

# THE CAL GAB



Cancer & Leukemia  
Group B  
Newsletter

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208 South LaSalle Street, Suite 2000  
Chicago, IL 60604-1104

## The CALGB Celebrates 40 Years

This Spring marks the 40th anniversary of the founding of the Cancer and Leukemia Group B (CALGB). To mark this event, the three former Group Chairs—Drs. Emil Frei, III, James F. Holland, and O. Ross McIntyre—have been invited to address the Plenary Session where they will reflect upon their tenures and the subsequent strides the Group has made.

The precursor of the CALGB, the Acute Leukemia Group B (ALGB), was designated in 1956 by the clinical studies panel of the Cancer Chemotherapy National Service Center. Under the leadership of Emil Frei, III, M.D., the first Group Chairman, the ALGB performed controlled clinical trials in the acute leukemias, which attracted pediatricians, hematologists, and internists with an interest in chemotherapy. During this time, Dr. Oliver Glidewell served as Group Statistician. In 1963, Dr. James F. Holland was named Group Chair, a position he held until 1981. The Group's focus of research expanded to include pediatric neoplasms,

multi-modality treatment of Wilms' tumor, certain adult solid tumors, and breast cancer. Principles of chemotherapy derived from acute leukemia studies were translated into applications for solid tumors during this time, as well.

In 1976, the Group's name was changed to the Cancer and Leukemia Group B to reflect the inclusion of solid tumors addressed by Group studies. Dr. Frei returned to the CALGB in 1981 as Group Chair, and Dr. James Anderson was appointed Group Statistician. During this period, the Group's clinical research efforts focused on the areas of leukemia and lymphoma, as well as breast and respiratory cancer. In addition, emphasis was placed on the Group's considerable expertise in immunology and the application of immunologic methods for the identification and classification of leukemia and lymphoma cells. In 1983, the CALGB became a research base for Community Clinical Oncology Programs (CCOPs), and

*continued on page 3*

### Inside:

CALGB Celebrates 40 Years .....	1
Message from the Group Chair .....	2
Transitions .....	3
Putting the Minimalist Theory into Practice .....	4
Oncology Nursing .....	5
Pharmacy .....	6
Protocol Updates .....	7
Meeting Information .....	8
Meeting Schedule .....	9
Registration Forms .....	Back Pages

*The Cal Gab is published quarterly by the Cancer and Leukemia Group B, and distributed to the active membership.*

*Suggestions for articles are encouraged.*

*Copy deadlines are:*

*January 15, April 15, July 15, October 15*

*Articles should be sent to:*

*Barbara Hower, Newsletter Editor  
Cancer and Leukemia Group B  
208 South LaSalle Street, Suite 2000  
Chicago, IL 60604-1104*

*(312) 702-9479 FAX (312) 345-0117*

*e-mail: bhower@midway.uchicago.edu*

### 1996 CALGB Meetings

**Fall Core Meeting**    **September 27 - 29**    **Raleigh (NC) Hilton**

**Fall Group Meeting**    **November 1-4, 1996**    **Pittsburgh Hilton and Towers**

**Spring Meeting Registration  
Deadline is April 12, 1996  
Hotel Reservation Deadline is  
April 1, 1996**

**All Spring Meeting Information and Registration Forms are in  
this issue.**

**There will not be a separate mailing.  
For extra forms, contact Dorothy Tibbs at (312) 702-9171**

## Message from the Group Chair...

The issue of “credit” for participation in CALGB studies is widely discussed and often misunderstood within the Group. It is time to set the record straight. CALGB investigators and institutions are recognized for their participation in CALGB activities in a number of ways, including study chairmanships, membership on core committees, authorship on abstracts and manuscripts, and, for certain studies, per case reimbursement for patient accrual. For enrolling patients on CALGB studies, CCOP institutions receive cancer treatment and cancer control credits, which are provided by the Division of Cancer Prevention and Control at the National Cancer Institute, not by the CALGB. Indeed, the CALGB does not have a system of assigning “credits” for participation in CALGB studies. The CALGB does, however, keep track of patient registrations on protocol. For example, whenever a patient is registered to a CALGB study, the accrual is noted in the database and “credited” to the institution. At the present time, all CALGB protocols are counted equally. Thus, registration of a patient to a bone marrow transplant study, an adjuvant breast cancer study, or a phase II study in non-small cell lung cancer all count the same, i.e., one registration is noted in the database. Registration of patients to companion protocols is handled exactly the same way. Thus, a patient who is registered to a treatment protocol and three companion protocols will garner four registrations for the institution.

As CALGB protocols have increased in complexity, institutions have questioned whether this system continues to be equitable. Clearly, some protocols require a great deal more work than others. Some members of the Group have suggested that we develop a “degree of difficulty scale” that would, in some way, allow us to weight protocols based on the workload involved and assign additional “credit” for participation in such studies. To address these issues, I appointed an *ad hoc* committee to consider the issue of assigning credit for participation in CALGB studies. The committee felt it was not appropriate to develop a method of assessing workload for individual studies, believing, rather, that such a process would be difficult to implement and fraught with subjective evaluations of how to determine “difficulty” for any particular study. The committee felt that any system of evaluating studies should be simple and consistent with our current practices for registering patients to CALGB protocols. Following additional discussion among the Group leadership and the Executive Committee, we have decided to make some modifications of the current system for developing protocols that will allow us to recognize the increasing complexity of certain studies while preserving the fundamental principle that CALGB workload be measured in terms of patient registration to studies rather than some arbitrary “credit” system.

In the coming months we will implement the following system. The CALGB will continue to count only patient registrations to studies. Each registration will be counted

as an accrual for the institution. Patients may be registered to treatment protocols, cancer prevention studies, cancer control studies, mandatory companion studies, or optional companion studies. Companion protocols that are considered optional or that apply to multiple treatment studies will be written as separate protocol documents with a separate protocol number and separate consent form. Companion protocols that apply to a single treatment study and are considered mandatory may also be written as a separate protocol document and will be assigned a separate protocol number and require a separate consent form. However, such mandatory companion protocols also may be included within the body of a treatment protocol. In such circumstances, a number for the treatment protocol and a second number for the companion study will be assigned and a single consent form will be used to obtain patient consent. A patient registered to such a study will be considered to have been registered to two protocols—a treatment study and a mandatory companion—and the institution will be “credited” with two patient accruals. Mandatory companion studies that are built into a treatment protocol will need to have their own specific objectives, research plan, and statistical analysis. Indeed, they should be able to “stand alone” as companion studies.

