



Transitions

Clara Bloomfield, M.D., will assume the William Greenville Pace III Chair in Cancer Research at The Ohio State University (OSU). Dr. Bloomfield will serve as Director of the Comprehensive Cancer Center and as Deputy Director of the Arthur G. James Cancer Hospital and Research Institute. She will also be the Director of the Division of Hematology and Oncology within the Department of Internal Medicine in OSU's College of Medicine. Dr. Bloomfield is the Chair of the CALGB's Correlative Sciences Leukemia/Lymphoma Committee.

For the past two decades, Dr. Bloomfield has made significant scientific observations in the study of leukemia and lymphoma. She was one of the first physicians to suggest and then prove that adult acute leukemia is curable with chemotherapy and that certain groups of leukemia patients can be cured with specialized drug treatments. She has also demonstrated how changes in chromosomes influence treatment and outcome in adult acute leukemia.

Michael Caligiuri, M.D., has been

appointed the John L. Marakas Nationwide Insurance Enterprise Foundation Chair in Cancer Research and will be a Professor and Co-Director for the Division of Hematology and Oncology within OSU's Department of Internal Medicine in the College of Medicine. He will also serve as Associate Director for Clinical Research at the University's Comprehensive Cancer Center. Dr. Caligiuri will also have a joint appointment as Professor in the Division of Human Cancer Genetics in the Department of Medical Microbiology and Immunology in the College of Medicine and will be designated as a Comprehensive Cancer Center Genetics Scholar. He is the Chair of the CALGB's AIDS Malignancies Working Group.

Dr. Caligiuri's laboratory has made a number of important discoveries in the basic understanding of the immune system. His laboratory is specialized in the characterization of human natural killer cells, and he has developed novel immune therapies for patients who have leukemia, lymphoma and AIDS-related malignancies.

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Suggestions for articles are encouraged.

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**Please Note: While we make every effort to provide accurate dosing information in the Cal Gab, you should always check the appropriate drug dosages before prescribing and/or administering any medication.*

Future CALGB Meetings

Fall Combined Core/Group Meeting

November 20 - 23, 1997

Hilton at Walt Disney World Village

Orlando, FL

Spring Meeting Registration and

Hotel Reservation Deadlines are May 30, 1997.

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

There will not be a separate mailing.

For extra forms, contact Elmetrica Holman at (773) 702-9163

Message from the Group Chair...

A fundamental goal of CALGB research is to improve the outcome of cancer treatment for the patients we care for every day in our hospitals, clinics, and offices. Patients are the ultimate beneficiaries of our work, and our studies depend on their ability and willingness to participate. It is, therefore, entirely appropriate that patients and/or their representatives be involved in the development and analysis of CALGB protocols and in the application of study results in community practice. Patient advocates began to participate in CALGB committees several years ago, but their role in the Group was not formalized until recently. Last summer, I appointed an ad hoc committee, chaired by David Duggan, M.D., to consider the role of patient advocates in the CALGB and to develop recommendations for the CALGB Executive Committee. Based upon valuable discussions with Deborah Collyar, CALGB Patient Advocate for the Breast Committee, these recommendations were modified and accepted by the Executive Committee in November 1996. We are now in the process of appointing patient advocates to CALGB Disease and Modality Committees and invite the membership to recommend appropriate candidates for these positions.

The role of patient advocates in the CALGB is to actively participate in the scientific affairs of the Group by bringing the patient's perspective into the clinical trials process in order to enhance the scientific quality, feasibility, and applicability of our studies. Advocates will be appointed to Disease and Modality Committees and will participate in the protocol review process and development of model informed consents. They will also be involved in evaluating study results as voting members of the Data and Safety Monitoring Board. Ideally, patient advocates should be nonscientist/nonhealth professionals who can represent the perspective of patients in our clinical research programs. We are looking for individuals who understand the physical, emotional, and economic costs of cancer and its treatment. These individuals could be cancer survivors, but they might also appropriately be family members of cancer patients, particularly with respect to discussions about germline DNA testing for cancer susceptibility. It is critical that the patient advocates who serve on CALGB committees be able to separate their personal situation from their broader role

as representatives of cancer patients in general. Other criteria to be considered in making these appointments are:

- experience as a patient advocate;
- formal affiliation with a patient advocacy organization; and
- ability to identify issues through communications with patient constituencies.

