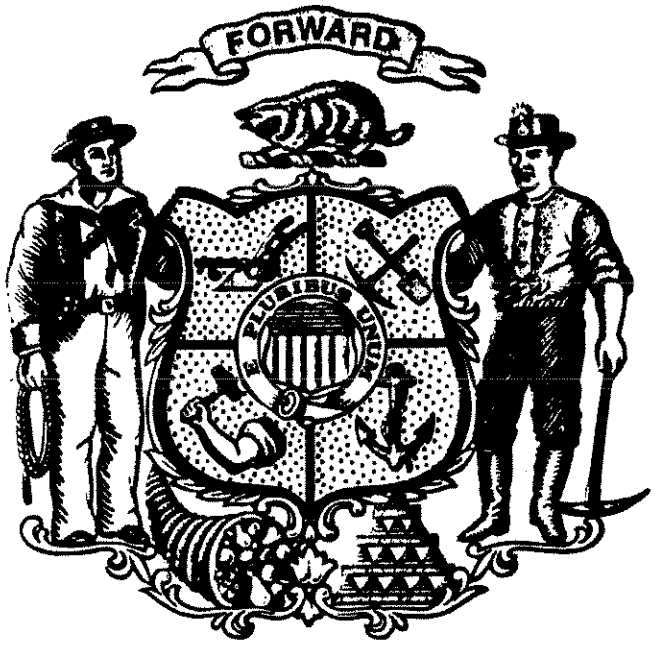
Appendices.

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: 2805-10, 2000

Bennett CL et al. Clinical trials: Are they a good buy? Journal of Clinical Oncology. 19: 4330-4339, 2001.

Bennett CL et al. The Research on Adverse Drug Events and Reports (RADAR) project. JAMA. 2005 May 4;293(17):2131-40.

Goldman DP et al. Incremental treatment costs in NCI-sponsored clinical trials. JAMA 2003; 289: 2970- 77.


FORWARD

November 3, 2005
James A. Stewart, MD

Comments For Public Hearing on Assembly Bill 617

My name is Jim Stewart, I work as a Medical Oncologist here in Madison at the Cancer Center and have practiced as a cancer clinician for 25 years. I support this bill because of the benefit to Wisconsin's 26,000 residents who will be diagnosed with cancer this year. I also believe that passage of this bill will help control cancer care costs, not increase them. In the past 25 years I've treated thousands of patients and been involved in many clinical trials. Clinical trials have two objectives. They are designed to both treat the patient and to learn how to make the treatment better. Today we are seeing a revolution in cancer care. We are seeing the application in the clinic of lessons learned in the basic science laboratories over the last 30 years. Understanding how cancer works is leading to more effective treatments.

Patients are energized and come to clinic more than ever having done homework about their disease and armed with good questions and ideas about their plan of care. Cancer for most is no longer an unspoken diagnosis as it was only 30 years ago. However my excitement is diminished by the reality of what I see in cancer care, as you know, a large and very expensive area of health care. Let me explain by reviewing some history.

Twenty five to 30 years ago surgical and radiation treatments dominated cancer care. Chemotherapy was avoided by many patients, some surgeons advised patients to not get chemotherapy, we did not have good nausea control, there was much risk for infection and the chemotherapy treatments all too often were ineffective. For patients with colon, breast, lung, pancreas and prostate cancer if there was metastatic disease it was not considered curable. Oncologists in cancer centers and a few in community settings were dissatisfied with this, certainly patients were, and in concert with the National Cancer Institute developed systems of care called clinical trials providing cancer patients with access to the newest options for cancer treatment and at the same time studying the ongoing treatment plans and comparing them to new ones, always trying to make treatments more effective and less toxic. Today in the US and (we should all be proud to note) particularly throughout Wisconsin there is an outstanding network of oncology nurses and doctors trained to deliver care in the context of a clinical trial. Cancer clinical trials are part of treatment plans for patients in 30 Wisconsin communities. In Green Bay and Milwaukee, Madison and LaCrosse, Marshfield and Rhinelander patients have the opportunity to receive their cancer treatment as part of a clinical trial.