By structuring our protocols in this way, we hope to accomplish several things. Combining the treatment study and mandatory companions in a single protocol document will streamline the protocol development process. Although using a single consent form that addresses all components of the study may require a lengthy form, I believe this will be preferable to presenting a patient with a series of consent forms that must be signed for treatment as well as for mandatory companion studies. Assigning multiple protocol numbers to studies that are constructed this way will permit institutions to be “credited” with multiple registrations, thereby recognizing the additional work required to accomplish all of the objectives of the study. Finally, these procedures will be completely consistent with current CALGB policies to count only patient registrations without having to create a new and arbitrary system for assigning “credits.” This system will be periodically re-evaluated by the Executive Committee and modified if necessary.

There is no question that everyone who participates in CALGB activities devotes enormous effort on behalf of the Group and deserves a great deal of credit. We will continue to do our best to ensure that all institutions are represented in all aspects of CALGB activities, so that everyone can have an opportunity to be recognized for their efforts on behalf of the Group. One other measure of credit that everyone deserves is a hearty “Thank You” from the Group Chair. Keep up the good work!

**Richard L. Schilsky, M.D.**

in 1985, other community hospitals began to participate in CALGB clinical trials through the Cooperative Group Outreach Program (CGOP). In Spring 1990, Dr. O. Ross McIntyre assumed the position of Group Chairman, and in the Fall of 1990, Dr. Stephen George was named Group Statistician. During Dr. McIntyre's tenure, the Group directed its efforts toward the areas of cytogenetics, sophisticated immunophenotyping, and gene rearrangement studies. Additionally, the Group broadened its area of scientific interest to encompass GI tumors and prostate cancer. Finally, In 1994, Richard L. Schilsky, M.D., was elected to be the fourth Group Chair of the CALGB, and assumed the Chairmanship in 1995.

Plan on attending this unique Plenary Session as we recall the many and varied accomplishments of the CALGB.

## Cancer-Related Internet Sites

Following is a list of cancer-related organizations that maintain internet home pages.

### NCI

<http://www.nci.nih.gov>

### CANCERNET

<gopher://gopher.nih.gov/11/clin/cancernet>

### ONCOLINK

<http://cancer.med.upenn.edu/>

### PHYSICIAN DATA QUERY (PDQ)

<gopher://gopher.nih.gov:70/11/clin/cancernet/pdqinfo>

### MEMORIAL SLOAN-KETTERING CANCER CENTER

<http://www.ski.MSKCC.org:80/>

### BREAST CANCER INFORMATION

<http://nysernet.org/bcic/>

### CENTERWATCH: CLINICAL TRIALS LISTING SERVICES

<http://www.centerwatch.com/>

# T R A N S I T I O N S

## NEWS FROM THE DATA MANAGEMENT CENTER

**Judith Wheeler** is a new Data Coordinator for adjuvant breast studies and Intergroup coordinated breast studies at the CALGB Data Management Center (DMC). Ms. Wheeler was the former Registrar at the CALGB. She has a M.P.H. from the University of North Carolina. Previously, she worked in research at Duke University's Cardiology Department. Her e-mail address is [cjwheeler@ccstat.mc.duke.edu](mailto:cjwheeler@ccstat.mc.duke.edu)

**Laura Gross** is a new Data Coordinator with the CALGB Data Management Center. Ms. Gross has a B.A. degree in Education from Emory University and an M.Ed. in Counseling from North Carolina State University. She has worked as a clinical research coordinator for a private medical practice in Raleigh where she conducted multiple clinical trials. She has also performed data management as a contractor for ClinTrials Research and Glaxo Pharmaceuticals. Most recently, she collected cardiovascular data for Duke University's Department of Thoracic Surgery. Her e-mail address is [clgross@ccstat.mc.duke.edu](mailto:clgross@ccstat.mc.duke.edu)

**Ajiri Smith** is a new Data Technician with the CALGB Data Management Center. Ms. Smith has a B.S. degree in Health Psychology from Duke University. She previously worked with the Duke University Databank for Cardiovascular Diseases. Her e-mail address is [casmith@ccstat@mc.duke.edu](mailto:casmith@ccstat@mc.duke.edu)

**Karminder Gill** joined the CALGB Data Management Center as the new Registrar in late November. He replaces Judith Wheeler, who was promoted to a Data Coordinator position. Karminder has a B.A. in Economics from Davidson College and a M.S.P.H. in Health Policy from the University of North Carolina-Chapel Hill. His employment history ranges from working as a graduate assistant at UNC-Hospitals to an administrative internship at Pitt County Memorial Hospital. He can be reached by e-mail at [ckgill@ccstat.mc.duke.edu](mailto:ckgill@ccstat.mc.duke.edu)

## MEET THE NEW CENTRAL OFFICE STAFF

**Elmetrica (Meachie) Holman** joined the CALGB Central Office staff in December as the new Senior Clerk, replacing **Braunda Ridley**, who is now working as the CALGB's Accounting Assistant. Before coming to the CALGB, Ms. Holman was a Data Entry Operator for the Physicians Group at the University of Chicago. She can be reached at: (312) 702-9163; her e-mail address is: [eholman@midway.uchicago.edu](mailto:eholman@midway.uchicago.edu); Ms. Ridley's new phone number is: (312) 702-9775; e-mail: [bridley@midway.uchicago.edu](mailto:bridley@midway.uchicago.edu).

**Joycelyn Briscoe** is the new Protocol Assistant. She will be assisting the Protocol Editors on protocol mailings and distribution. Ms. Briscoe previously worked at the University of Chicago as a Clerical Assistant for the Dean of Students in the College. Her phone number and e-mail address are: (312) 702-9171; [jbriscoe@midway.uchicago.edu](mailto:jbriscoe@midway.uchicago.edu)

## CORRECTION

On page 8 of the Winter 1995 issue of the *Cal Gab* (Volume 4, Number 4) on Intergroup Eligibility Requirements, an incorrect phone number was listed for RTOG. All question concerning patient eligibility should be addressed to RTOG Headquarters personnel at: (215) 574-3191.

# Putting the Minimalist Eligibility Theory into Practice

by Kathleen S. Karas, Senior Protocol Editor

Recent presentations by the Group Chair and the Group Statistician at both the Spring and Fall 1995 CALGB Group meetings addressed the concept of a "minimalist" approach to the design and conduct of clinical trials, particularly in terms of eligibility criteria. As explained by Dr. Stephen George, CALGB Group Statistician, in the Fall 1995 edition of the *Cal Gab*, the restrictive eligibility criteria traditionally employed in Phase III cancer clinical trials have led to a number of problems, including "limitations on the generalizability of the results, failure to adequately mimic clinical practice, increased costs and complexity of the clinical trial, and decreased accrual."