Patient advocates will be considered consultants to the CALGB and, therefore, do not need to be affiliated with a CALGB institution. They will be appointed by me based on the recommendation of the Disease or Modality Committee Chair and will be approved by the Executive Committee. Each patient advocate will be appointed for a three-year term and may serve for up to two consecutive terms. They will be eligible for re-appointment following at least a three-year hiatus from committee service. Patient advocates will be subject to the same conflict of interest and confidentiality policies as other CALGB committee members. The Oncology Nursing Committee has proposed development of an orientation program for patient advocates to familiarize them with the policies and procedures of the CALGB. New appointees will also be encouraged to attend the Study Chair Workshop and the Beginning CRA Workshop at our Group Meetings.

The CALGB has already benefited enormously from the participation of Deborah Collyar, Sue Moore, Marge Lang, and Hank Porterfield in our scientific committees as well as from the contributions of Frances Carroll, Bliss Packer, and Edna MacQuilken to the Data and Safety Monitoring Board. We are grateful for their time and effort and welcome their continued participation. We encourage the membership at large to recommend appropriate candidates to serve as patient advocates in the CALGB. Letters of nomination with resumes may be sent to the Central Office or to the appropriate Disease or Modality Committee Chair. The real impact of CALGB research will ultimately be felt in the community by cancer patients and their families. It is time that the patients themselves had a voice in developing the best possible CALGB studies.

Richard L. Schilsky, M.D.

NEW STAFF

Rena Cristwell has assumed the position of Regulatory Affairs Coordinator at the CALGB Central Office. Prior to joining the CALGB, Ms. Cristwell worked for the University of Chicago's MBA Career Services office at the Graduate School of Business. Ms. Cristwell's phone number and e-mail address are: (773)702-9860; rcristwe@midway.uchicago.edu.

Donna Niedzwiecki, Ph.D., has recently joined the CALGB Statistical Center as faculty statistician for the Lymphoma and GI Committees. She is a former employee of Memorial Sloan-Kettering Cancer Center's Department of Biostatistics and Epidemiology. Her previous work experience primarily focused on the design and monitoring of clinical trials in cancer research. In addition, she has served as a consultant in other areas of medical research as well as in the pharmaceutical and biotech industries. Dr. Niedzwiecki is a graduate of Yale University, Brown University, and Boston University.

Kenneth W. Tinnin, Jr., is a new Data Coordinator at the CALGB Data Management Center (DMC) and is assigned to adjuvant breast studies. Kenneth received a B.A. in Biology from the University of North Carolina at Chapel Hill. Previously, Mr. Tinnin worked as a Clinical Trials Assistant and Research Aide in the Division of Cardiology at Duke University. His e-mail address is cktinnin@ccstat.mc.duke.edu.

Eva Hoke is a new Data Coordinator with the DMC and will be working on leukemia studies. Ms. Hoke has a B.S. in Medical Technology from The Ohio State University. Most recently, she worked at the University of North Carolina, School of Medicine, Department of Radiology coordinating a mammography clinical trial. Her e-mail address is cehoke@ccstat.mc.duke.edu.

Robin Heinze, former CALGB Data Technician, has been appointed to a Data Coordinator position on the Lymphoma Committee. Her e-mail address is crheinze@ccstat.mc.duke.edu.

CALGB/Pharmaceutical Industry Collaboration

By David L. Grinblatt, M.D., CALGB Executive Officer

As the CALGB continues in its mission to develop new and better treatments for neoplastic diseases, interaction with the pharmaceutical industry is of increasing importance. The development and availability of a number of new agents has spurred new research initiatives in many disease committees. The cooperative groups remain an important avenue for the assessment of the toxicities, efficacy, and, ultimately, the role of new agents in the management of solid tumors and leukemias.

Along with the increase in the number of new agents, there has been increasing interest in the effect of cancer therapy on quality of life as well as on the economic impact of cancer treatments. Assessing these endpoints requires extra resources on the part of the CALGB. Correlative science questions continue to require more advanced and expensive technologies for both molecular and pharmacokinetic studies. Federal support for cancer research has increased only modestly over the past five years, while the costs of studying new agents and endpoints have burgeoned.