Where is the problem then? In one generation, in just the few decades I've described, some progress has of course been made, and certainly there has been dramatic growth in the number of oncologists and cancer clinics, in the number of drugs available. There has also been an extraordinary increase in cancer care costs and what is perhaps most striking to me a dramatic increase in the willingness of patients and clinicians to use expensive and often still too toxic treatments that all too often don't work. But for most patients with metastatic colon, breast, lung, pancreas or prostate cancer there is still no curable treatment. The average survival in pancreas cancer is less then a year with only

3% of patients living to 5 years. For lung cancer only 12% of patients live 5 years. Yet we have in all cancer clinics routine use of expensive therapy that is considered "standard" yet doesn't work well. This standard therapy that is given outside of a trial setting is readily paid for by HMO's and other insurance plans. In fact we have become too content with these standards and too quick to label poor treatment as standard. The dissatisfaction with ineffective treatment that stimulated things 25 years ago is too often absent in all of us.

The clinical trials process should be considered standard mainstream cancer care. All trials involve treatment for cancer that is given with therapeutic intent. It is part of the patient's treatment. Often it is the best treatment choice. All trials undergo extensive review for safety by Institutional Review Boards at the local hospital/clinic level and many studies receive multiple levels of review with national review as well. This is a federal requirement for clinical research done not only in cancer but other diseases, whether at a university or community hospital.

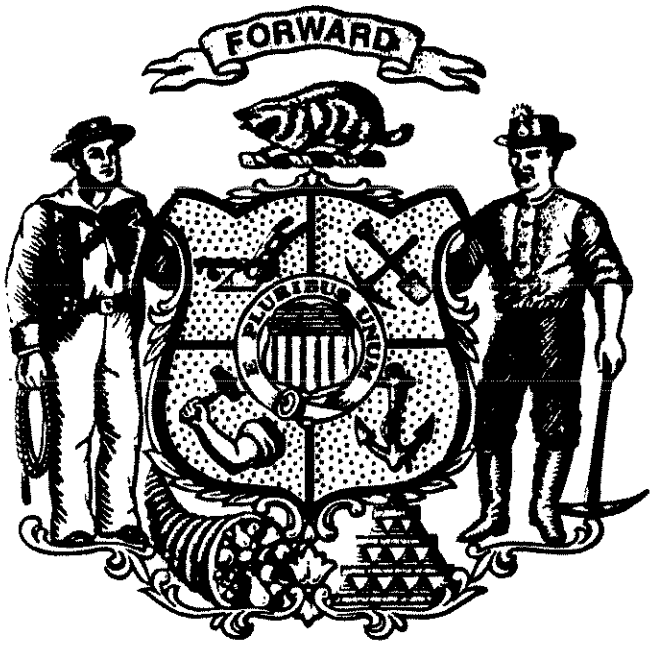
Now for one of the most important points of this bill. This bill does not mandate new coverage by insurers. The bill asks for coverage of the routine care costs of treatment whether or not the patient is part of a clinical trial. It does not require payment for the research costs. It is clear that insurers will already pay for chemotherapy for a patient with lung cancer. They routinely pay for doctor visits, x-rays to see if the cancer is shrinking or progressing, the nurses time for administering the treatment and so on...costs that would be expected for any treatment. Yet if the patient elects to get treatment in the context of a well designed, well reviewed clinical trial where research costs will be covered by the sponsor of the clinical trial and we will learn something that will lead to better treatment the insurance company will many times say no....we don't participate in experimental treatment....even if routine standard treatment is expected to yield minimal benefit.

Passage of this bill will encourage rather than discourage treatment in a clinical trial setting and I would argue that both in the short and long run this will actually save the insurer dollars. Often, overall costs to insurers can be less because the research funding agency, be it the NCI or industry will supply the drug being used. For those concerned about potential increased "routine" costs because a study setting is involved it is important to know that the IRB review process requires that testing done just for research be identified and excluded from routine costs. This prevents the insurer from paying for excess doctor visits or excess imaging tests. In addition insurers will have their subscribers participating in a highly audited system of care (because clinical trials based care is extensively reviewed), a system of care with greater uniformity of practice across the doctors and clinic sites, and they will have outcome data that is difficult to get otherwise. Some insurers I speak with think this is an excellent setting for treatment of a difficult high cost like cancer.

We have wonderful health care systems in Wisconsin. UW Health and the Comprehensive Cancer Center are certainly important components of Wisconsin's cancer care systems and I hope you are as proud of our Cancer Center as I am. But we have a well established and geographically wide cancer clinical trials network that is independent of UW. So it is important to note that this is not a bill centered on UW Madison activities. It is centered on the people of Wisconsin who have or will develop cancer. Nationally in terms of statewide cancer clinical trials legislation or agreements we are not ahead of the curve. Over 20 states have programs that prevent

discrimination against a patient with cancer just because they choose to receive treatment in study setting. Medicare approved such coverage several years ago.