The change to a more minimalist approach has implications for the manner in which CALGB protocols are written, particularly for Phase III studies. In the past, the schema, eligibility section, and the Required Data table included all tests, laboratory values, and medical information—such as stage of disease, prior therapy, etc.—needed to determine if a patient was eligible for the study. Due to the comprehensiveness of these sections, Clinical Research Associates (CRAs), oncology nurses, and physicians may have used these sections as a "quick reference" not only to determine if the patient was eligible for the study, but also as a check to ensure that all required prestudy tests had been completed.

In the minimalist approach, eligibility criteria are reduced. Regulatory, legal, or other requirements, while still necessary to register a patient, are not included (e.g., requirement for informed consent) as eligibility criteria. Some criteria, such as life expectancy, may also be eliminated, as these are ambiguous and difficult to verify by an auditor. Only those criteria that are felt to be absolutely necessary either to answer the scientific question or to ensure patient safety are retained as part of the eligibility criteria.

What are the implications of this approach in the writing of CALGB studies? Most importantly, the eligibility section will be shorter. Regulatory items, such as requirements for written informed consent, may be moved to other sections, such as Registration. In addition, there are likely to be advisory remarks, listing circumstances that should be taken into consideration by the physician when considering a patient for the study. The number of actual required laboratory values will be reduced, and required prestudy tests will be reflected in the Required Data table, rather than the Eligibility Criteria section. For example, a bilirubin may be required prestudy, and thus be listed in Required Data, but if there is no value required for registration, it will not appear in the Eligibility Criteria section. Finally, the schema is likely to contain less information, corresponding to reduced eligibility criteria.

The model protocol is currently undergoing revision at the Central Office, with an emphasis on standardizing the placement of information formerly found in the eligibility section. While that task proceeds, there are protocols that have been and will be activated using this new approach (for example, see recently activated CALGB protocol 9481).

It will be important for CRAs, nurses, and physicians to read the protocol carefully in order not to miss required prestudy tests, and to gain information deemed important by the study chair (e.g., remarks concerning medical considerations for potential study participants). The less restrictive approach to eligibility relies on the physician and the patient making an informed joint decision on whether a particular study is appropriate, including consideration of the patient's previous and current medical condition.

## ACKNOWLEDGMENTS

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Integrated Therapeutics Corporation,  
A Schering Subsidiary  
Merck Research Laboratories  
Merck U.S. Human Health  
Ortho Biotech Inc.  
Pfizer Inc.  
Pharmacia Inc.  
Rhône-Poulenc Rorer Pharmaceuticals Inc.  
Sandoz Pharmaceuticals Corporation  
The Upjohn Company  
The Breast Cancer Research Foundation  
T.J. Martell Foundation for Leukemia,  
Cancer and AIDS Research

# ONCOLOGY NURSING

## TREATMENT OF MALIGNANT PLEURAL EFFUSIONS

By Sandra L. Muchka, R.N., M.S. O.C.N., CALGB Research Nurse, St. Luke's Medical Center, Milwaukee, Wisconsin

**QUESTION:** What are the therapeutic options for treating malignant pleural effusions?

**ANSWER:**

A pleural effusion containing malignant cells is called a malignant pleural effusion (MPE). However, only approximately 70% of effusions due to malignancy are positive on the first thoracentesis. Malignant involvement of the pleural surface can shed cells into the pleural space. Irritation of these surfaces results in an inflammatory response and increased capillary permeability.

The presence of a malignant pleural effusion in most patients is a sign of advanced disease. Breast and lymphoma patients may have a more prolonged survival than individuals with other types of cancer. Aggressive control of the accumulation of pleural fluid can alleviate symptoms, lengthen survival time, and improve quality of life for the person with cancer.

The optimal treatment of a pleural effusion is to remove the pleural fluid and prevent its reaccumulation. In a responsive tumor, such as breast carcinoma or lymphoma, systemic therapy alone may be effective in eliminating a small effusion. A thoracentesis may be performed, but it is often of limited value for treating recurrent pleural effusions because reaccumulation of the fluid is common and repeat thoracenteses may cause patients undue anxiety, pain, and dyspnea and expose them to additional risks and complications.

Alternative treatments to thoracentesis are the insertion of chest tubes for drainage or the combination of chest tube drainage followed by the installation of a sclerosing agent. Chest tubes attached to continuous suction ensure complete evacuation of fluid to promote adherence of the pleural surfaces. The addition of an intrapleural sclerosing agent usually provides an effective response.

Until recently, the two most commonly used agents for treating MPE were tetracycline and bleomycin. Presently, tetracycline is not available for this purpose in the United States and has been replaced by doxycycline or minocycline; however, there is inadequate documentation of their efficacy. Bleomycin is very expensive for even a single episode of sclerosis and may eliminate patients from participating in other clinical trials.

An active CALGB trial (CALGB 9334) for the management of pleural effusions randomizes patients either to talc slurry pleurodesis or thoracoscopy and pleurodesis at the time of the decision to sclerose the pleura of the patient. This study will attempt to determine the best method of controlling malignant pleural effusions, costs for managing MPE, and quality of life.

Once the patient has been deemed a candidate for pleural

sclerosis and is able to undergo a thoroscopic procedure, he or she will be randomized to one of the two arms. Talc sclerosis, if performed by thoracoscopy, is done by insufflation of dry talc, ensuring uniform dispersion by visual inspection. If a chest tube–bedside technique is used, a talc slurry is instilled through the tube. Thus, both methods employ a chest tube to drain remaining or developing fluid and to assure complete expansion of the lung for pleural symphysis.

As specified in protocol 9334, pain will be assessed for two days while the chest tube is in place. Baseline measurement of pain should be determined by the Visual Analog Scale when the consent form is signed. Also included in the protocol is a quality of life (QOL) component, which includes obtaining general QOL and symptom-specific evaluations and assessing the major aspects of a person's life that may be affected by the two regimens.

Malignant pleural effusions are a common, debilitating complication of advanced cancer. It is uncertain which is the best method of treating malignant pleural effusions for both efficacy and cost-effectiveness, but it is hoped that participating in CALGB 9334 will help us find the answers to these important questions.