The CALGB conducts the majority of its trials independent of any pharmaceutical support. When the interests of the Group and a pharmaceutical company overlap, however, additional support is welcomed. Sometimes to meet the needs of pharmaceutical companies, which require data beyond the standard information normally collected by the CALGB, the CALGB Foundation will request that support for the extra effort by the Group be provided. When institutional effort is increased as the result of such collaborations, funds can then be conveyed to the institutions via the CALGB Foundation. In some instances, support is limited to the provision of drugs for use on CALGB trials, which, of course, helps defray the cost of participation for patients and insurance companies. In the final analysis, all of our trials must be part of the Group's scientific agenda and designed to answer questions that our committees deem important, regardless of outside support.

The CALGB Central Office is primarily responsible for all interactions

with the pharmaceutical industry. Initially, a Study or Committee Chair may identify potential interest at a pharmaceutical company in a proposed trial. This information is transmitted to one of the CALGB Executive Officers, who then follows up with the company representatives and negotiates the terms of the interaction and support. Study and Committee Chairs do not independently collaborate with pharmaceutical companies in the development and management of CALGB trials. Likewise, institutional interactions are managed through the CALGB Central Office.

Following are issues that often need to be addressed in trials for which drugs are being provided by a pharmaceutical company. An Investigational New Drug (IND) is required if the agent is investigational. Similarly, an IND is needed for commercial agents that will be used at a dose or in a population for which the risks are expected to be significantly greater than the FDA-approved dose and indication. Next to be resolved is who will hold the IND—the company, the CALGB, or the NCI. Finally, who will distribute the agent? In many cases, for drugs supplied under an IND, the NCI will distribute the agent. If the drug is not under an IND, however, the company will generally need to distribute the agent. The CALGB does not have a drug distribution mechanism of its own in place.

Many times there are questions a pharmaceutical company wishes to answer that are not part of our planned protocol. Additional forms may be requested, as well as additional testing. If a company will be seeking FDA approval based on a given trial, generally an IND and additional regulatory requirements may need to be satisfied. This obviously increases the work load for our institutions and Data Management Center. Clarifying these issues early helps us to develop an appropriate budget in working with the company.

In many situations, our interests and strategies overlap with those of the pharmaceutical company, while in some they do not. Our ultimate goal in the Central Office is to facilitate the progress of the Group's scientific agenda through the support of our colleagues in the pharmaceutical industry, generally to the mutual benefit of both parties and our institutions.

ACKNOWLEDGMENTS

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Lilly Oncology
Merck U.S. Human Health
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Schering Corporation
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Strato/Infusaid, Inc.
T.J. Martell Foundation for Leukemia, Cancer and AIDS Research
Vince Lombardi Memorial Classic
Vysis/ATC Diagnostics, Inc.

DATA MANAGEMENT

Data Dos and Don'ts

We will be publishing a column two times a year to help CRAs manage specific CALGB studies. If you are encountering problems with the protocols that are discussed, please call the responsible Data Coordinator at (919) 286-0045. Their names and extension numbers are provided below.

CALGB 9344: Doxorubicin Dose Escalation with or without Taxol

Now that a new adjuvant breast study is about to open, it is very important that all delinquent data on 9344 be sent to the CALGB Data Management Center as soon as possible. Please remember that version 3.0 of the C-297 form is to be submitted *only* for patients registered AFTER 7-15-96. Check to make sure you are using the correct version number before submitting the C-297 form. Also, remember to send in a flowsheet with the C-293 follow-up form if a significant clinical event has occurred during that time period. Detailed comments about patient treatment should be written on the flowsheets, not on the C-293 forms.

Sandy Bothun, ex. 234

CALGB 9342: Taxol in Metastatic Breast Cancer

There has been much confusion regarding the correct way to document the "From" and "To" dates on follow-up and toxicity forms for this study. In particular, there have been problems with recording the date *treatment ended* permanently and the date of *progression* on the appropriate forms. The example below describes how these situations should be handled.

The "From" date on a follow-up form should be the date on which treatment began for that cycle. If *treatment ends* permanently during a follow-up period, the "To" date should be the date on which that treatment ended, regardless of the reason for ending treatment. The "From" date for the next follow-up form should be identical to the previous form's "To" date (i.e., the date treatment ended).

Similarly, if *progression* occurs during a follow-up period, the "To" date should be the date of progression. On the next follow-up form, the "From" date again will be identical to the previous form's "To" date.

Please contact me if you have any

questions regarding this or other 9342 data management issues.