As an aside, when this bill is passed I think it offers opportunity for the cancer clinical and research community to work together with insurers to find ways to reduce costs both in and outside of the trial setting. I've learned a great deal in discussions with insurance interests during development of this bill. I think passage of this bill will actually make these kinds of discussions easier. Another important history lesson is the 1990's when high dose chemotherapy and bone marrow transplant became a community standard for breast cancer. The ongoing trials to test the value of transplant were not being routinely supported by insurers but this treatment strategy became common via litigation. When the trials were finally done and showed that the transplant based treatment was not an advance the use of transplant in breast cancer stopped in a few months. Think of the unnecessary toxicity and millions of dollars that could have been saved if the right trials had been done first. I don't want a repeat of that story and so would strongly support this bill to help make trials based treatment part of mainstream cancer care.


FORWARD
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MEDICAL COLLEGE OF WISCONSIN

November 3, 2005

Office of Planning and
Government Affairs

Representative Ann Nischke, Chair
Assembly Committee on Insurance
Room 8 North, State Capitol
P.O. Box 8953
Madison, WI 53708-8953

Dear Chairman Nischke:

On behalf of the Medical College of Wisconsin, I want to express my strong support for Assembly Bill 617 relating to coverage of certain health care costs in cancer clinical trials. This bill prohibits health care plans from denying coverage for a health care service, item, or drug administered in a clinical trial if the service, item, or drug would have been covered had it not been administered in a clinical trial that meets certain requirements.

As you know, clinical trials are critical for ultimately curing diseases that afflict our patients every day. Often, a new drug or therapy offered through a clinical trial is a cancer patient's only hope for survival and countless patients have gone on to be cancer survivors after participating in new and emerging cancer therapy studies.

MCW supports the coverage of all routine care for cancer patients who are on clinical trials. These trials are offered only after rigorous review up to, and often including, the National Cancer Institute (NCI) and the Food and Drug Administration (FDA). The testing that is required by the trials is not frivolous, only with careful study and review can the results of the trials be validated and the safety, risks, and patient benefits be ascertained. This is not only in the interest of the patient who is being treated, but in the interest of society, since the results of trials are only valuable if full data sets are collected. Quality data guarantees that future patients will get the highest quality of care. If patients lack coverage for portions of these trials, many may choose not to participate.

I urge you to support Assembly Bill 617. Only through clinical trials and the data ascertained through the studies will we eventually cure the cancers that afflict our patients and their families.

Please feel free to contact me for any additional information.

Sincerely,

Bruce H. Campbell, M.D.
Interim Director
Medical College of Wisconsin Cancer Center

cc: Honorable Members of the Assembly Committee on Insurance

8701 Watertown Plank Road
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Milwaukee, Wisconsin 53226-0509
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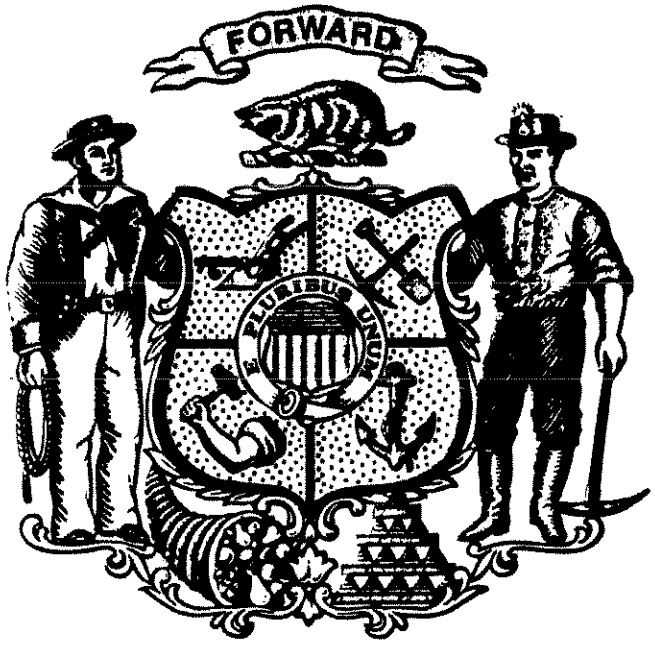
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Wisconsin Association of Health Plans