For further information about CALGB 9334, please contact:

Jemi Olak, M.D., Study Chair  
University of Chicago/Division of Surgery  
(312)702-2644; e-mail: jolak@surgery.bsdu.uchicago.edu  
OR  
Carolyn Dresler, M.D., Study Co-Chair  
Fox Chase Cancer Center  
(215) 728-2596; e-mail: cdresler@dante.fccc.edu

**Please Note:**

For CALGB institutions ONLY: While every effort should be made to randomize patients during regular business hours, after hours randomization of patients is permitted for CALGB 9334 (see protocol for specifics).

It is important to remember that the registration/randomization procedure will not be complete until the CALGB Registrar has been contacted by the registering institution to be assigned a CALGB patient number.

During the next business day, the institution that registered the patient after hours **MUST** formally complete the registration by following standard CALGB procedures (see section 5.2 of the protocol).

## P H A R M A C Y

## Paclitaxel and Docetaxel

by Charles L. Bean, R. Ph., Mary Hitchcock Memorial Hospital,  
Lebanon, NH

Taxanes belong to a new group of antineoplastic agents with a novel mechanism of action directed against microtubules. Microtubules are important structural elements in all eukaryotic cells and are essential for mitosis, intracellular transport, and cellular motility, as well as providing the cytoskeleton of the cell.

Taxanes enhance tubulin polymerization by decreasing the concentration of tubulin needed for and altering the thermodynamics of microtubule assembly.<sup>(1, 2)</sup> Since microtubules are usually in dynamic equilibrium with tubulin dimers, such alterations in tubulin dynamics produce nonfunctional microtubules.

The FDA initially approved Paclitaxel in December 1992 for treating metastatic ovarian cancer and, more recently, for treating relapsed or metastatic breast cancer. Therapeutic trials have also been conducted using paclitaxel, either alone or in combination, with other active drugs, in many other solid tumors, including advanced bladder cancer, prostate cancer, germ cell tumors, head and neck cancer, advanced small cell and non-small cell lung cancer, and in refractory and relapsed non-Hodgkin's lymphoma.<sup>(3,4)</sup> Docetaxel (Taxotere), currently awaiting FDA approval, has been shown to have excellent single-agent activity for treating metastatic breast cancer and advanced non-small cell lung cancer.<sup>(5,13)</sup> A recent review of 17 docetaxel trials in eight tumor types involving almost 500 cases showed activity in ovarian cancer, pancreatic and gastric cancer, head and neck cancer, melanoma, and soft tissue sarcomas.<sup>(6)</sup> A respiratory protocol using docetaxel, CALGB 9X3F—"Stage IIIA Non Small Cell Lung Cancer: Taxotere + cDPP Followed by Surgery + RT"—is currently in development.

In the laboratory, docetaxel is approximately twice as potent as paclitaxel, apparently for two reasons: It has a higher affinity for microtubules and attains higher drug levels in the cell.<sup>(1,7)</sup> One investigator has reported that docetaxel can alter some classes of Tau-dependent microtubules.<sup>(7)</sup> Paclitaxel has been shown to

have a radiosensitizing effect in laboratory studies.<sup>(8)</sup>

Paclitaxel is highly protein-bound in plasma. Systemic clearance is reported to be about 8L/hr/m<sup>2</sup> at a dose of 175 mg/m<sup>2</sup>; renal clearance is about 7 ml/min/m<sup>2</sup>.<sup>(14)</sup> Paclitaxel pharmacokinetics in humans is nonlinear. As the dose is increased, both the peak plasma level and the area-under-the-curve increase at a markedly greater rate.<sup>(9, 10)</sup> Plasma pharmacokinetics of docetaxel is best described by either a bi- or a tri-exponential model.

Paclitaxel is selectively biotransformed to 6a-hydroxytaxol by cytochrome P450-2C8.<sup>(15)</sup> Although this metabolite is less cytotoxic than the parent drug, it and other metabolites are excreted into the bile and can accumulate in the plasma of patients with biliary obstruction, causing significant toxicity.<sup>(11)</sup> Given the importance of the cytochrome P450 system in the metabolism of paclitaxel, other significant drug interactions should be anticipated. A greater degree of neutropenia resulting from reduced paclitaxel metabolism has been demonstrated when platinum is administered prior to paclitaxel,<sup>(12)</sup> although the mechanism of the increased toxicity has not been determined.

Little information has been published about the metabolism of docetaxel in humans or animals. No reports describing docetaxel metabolites have been reported in humans, to date. Current studies have not demonstrated accumulation of docetaxel in humans.<sup>(14)</sup>

Paclitaxel preparation for patient administration must be in either glass or polyolefin containers and drug administration must be through polyethylene-lined I.V. sets. Pretreatment with a histamine-2 blocker, dexamethasone and diphenhydramine, is recommended to reduce hypersensitivity reactions. Docetaxel must be administered in a concentration not greater than 0.3 mg/ml.<sup>(14)</sup>

The major toxicities of paclitaxel are neutropenia and mild-to-moderate sensory neurotoxicity. Neutropenia and fluid retention have been reported with docetaxel.

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# P R O T O C O L U P D A T E S

*In an effort to increase awareness of CALGB trials that are experiencing low accrual, we will highlight one trial in each issue of the Cal Gab.*

## CALGB Protocol 9170; Home I.V. Antibiotics for Low-Risk Cancer Patients With Febrile Neutropenia; Study Chair, James Talcott, M.D.

Febrile neutropenia is the leading cause of emergency hospital admission for cancer patients. Traditionally, these patients have been treated with broad-spectrum, high-dose intravenous antibiotics in the hospital until both fever and neutropenia have resolved. More recently, both the desires of patients for time at home and the economic pressures to shorten inpatient stays have led some physicians to improvise outpatient therapy for some of these patients. However, while home I.V. therapy is technically feasible, treating patients at home may be risky, since it is much harder to identify and treat medical problems there.

To identify those patients whose risk levels were low enough to treat at home, a model was developed and validated to identify low-risk patients in two studies of more than 700 episodes of febrile neutropenia.<sup>1,2</sup> In a pilot study based on this model, 30 low-risk but highly neutropenic patients (almost half presented with no granulocytes) were successfully discharged to receive I.V. antibiotics for as long as 24 days at home.<sup>3</sup> Based on these studies, "A Multi-Center Trial of Hospital Versus Early Discharge Therapy of Low-Risk Patients with Fever and Neutropenia: A Phase III Study, CALGB 9170" was designed. This study compares the proportion of serious medical complications among low-risk cancer patients with febrile neutropenia who have been randomized to either early discharge from the hospital with home antibiotic therapy or the usual pattern of care within the hospital. Among the secondary objectives are comparing the costs of the two treatment strategies and comparing the quality of life and psychological state of the patients in the two groups.