Laura Gross, ex. 235.

CALGB 9550: Interleukin-2 in AIDS Lymphoma

Please consider participating in CALGB 9550. Patients with *any* evidence of partial response after *any* induction chemotherapy (e.g., residual abnormality on CT or exam—regardless of gallium—as long as it fulfills the measurement criteria for PR) are likely to be eligible for this simple study. Patients will be instructed to give themselves a daily subcutaneous injection of IL-2 for one year or until disease progresses. Data will be collected at weeks 6, 10, 12, and then every 12 weeks for a year. After that, their progress will be followed every 16 weeks until the disease progresses. If you have any questions concerning this study, please feel free to contact me.

Donna Harper, ex. 239

CALGB 9270: Colorectal Adenoma Chemoprevention + Aspirin

C-236 On-study: The Date Treatment Started should be the actual date the patient started the run-in drug, not the date the patient was registered. The institution is responsible for obtaining this information from the patient once the patient has received the run-in drug.

Operative and Pathology reports from the patient's resection are *required* with on-study data. Try to submit this information for review by the DMC *before* the patient is randomized to step two. The patient's tumor stage (and, therefore, eligibility) cannot be verified until the operative and pathology reports are received. The single most common reason for patient ineligibility on this trial is disease stage (i.e., advanced-stage patients who are not >5 years from diagnosis). All efforts should be made to avoid randomizing ineligible patients.

Staging note: Per CALGB standard staging criteria, a tumor that penetrates *through the muscularis propria* should be considered at least a Dukes' B2.

C-238 Interval Questionnaire: Each form should cover six months, beginning with the date the patient is *randomized* to step two. The C-238 should not be used to cover the run-in period.

C-239 Follow-up Colonoscopy Form: This form should be submitted with the operative and pathology reports for *all* endoscopies, including flexible sigmoidoscopies.

C-240 Change of Status/Address Form: After randomization, use this form to document any suspensions of study drug (permanent or temporary), changes of address, or new clinical status.

Food Questionnaire: An *original* of this form must be used for each patient. *Do not submit photocopies.* Questionnaires are available from the DMC. Use the CALGB patient ID for the Identification Number required on the front cover of the Questionnaire. Be sure the Questionnaire is completed with a Number 2 pencil, not a pen.

Please call me if you have any questions.

Sue Budinger, ex. 230

CALGB 9334: Sclerosis of Pleural Effusions with Talc Thoracoscopy vs. Talc Slurry

Many institutions that have treated patients on 9334 are delinquent in sending in chest X-rays for central review. The C-295 Chest X-Ray Central Review Form needs to be sent along with chest films to Dr. Ernest Scalzetti at Syracuse University as soon as the patient has completed 60 days of follow-up. Send only *original films* that pertain to the time periods covered on the form. Dr. Scalzetti will return them to you once he has completed his review. Make sure the dates on the films match the dates documented on the form. If you have any questions concerning data submission on this study, please call me.

Michael Leonard, ex. 224

CALGB 9671: Long-Term Psychosocial Adaptation of Survivors of Breast Cancer Treated by Adjuvant Chemotherapy Fifteen Years Ago (Companion to CALGB 7581—Closed)

Study Chair: Alice B. Kornblith, Ph.D.; Study Co-Chairs: Raymond B. Weiss, M.D., Jimmie Holland, M.D., and Mary Jane Massie, M.D.

The long-term psychosocial effects of adjuvant treatment regimens for breast cancer remain largely unknown. The vast majority of studies involving women with breast cancer have been conducted within the first two years of treatment completion, with a few that follow patients for more than five years. With CALGB 9671, we have a unique opportunity to examine the long-term psychological, social, and vocational consequences of specific adjuvant treatment regimens in women with breast cancer who were treated more than 15 years ago (some as many as 21 years ago) on a Phase III trial—CALGB 7581. In CALGB 7581, patients were treated with cyclophosphamide, methotrexate, and 5-fluorouracil (CMF) alone and in combination with other agents. Based on the value of adjuvant chemotherapy established in CALGB 7581 and other studies, CMF and its variants continue to be used in the adjuvant setting. With three-quarters of this sample of survivors currently over 60 years of age, and 48% of women with breast cancer diagnosed when over 65 years of age, our results will help identify problems commonly experienced by elderly survivors, a segment of the survivor population that has been neglected by researchers.