November 3, 2005

TO: Members, Assembly Committee on Insurance
Representative Ann Nischke, Chair

FROM: Paul Merline, Legislative/Agency Liaison

RE: Testimony for Information Only on AB 617 / SB 288

The Wisconsin Association of Health Plans had several concerns with AB 617 / SB 288 as originally drafted. Specifically, we felt the bill was too broadly drafted to apply solely to coverage of routine care. Through the good work and time commitment of the authors and their offices, Senator Roessler, and proponents of the bill, we have been able to reach a compromise agreement that addresses many of our concerns. Because of this good effort and compromise, we are no longer opposed to this bill and will not seek any further modifications.

Included among the key items of compromise:

- The inclusion of a more detailed definition of routine care, including the type and frequency of that care
- Language assuring that the trial itself be designed with therapeutic intent and that the treatment provided as part of the trial be given with the intention of improving the trial participant's health
- Language assuring that this routine care coverage is subject to the same terms and conditions as all other plan coverage
- The removal of an institution's own Institutional Review Board as having sole authority to approve a clinical trial

We are encouraged that all of the compromise items are being included in substitute amendments for both AB 617 and SB 288 and encourage your support of that substitute amendment.

I would again like to thank the authors and their offices, Senator Roessler and proponents for their good work and time commitments. All those involved in the discussions and negotiations worked very hard to complete this compromise.

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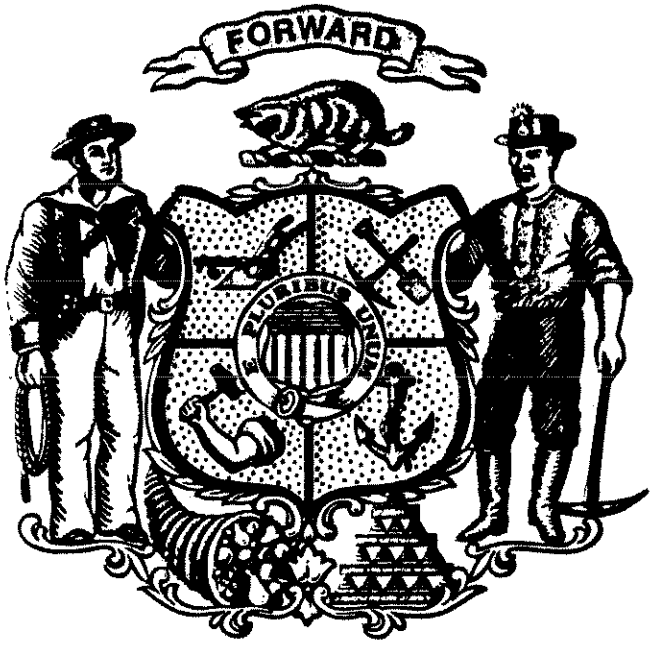
FORWARD

STATEMENT OF CHARLES BENNETT MD, PhD, MPP.

Professor of Medicine, Northwestern University

ON REIMBURSEMENT
OF ROUTINE PATIENT CARE COSTS
FOR PATIENTS
ENROLLED IN CLINICAL TRIALS

November 3, 2005

My name is Charles Bennett and I am a clinician and Professor of Medicine at the Robert H Lurie Comprehensive Cancer Center and the Jesse Brown VA Medical Center in Chicago. The Lurie Cancer Center is one of 41 centers designated as comprehensive by the National Cancer Institute on the basis of its breadth of clinical and basic science activities. I am also a practicing hematologist and medical oncologist with PhD in public policy from the RAND Corporation. I have been practicing clinically in oncology since 1984 and have two decades of experience in cancer care and research. I am pleased to present to you my views—which are based on my direct clinical experience as well as results of my own research—about the critical importance of clinical trials in bringing life-saving new treatments to cancer patients.

For people with serious or life-threatening illnesses like cancer, completely satisfactory or curative treatment often is not available. Those patients are nevertheless able to receive state-of-the-art therapy through high-quality clinical trials, offering not only an important treatment option, but an opportunity to advance medical knowledge.