Currently, 22 patients have been

enrolled in CALGB 9170. Some reasons for low accrual include a lack of funding for Medicare patients, eligibility requirements that may be overly restrictive, and the need for medical staff and patients to be aware of and accept novel treatment approaches. Another impediment to accrual is the widespread use of growth factors, which emerged since this study was initially designed, which has resulted in fewer patients with febrile neutropenia and shorter episodes, despite guidelines by the CALGB and ASCO recommending limited use.

Strategies being considered for increasing accrual to CALGB 9170 include removing the exclusion of patients with acute leukemia, the patients with the most prolonged episodes of neutropenia; reducing the current 24 hours of inpatient observation; and increasing the number of study sites. Closer adherence to the guidelines for use of growth factors—reserving use until after the first episode of febrile neutropenia—might increase the number of patients eligible for the study. With the assistance of the CALGB's Data Management Center, the study's forms continue to be streamlined. Additional ROI funding support has been approved by the NCI for this study, which will enable evaluation of the particular problems at each site by the study chair.

The trial, with its thorough preliminary studies and the careful methods used to assess efficacy, quality of life, and cost, is very important, given the current pressures on oncologic practice. It may be a model for assessing oncology clinical practices rationally from a clinician's perspective, rather than by financial officers who lack medical experience and whose eyes are focused solely on the bottom line.

### \* Protocol Activations

◆ 12/15/95:

**CALGB 9530:** Gemcitabine (NSC #613327) for Malignant Mesothelioma: A Phase II Study. Study Chair: Elizabeth Johnson, M.D.

**CALGB 9480:** A Phase III Study of Three Different Doses of Suramin (NSC #34936) Administered with a Fixed Dosing Schedule in Patients with Advanced Prostate Cancer. Study Chair: Eric Small, M.D.

◆ 1/15/96:

**CALGB 9481:** Phase III Study of Hepatic Artery Floxuridine (FUdR), Leucovorin (LV), and Dexamethasone (DEX) Versus Systemic 5-Fluorouracil (5-FU) and Leucovorin (LV) as Treatment for Hepatic Metastases from Colorectal Cancer (Limited Access Study). Study Chair: Nancy E. Kemeny, M.D.

### \* Study Funding

Support is available to qualifying institutions for participation in these studies. Payments are made through the main member institution.

- 9170 Febrile Episodes in Neutropenia III
- 9254 NHL: Anti-B4-bR Post-ABMT
- 9270 Asprn: Early Stage Colorect. in Hi Risk Pats
- 9293 13-cRetin.: 2o Prim. Tmrs (NSCLC) (MDAnderson)
- 9332 Navel/Navel+Doxorubicin, Small Cell Lung
- 9334 Sclerosis: Pleural Effusns- Talc Thoracos. vs Slurry
- 9335 NSC: Video Asstd Wedge Resctn + RT in High risk T1
- 9371 Weight Loss Prgrm of Women w. BR Cancer
- 9399 Prostate Cancer Prevention Trial (SWOG 9217)
- 9473 Trial of Omega 3 Fatty Acids for Cancer Cachexia
- 9484 Linkage Mol & Epidem Br Ca Invest Spec Registry Comp
- 9490 Oral Analgesic Protocol Improve Pain Control?
- 9499 13-cRetin.:2nd Prim Tmrs H&N (RTOG 9115/MDACC)
- 9511 PEG-Asparaginase During Chemo for Acute ALL

For more information, contact:

Mary Sherrell  
CALGB Financial Officer  
(312) 702-9856.

## R E F E R E N C E S

1. Talcott JA, Finberg R, Mayer RJ, Goldman L. The medical course of cancer patients with fever and neutropenia. Clinical identification of a low-risk subgroup at presentation. Arch Intern Med. 1988;148(12):2561-8.
2. Talcott JA, Siegel RD, Finberg R, Goldman L. Risk assessment in cancer patients with fever and neutropenia: a prospective, two-center validation of a prediction rule. J Clin Oncol. 1992;10(2):316-22.
3. Talcott JA, Whalen A, Clark J, Rieker PP, Finberg R. Home antibiotic therapy for low-risk cancer patients with fever and neutropenia: a pilot study of 30 patients based on a validated prediction rule. J Clin Oncol. 1994;12(1):107-14.

# CALGB SPRING MEETING INFORMATION

Fontainebleau Hilton - 4441 Collins Avenue, Miami Beach, Florida 33140  
May 3-6, 1996

## • INFORMATION ON MIAMI BEACH

Miami Beach is enjoying a renaissance thanks in part to the multi-million dollar restorations of many of the luxury resort hotels along the coast. Transplanted celebrities have converged on the area to work and play, transforming it into a year-round playground of the stars. The Art Deco District, dubbed "South Beach," brings a stylish era back to life and is home to a number of art museums and galleries. South Beach is definitely a neighborhood on the move. European-type outdoor cafes, international specialty restaurants, shops, and entertainment abound along the Atlantic coastline community of South Beach. Additionally, nearby Bayside Marketplace is an exceptional shopping establishment with great dining right on the water.

The world-famous Fontainebleau Hilton will host the CALGB's 1996 Spring Group Meeting. Located on 20 acres of beachfront, this four-star, four-diamond resort offers guests first-class recreational, dining, and nightlife enjoyment. The Hilton is conveniently located near area attractions, the renowned Bal Harbour Shops, and the exciting Art Deco District/"South Beach."

## • MEETING REGISTRATION

Group Meetings are open to the membership of the CALGB, as well as to invited guests.

**Funding:** The purpose of the committee budgets in the Central Office grant is to support Core Meetings, not Group Meetings. Committee Chairs may, however, request that their budgets be used to support the travel and lecture fees of non-CALGB speakers at their Group Meeting Committee meetings, providing that the constraints of their budgets will permit these expenses.

**Deadline and Fees:** \$35 (for registrations received before April 12); \$55 (on-site).

**Registration fees are nonrefundable.**

**Substitutions:** If you are unable to attend the meeting, substitutions are permissible, providing, however, you inform the Central Office in writing by April 12. After this date,

we will be unable to accept substitutions.

## • TRANSPORTATION

**Airline:** The CALGB has contracted with American Airlines for a 5% discount for travelers attending the CALGB Luxury Meeting. In order to receive the discount, you MUST contact Arrington Travel, CALGB's official travel management company, at 1-800-449-0040. Be sure to indicate to the Arrington travel representative that you are attending CALGB's Group Meeting in order to receive the discount.