What is known about the long-term psychosocial adaptation of cancer survivors has been obtained primarily from studies of Hodgkin's disease, childhood and adult leukemias, and testicular cancer survivors, and those who underwent bone marrow transplantation. The collective data have indicated that, while survivors have an elevated level of psychological distress compared with people who have not had cancer, they do not meet criteria for psychiatric diagnoses. A subset of patients, however, have levels of distress that are significantly above the mean. For example, in our CALGB studies, 22% of 273 Hodgkin's disease survivors and 14% of 206 leukemia survivors had distress scores that potentially met criteria for psychiatric diagnoses.

Survivors attribute an array of physical and psychosocial problems to having had cancer: physical problems of diminished energy, somatic symptoms and distress, decreased sexual interest and activity, and

persistent conditioned nausea as long as 12 years after treatment in response to reminders of chemotherapy. Social and work problems also have been identified and attributed to the illness: divorce or separation, life and health insurance problems, work-related problems, and diminished socioeconomic status. CALGB 9671 seeks to determine the prevalence of these problems in long-term breast cancer survivors and to compare them to other survivor groups.

Objectives of the study include:

1. To determine the current psychological status and the prevalence of cancer-attributed psychosocial problems of long-term breast cancer survivors;
2. To identify the subset of patients exhibiting poor adjustment who are in need of psychiatric evaluation, and to provide referral to their community for appropriate treatment; and
3. To identify illness, treatment, family, and sociodemographic characteristics that predict survivors' adaptation and performance of cancer detection behaviors according to the vulnerability model (Dohrenwend and Dohrenwend, 1982; Kornblith et al., 1995).

Research Methods

Eligible patients will have been treated on CALGB 7581, have no current evidence of disease, and have completed all cancer treatment (recurrence or new primary cancer) a minimum of one year ago; additionally, they must not be suffering from psychosis or have significant cognitive impairment that would preclude their participation or render them unable to give informed consent. The CALGB DMC will provide a list of potential participants whose eligibility will then be confirmed by CRAs at each institution, who may also assist in locating these patients. Patients will be interviewed by telephone by the Psycho-Oncology research interviewer, Enid Zuckerman, who will use a battery of

questionnaires to assess their psychosocial adaptation. Among the measures used are those that form the "core set" of measures for CALGB survivor studies: Psychosocial Adjustment to Illness Scale (PAIS), Brief Symptom Inventory (BSI), Reminders of Your Treatment, The Effect of Cancer on Your Employment and Insurance, Sexual Problems, and CALGB Background Information Form and its Socioeconomic Supplement.

The theoretical model for understanding breast cancer survivors' adaptation is the vulnerability model. In the vulnerability model, the accumulation of losses and stresses (e.g., continuing physical health problems, lack of breast reconstruction, diminished socioeconomic resources, or other stressful events) increases the vulnerability of the cancer survivor to the stresses of having had cancer and may, ultimately, increase the likelihood of worse adaptation. Adequate support from family, friends, and the oncology medical care team may, however, offset the survivor's vulnerability. Consequently, survivors' adaptation to the same disease and treatment may differ widely, depending upon the balance of these forces. In order to test the vulnerability model in relation to some of these factors, additional measures were added, including patient satisfaction with their medical care, social support, stressful life events, body image, and breast cancer treatment-specific anxiety and screening behaviors. The length of the interview—75-90 minutes, longer than previous psycho-oncology studies—is necessary to adequately assess issues of importance to long-term survivors related to being treated for breast cancer. Patients in significant distress will be evaluated by Study Co-Chair and Psychiatrist, Mary Jane Massie, M.D., with referrals back to their community for appropriate treatment.

With the results generated from this study, our clinical understanding of long-term adaptation of breast cancer survivors will be enhanced, and oncologists and mental health professionals may be better able to anticipate delayed effects from adjuvant chemotherapies and their psychological consequences.

Peripheral Neuropathy Oncology Nursing Assessment of Toxicity

by Karleen R. Habin, R.N., Clinical Research Coordinator, University of Massachusetts Medical Center

Question:

Grading peripheral neuropathy associated with Taxol (paclitaxel) often can be very subjective and confusing. Is peripheral neuropathy graded as a neuro-sensory and/or neuro-motor toxicity?