In oncology, the majority of what we know to be effective as well as safe comes from clinical research. Unfortunately, today only 5% of adults with cancer participate in clinical trials. Why? A Harris Poll found that 71% of cancer patients chose not to participate in clinical trials because of fear that their insurance company may deny payment.[1] What patient would enter a study under these circumstances? At a time when a patient is making a difficult decision about treatment, added uncertainty about insurance payment may dissuade them from even considering clinical trials enrollment. The result: cancer clinical trials are slow to enroll patients, take much longer to complete and, ultimately, delay what could be lifesaving therapy for cancer patients. Moreover, because clinical trials represent the best chance of identifying serious adverse drug reactions and developing ways to predict, prevent or treat these events, cancer patients face years of therapy with chemotherapeutic agents whose safety profile is not completely understood.

The Medicare program, the Department of Defense, the Veteran's Administration, the United Healthcare Group, Aetna US Healthcare, and twenty-two states have recognized the importance of providing access to clinical trials and have included provisions in regulation, law or voluntary agreements. I urge Wisconsin—a state that stands out nationally for its progressive thinking on social issues and the delivery of health care to all of its citizens—to do the same.

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[1] Comis RL et al. Public attitudes toward participation in cancer clinical trials. Journal of Clinical Oncology. 2003 Mar 1;21(5):830-5.

A key reason many insurers exclude participation in clinical trials is concern about cost. My own research, published in 2000 in the Journal of Clinical Oncology[2]—and that of five other studies by distinguished health economists—all indicate that there is no reason to believe the fiscal impact on insurers would be changed. My initial study was based on cost data for cancer patients who received cancer care at Northwestern, the Fox Chase Cancer Center in Philadelphia, UCLA, the University of Pittsburgh, and the Moffett Cancer Center in Tampa (five of the most experienced centers in the country) found that medical costs were 10% LESS when patients received care as part of a clinical trial. Coverage of routine patient care costs should not vary depending on whether one is enrolled in a trial or not. A follow-up study in 2003 from my former research partners at RAND from 83 institutions in the country found similar results. [3]

The costs incurred in treating a patient in a clinical trial are basically three-fold:

- The pure cost of research (collecting and analyzing data), which is covered by the research grant from the sponsoring institution, whether it be NIH or a pharmaceutical company,
- The cost of any investigational agent, which must be covered by the industrial sponsor and would not be the responsibility of third party payors under FDA rules, and
- Routine patient care costs, which should be the responsibility of third party payors.

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[2] 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. Journal of Clinical Oncology 2000; 18: 2805- 10.

[3] Goldman DP et al. Incremental treatment costs in NCI-sponsored clinical trials. JAMA 2003; 289: 2970-77.

Beneficiaries pay premiums in the reasonable expectation that, when they are stricken with illnesses like cancer, the program will be there for them, paying the cost of physician services, hospital stays and usual and necessary diagnostic tests. These routine costs are incurred for patients in trials just as for patients receiving standard therapy. In either case, insurers should pay them.

An important point that is rarely considered in the context of clinical trials is patient safety. Over half of all new cancer drugs approved by the FDA currently receive accelerated approval and are used by thousands of cancer patients way before their safety profile is well understood. Findings from my research program, the Research on Adverse Drug Events and Reports (or RADAR) project indicate that the FDA rarely receives comprehensive reports describing previously unknown and potentially fatal adverse drug reactions outside of the clinical trial setting. In contrast, these reports are unbelievable complete when they occur in the context of a clinical trial—in a sense I am suggesting that in this instance there is a "free lunch." [4]Had clinical trials been conducted for a longer period of time with a focus on both safety and efficacy, the Merck Corporation would not be defending thousands of Vioxx cases in courts all over the country.

Coverage of patient care costs in clinical trials becomes a compelling consumer protection issue. If payers persist in the position that these routine costs are not their programmatic responsibility, beneficiaries will continue to be at risk of losing much of the value of their insurance, just at their moment of greatest vulnerability—when they are given a diagnosis of cancer. And of course society remains at a disadvantage

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[4] Bennett CL et al. The Research on Adverse Drug Events and Reports (RADAR) project. JAMA. 2005 May 4;293(17):2131-40.

with respect to our knowledge of both how new agents might affect the course of this deadly disease as well as a complete understanding of the safety of these drugs.

Insurance coverage of the routine patient care costs associated with participation in clinical trials—the same costs insurance pays for standard care—have not placed financial burdens in programs that have included this coverage. I urge you to consider this legislation favorably, for cancer patients in Wisconsin—and for those who will benefit, both now and in the future, from this critical step towards life-saving cures.

Thank you for the opportunity to speak today. I am happy to answer any questions you may have.