**Ground Transportation:** We recommend that you use "Supershuttle." Upon arrival at the Miami International Airport, just outside the baggage claim area, Supershuttle reps will be available to assist you for transportation to the hotel. Regular fares from the airport to the hotel are \$10 each way. To make reservations back to the airport after the meeting, see a Supershuttle rep at the tour desk located in the hotel lobby. (Normal one-way taxi fares are about \$25.) Driving time from the airport to the hotel is approximately 25-30 minutes.

**Parking:** Hotel valet parking is available to hotel guests only at a rate of \$10/day chargeable to the guest's room.

## • HOTEL RESERVATIONS

**Rates:** \$99 (single or double occupancy; including a limited number of oceanfront rooms); \$139 (oceanfront with terraces; single or double occupancy; subject to availability); and \$95 government rate (for those carrying official government IDs; rooms subject to availability)

Room rates are subject to 11.5% city and state occupancy taxes.

**Hotel Check-in/Check-out Times:** Check-in is 3:00 p.m.; Check-out is 11:00 a.m.

**Reservations Deadline:** April 1, 1996. Reservations received after the cut-off date will be accepted on a space-available basis only.

**Deposits:** A one-night's deposit will be required when making your reservations. Should you fail to cancel your reservation

5 days prior to arrival, your deposit will be forfeited. (Note: your room will be guaranteed for late arrival when reservation is accompanied by a deposit, paid by either check or credit-card).

**Reservations Procedures:** You may make reservations by phone, fax, or mail as follows:

• **Phone Reservations:** Call the Fontainebleau at 1-800-548-8886 or 1-305-538-2000. Be sure to identify yourself as a Cancer and Leukemia Group B attendee in order to receive the special convention rate and have credit card information available at the time of your call.

• **Fax Reservations:** 1-305-673-5351. Fax a completed photocopy of the Hotel Reservation Form from this Newsletter directly to the hotel. Be sure to include your credit card information on the form along with expiration date.

• **Reservations by Mail:** Photocopy and send the completed Hotel Registration Form from this Newsletter directly to the Fontainebleau Hilton, 4441 Collins Avenue, Miami Beach, FL 33140. If using the mail-in method, be aware of your mailing date. Reservations should be received at the hotel by April 1, 1996, to ensure availability.

• **Cancellations:** If you must cancel your reservation, be sure to notify the hotel **5 days prior to scheduled arrival in order to avoid forfeiture of deposit.** Also, be sure to obtain a cancellation number plus the name of the person with whom you canceled your reservation.

## • HOTEL SERVICES

**Business Center Services:** The hotel operates a full-service business center. Hours are: M-F 9 a.m.-5 p.m.; Sat/Sun 10 a.m.-2 p.m.

## • A/V PREPARATION

- All slides and transparencies should be clear, crisp, and legible from a long distance.
- Slides: To project well, a 35mm slide should be easy to read with the naked eye. All slides should be horizontal.
- Overhead transparencies: Use large type and be aware that the image narrows from top to bottom.

### MEETING INFORMATION

If you have questions regarding your Meeting Registration, contact:  
Dorothy Tibbs (312) 702-9171.

If you have questions about reimbursement, contact Braunda Ridley (312) 702-9775.

For other meetings-related questions, contact Helen Pollard, Meetings Manager (312) 702-4129.

# CALGB 1996 TENTATIVE GROUP MEETINGS SCHEDULE/RESPONSE FORM

\* Closed Meetings  
 \*\* Additional registration fee required

## FRIDAY, May 3, 1996

Registration	7:00 am	-	6:00 pm
Genetics Education Workshop**	7:30 am	-	3:00 pm
Clinical Trial Mgmt Workshop for Beginning Clinical Research Associates (CRAs)*	8:00 am	-	4:00 pm
Data and Safety Monitoring Board*	12:00 Noon	-	4:00 pm
Psycho-Oncology Core Committee*	2:00 pm	-	5:00 pm
GI Committee	2:00 pm	-	5:00 pm
Institution Performance Evaluation Committee (IPEC)*	2:00 pm	-	5:00 pm
Oncology Nursing Core Committee*	3:00 pm	-	6:00 pm
CRA Liaisons*	5:00 pm	-	6:00 pm
Executive Committee*	5:00 pm	-	9:00 pm

## SATURDAY, May 4, 1996

Registration	7:00 am	-	7:00 pm
Constitution Committee*	7:00 am	-	8:00 am
PLENARY SESSION	8:00 am	-	11:30 pm
Study Chair Workshop	11:30 pm	-	12:30 pm
Minority Consortia	12:00 Noon	-	1:30 pm
Data Audit Committee*	12:00 Noon	-	2:00 pm
Radiation Oncology Workshop: Radioimmune Therapy & Future CALGB Trials	12:30 pm	-	2:00 pm
CALGB Information Systems Demonstration	1:00 pm	-	2:00 pm
Psycho-Oncology Committee	1:00 pm	-	4:00 pm
Cytogenetics Committee	1:00 pm	-	5:00 pm
Breast Committee	1:00 pm	-	5:00 pm
Surgical Protocols Workshop for Clinical Research Associates (CRAs)	1:00 pm	-	5:00 pm
Correlative Sciences/Prostate Cancer	2:00 pm	-	4:00 pm
CALGB Information Systems Demonstration	3:00 pm	-	4:00 pm
Prostate Committee & Prostate Surgery Sub-Committee	4:00 pm	-	7:00 pm
CALGB Information Systems Demonstration	5:00 pm	-	6:00 pm
Membership Committee*	5:00 pm	-	6:00 pm
CRA Committee	5:00 pm	-	6:30 pm
Epidemiology Working Group	5:00 pm	-	7:00 pm
Breast Surgery Sub-Committee	5:00 pm	-	7:00 pm
Reception (off-site)	7:00 pm	-	10:00 pm

## SUNDAY, May 5, 1996

Registration	7:30 am	-	5:00 pm
Pharmacy Core Committee*	8:00 am	-	9:00 am
CALGB Information Systems Demonstration	8:00 am	-	9:00 am
CCOP/CGOP Committee	8:00 am	-	9:30 am
Surgery Committee	8:00 am	-	10:00 am
Oncology Nursing Committee	8:00 am	-	12:00 Noon
Lymphoma Committee	9:00 am	-	12:00 Noon
Correlative Sciences/Solid Tumors Committee	9:00 am	-	12:00 Noon
CALGB Information Systems Demonstration	9:30 am	-	10:30 am
Cancer in the Elderly Working Group	10:00 am	-	12:00 Noon
Cancer Control Committee	10:30 am	-	12:30 pm
CALGB Information Systems Demonstration	11:00 am	-	12:00 Noon
Membership Committee*	12:00 Noon	-	1:00 pm
Pharmacy Committee	1:00 pm	-	3:00 pm
GI Surgery Sub-Committee	1:00 pm	-	3:00 pm
Radiation Oncology Committee	1:00 pm	-	4:00 pm
Correlative Sciences Leukemia/Lymphoma Committee	1:00 pm	-	4:00 pm
Respiratory Committee & Thoracic Surgery Sub-Committee	1:00 pm	-	5:00 pm
CALGB Information Systems Demonstration	1:30 pm	-	2:30 pm
CALGB Information Systems Demonstration	3:00 pm	-	4:00 pm
AIDS/Lymphoma Sub-Committee	4:00 pm	-	5:30 pm
Board of Directors*	5:00 pm	-	8:00 pm

## MONDAY, May 6, 1996

Registration	7:00 am	-	12:00 Noon
Foundation Finance Committee*	7:00 am	-	8:00 am
Foundation Board of Trustees*	8:00 am	-	9:00 am
Clinical Research Associates (CRAs) Continuing Education Workshop	8:00 am	-	11:00 am
Leukemia Committee	9:00 am	-	12:00 Noon
PET Committee	9:00 am	-	12:00 Noon

## PLENARY SESSION SPEAKERS

### **“Reflections on 40 Years of the CALGB”**

**Emil Freii, III, M.D.**

**James F. Holland, M.D.**

**O. Ross McIntyre, M.D.**

**Former Group Chairs of the Cancer and Leukemia Group B**

### **“Recruiting Women and Minorities into Clinical Trials”**

**G. Marie Swanson, Ph.D., M.P.H., Director**

**Cancer Center, Michigan State University**

## CONTINUING MEDICAL EDUCATION CREDITS

### M.D., Ph.D., D.O., and P.A.s

An application for approval to co-sponsor CALGB’s Spring Group Program has been submitted to the University of Chicago. The University of Chicago is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians. An application for approval of approximately 29.5 credit hours in Category I of the Physician’s Recognition Award of the American Medical Association has been submitted.

### R.N., O.C.N., and A.R.N.P.s

The Illinois Nurses Association has approved Continuing Education Credit (39.6 contact hours) for nurses.

### **PROGRAM OBJECTIVES:**

Nurses attending CALGB Group Meeting sessions will:

- 1) Acquire information regarding the importance of recent advances in the field of genetics;
- 2) Have a better understanding of their central role in the clinical applications of DNA diagnostic technologies;
- 3) Be able to identify and integrate the health care professional role in the partnership between primary care health professionals and the existing genetic services; and
- 4) Exchange information relative to the importance of recruiting minorities to clinical trials.

### C.C.R.A.s

An application for approval of approximately 16.0 CEUs has been submitted to the Society of Clinical Research Associates.

### **PROGRAM OBJECTIVES:**

CRAs attending CALGB Group Meeting sessions will:

- 1) Obtain the most recent information regarding nurse/data management issues on CALGB protocols; and
- 2) Be able to promote quality data management and protocol compliance of patients entered on CALGB trials in the clinical setting.

CME and CEU forms and instructions will be available at the Information Table at the Group Meeting located at the CALGB Registration desk.

# MEETING REGISTRATION FORMS

## Beginning Clinical Research Associates Workshop

Included in this Newsletter are required forms to complete in order to register for the Group Meeting:

- ✓ Beginning Clinical Research Associates Workshop: Due April 1, 1996 (to Jean Roark, CRA Chair)
- ✓ Meeting Registration Form: Due April 12, 1996 (for discounted rate)
- ✓ Hotel Reservation Form: Due April 1, 1996 (at the Fontainebleau Hilton)

**Clinical Research Associates with less than 6 months' experience are encouraged to attend this Workshop.**

The Central Office will fund up to \$500 transportation costs (i.e., airline, auto mileage, parking) for CRAs whose participation is approved. After receipt of your Beginning Clinical Research Associates Workshop Registration Form, a letter confirming approval will be sent with instructions regarding reimbursement of your travel. The Central Office will not reimburse meeting registration fees, hotel, meals, or other incidentals.

- Please forward a registration form to any new CRA who may not be on the mailing list.
- To be placed on the mailing list, send a Roster Update Form to the Central Office.

BEGINNING CLINICAL RESEARCH ASSOCIATES WORKSHOP  
CALGB Spring Group Meeting—Friday, May 3, 1996  
8:00 a.m.—4:00 p.m.

**(NOTE: You must be registered for the Group Meeting in order to attend this Workshop)**

Name: \_\_\_\_\_ Degree: \_\_\_\_\_

Institution: \_\_\_\_\_

Business Address: \_\_\_\_\_

Business Telephone: \_\_\_\_\_ FAX: \_\_\_\_\_

Main Member: \_\_\_\_\_ Affiliate: \_\_\_\_\_

I have been a CALGB Clinical Research Associate for:       <3       4-6       > 6 months

There is no registration fee for the Workshop. To request approval to register, FAX or mail this form to:  
Jean M. Roark, Clinical Research Associates Chair  
Missouri Baptist Medical Center  
Cancer Center Research Office  
3015 N. Ballas Road  
St. Louis, MO 63131  
FAX: (314) 994-6955

# MEETING REGISTRATION FORMS

## GENETICS EDUCATION WORKSHOP

Friday, May 3, 1996  
7:30 a.m.-3:00 p.m.

### Schedule-at-a-Glance

- Introduction to Molecular Genetics:
  - Basic Concepts
  - Patterns of Inheritance
  - Past, Current, & Future Endeavors of the Human Genome Project
- Predictive Testing for Cancer—Olufunmilayo (Funmi) Olopade, M.D., Director, Cancer Risk Clinic, University of Chicago
- Obstacles to Testing—Genny Grana, M.D., Robert Wood Johnson Medical School
- Psychological Aspects of Presymptomatic Testing—Jimmie Holland, M.D., Memorial Sloan-Kettering Cancer Center
- Social, Legal, and Ethical Implications of DNA Testing—Speaker TBA
- Role-Playing Focused Around the Informed Consent Process—Judy Garber, M.D., Dana-Farber Cancer Institute

## Genetics Education Workshop Registration Form

(NOTE: You must be registered for the Group Meeting in order to attend this Workshop.)

WORKSHOP FEE: \$20, if received by April 12. On-site registration fee is \$25. (Lunch on own.)

Name: \_\_\_\_\_ Degree: \_\_\_\_\_

Institution: \_\_\_\_\_

Business Address: \_\_\_\_\_

Business Telephone: \_\_\_\_\_ FAX: \_\_\_\_\_

Main Member: \_\_\_\_\_ Affiliate: \_\_\_\_\_

To register, FAX or mail a photocopy of this completed form along with payment to:

CALGB  
Dorothy Tibbs  
208 S. LaSalle, Suite 2000  
Chicago, IL 60604-1104  
FAX: (312) 345-0117  
Telephone: (312) 702-9171

FONTAINEBLEAU HILTON  
RESERVATION FORM  
Cancer and Leukemia Group B (CALGB)  
1996 Spring Group Meeting  
May 3-6, 1996

Note: Hotel Reservation Deadline is April 1, 1996

Please Print or Type:

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Daytime Tel. No.: \_\_\_\_\_

Arrival Day/Date: \_\_\_\_\_ Departure Day/Date: \_\_\_\_\_

(Check-in time is 3:00 p.m.)

(Check-out time is 11:00 a.m.)

Name of person(s) sharing Accommodations: \_\_\_\_\_

- Single/Double Occupancy- \$99  
 Oceanfront room-\$99\*  
 Single/Double Occupancy Oceanfront with Terraces-\$139\*  
 Government Rate Requested-\$95\*

\* Subject to availability

I request a non-smoking room

I request a handicapped-accessible room

please describe handicap: \_\_\_\_\_

Fontainebleau Hilton meets and exceeds all ANSI Handicap Codes.

Room rates are in effect for the entire duration of your stay, based on availability. Rates do not include state and local tax of 11.5%.

Deadline for receipt of reservations is April 1, 1996. Reservations received after this date will be accommodated on a space-available basis.

Please enclose a check or money order for one night's deposit or provide credit card information below to guarantee your room. Be advised credit card will be immediately charged for 1st night's deposit.

**Make your check payable to: Fontainebleau Hilton**

My check is enclosed

**Credit Card Information**

American Express

VISA

Master Card

Diner's Club

Discover

Carte Blanche

Credit Card #: \_\_\_\_\_

Exp. Date: \_\_\_\_\_ Signature: \_\_\_\_\_

MAIL (with check or credit card information) or FAX (with credit card information) this Hotel Reservation Form to:

**Fontainebleau Hilton  
Hotel Reservations Office  
4441 Collins Avenue  
Miami Beach, FL 33140  
FAX: 305-671-5351 ATTN: Reservations**



**CALGB FALL GROUP MEETING  
REGISTRATION FORM  
May 3-6, 1996**

**Please print or type:**

Name: \_\_\_\_\_ Degree: \_\_\_\_\_

Institution: \_\_\_\_\_

Business Address: \_\_\_\_\_

\_\_\_\_\_

Business Telephone: \_\_\_\_\_ FAX: \_\_\_\_\_

Please check your area of practice or specialty below:

- |  |  |
|--|--|
| <input type="checkbox"/> Administration    | <input type="checkbox"/> Onc Nursing/Clinical Research |
| <input type="checkbox"/> Cytogenetics      | <input type="checkbox"/> Pathology                     |
| <input type="checkbox"/> Clinical Research | <input type="checkbox"/> Pharmacy                      |
| <input type="checkbox"/> Epidemiology      | <input type="checkbox"/> Psycho-Oncology               |
| <input type="checkbox"/> Hematology        | <input type="checkbox"/> Radiation Oncology            |
| <input type="checkbox"/> Hem/Oncology      | <input type="checkbox"/> Statistics                    |
| <input type="checkbox"/> Immunology        | <input type="checkbox"/> Surgery                       |
| <input type="checkbox"/> Oncology          | <input type="checkbox"/> Urology                       |
| <input type="checkbox"/> Oncology Nursing  | <input type="checkbox"/> Other _____                   |

**PAYMENTS:**

- |  |  |
|--|--|
| <input type="checkbox"/> Advance Registration Fee <b>\$35.00</b> <b>-OR-</b>   | <input type="checkbox"/> <b>**AGENDA BOOK ONLY: \$30.00</b> \$ _____ |
| if received by April 12.   | (if you're not attending the meeting.)                               |
| On-site registration fee is \$55.  |  |
| <input type="checkbox"/> Genetics Education Workshop Fee                       | \$ _____   |
| \$20.00  |  |
| if received by April 12.   |  |
| On-site registration fee is \$25.  |  |
| <input type="checkbox"/> I wish to make a tax-deductible donation to the CALGB | \$ _____   |
| Foundation.  |  |
| (You will receive an acknowledgment from the Foundation in the mail.)          |  |

**Total \$ \_\_\_\_\_**

Return this form with your check payable to the University of Chicago/CALGB

**CANCELLATIONS AND SUBSTITUTIONS:** Regretfully, we are unable to issue refunds for meeting cancellations. If your registration has been processed and you cannot attend the meeting, you may send a substitute provided we receive your request in writing by April 12.

**\*\*AGENDA BOOKS:** The registration fee for the meeting includes the Agenda Book. However, if you cannot attend the meeting, to obtain an Agenda Book, return this form (see above) with a check for \$30 made payable to University of Chicago/CALGB by April 12.

We cannot process registrations received by FAX and do not accept registrations by credit card. Return a photocopy of this completed form with your check payable to University of Chicago/CALGB to:

CALGB  
Dorothy Tibbs  
208 S. LaSalle, Suite 2000  
Chicago, IL 60604-1104

## **ACKNOWLEDGMENTS**

The Following Firms Have Generously Supported  
CALGB Educational Programs, Publications, and Data Resources  
During 1995.

Amgen Inc.  
Berlex Laboratories, Inc.  
Bristol-Myers Squibb Oncology  
Glaxo Wellcome Oncology  
Hoffmann-LaRoche Inc.  
Immunex Corporation  
ImmunoGen, Inc.  
Integrated Therapeutics Corporation, A Schering Subsidiary  
Merck Research Laboratories  
Merck U.S. Human Health  
Ortho Biotech Inc.  
Pfizer Inc.  
Pharmacia Inc.  
Rhône-Poulenc Rorer Pharmaceuticals Inc.  
Sandoz Pharmaceuticals Corporation  
The Upjohn Company  
The Breast Cancer Research Foundation  
T.J. Martell Foundation for Leukemia, Cancer and AIDS Research