Answer:

Peripheral neuropathy has been reported with Taxol. The incidence and severity of Taxol-induced neuropathy is dose dependent. Most cases have been reported with doses exceeding 170 mg/m².¹ Clinically significant peripheral neurotoxicity has been reported in 55% of patients treated with doses of 200 mg/m² or greater, and it has been the major toxicity in some studies such as CALGB 9342: A Phase III Study of Taxol at Three Dose Levels in the Treatment of Patients With Metastatic Breast Cancer and CALGB 9344: Doxorubicin Dose Escalation, With or Without Taxol, as Part of the cytoxan/Adriamycin Adjuvant Chemotherapy Regimen for Node Positive Breast Cancer: A Phase III Intergroup Study. Further, on the average, peripheral neuropathy has been observed in 27% of all patients after their first course of Taxol treatment, and in 34% to 51% receiving 2–10 courses.²

In tissue culture, Taxol causes abnormal bundles of microtubules to form throughout the cytoplasm disrupting normal cell functions, including mitosis, cell proliferation, neurite initiation, and neurite branching. When Taxol is injected directly into rat sciatic nerve, microtubules aggregate into unusual arrangements in both axons and Schwann cells, which lead to acute demyelination and loss of cytoplasmic transport of the axon.¹

Peripheral neuropathy induced by Taxol is characterized primarily by neuro-sensory manifestations, although neuro-motor symptoms may occur.¹ Typically, symptoms occur one to three days following therapy with higher doses (200-275 mg/m²); symptoms have also been observed after multiple courses at lower doses.³ What may often confuse the assessment of toxicity is the differentiation between the neuro-sensory and neuro-motor symptoms. Patients may have such a significant neuro-sensory impairment that it may appear that they have neuro-motor deficit. One way to differentiate between neuro-sensory and neuro-motor toxicity is the presence or absence of deep tendon reflexes. If reflexes are absent then, indeed, a neuro-motor deficit is suggested.

Neuro-motor toxicity may also be noted on objective electrophysiological testing. Physical examination often reveals distal sensory loss to both large (proprioception, vibration) and small (temperature, pinprick) fiber modalities. The most common symptoms are as follows:

NEURO-SENSORY:

- Numbness, tingling, paresthesias, occurring in stocking-glove distribution; perioral numbness has also been reported.
- Burning or prickling sensations in extremities (which may be painful).
- Decreased perception of touch, pain, temperature and limb position.

NEURO-MOTOR:

- Difficulty with fine motor activities; such as writing, buttoning clothes and grasping objects; such as squeezing a tube of toothpaste.
- Gait changes; "flapping of feet" or broad-based stance.⁵

Most patients' neuropathic symptoms are mild to moderate and resolve—within several weeks to several months—when the drug is discontinued.⁶ Patients with prior exposure to known neurotoxic agents or medical disorders associated with peripheral neuropathies may be predisposed to Taxol neurotoxicity.

Question:

Do traditional pain medications, such as narcotics, help to alleviate the pain associated with peripheral neuropathy?

Answer:

Information regarding the use of various agents to ameliorate symptoms of neurotoxicity is inconclusive. Many authors cite narcotic analgesics as the most reliable treatment for clinically significant, drug-induced dysesthesias.⁴ Preliminary information, however, suggests that it is useful to administer antihistamines at the onset of symptoms to relieve pain.⁵ Rowinsky et al,⁴ in a recent review of Taxol-associated toxicities, describe how some, but not all, investigators found amitriptyline useful in improving residual neuropathic symptoms. Preclinical studies^{6, 7, 8} suggest that nerve-growth factors attenuate or prevent Taxol-associated neurotoxicities. Hamers et al⁹

investigated the effects of an ACTH analog (ORG 2766) in the prevention of Taxol-induced neuropathy. The authors concluded that "concomitant administration of ORG 2766 completely prevented the occurrence of neuropathy." Langer et al^{10, 11} reported that they used pyridoxine or carbamazepine for "symptomatic palliation" of neuropathy in their patients.

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Treatment of Advanced Cancer Pain

by Jonas M. Congelli, R.P.H., SUNY Health Science Center at Syracuse

Pain is the most common symptom of patients with advanced cancer, with 65% to 85% of these individuals having significant pain that is all too often inadequately controlled. Pain is described as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain is always subjective, and each individual learns the application of the word through experiences related to injury or illness early in life. It is unquestionably a sensation in a part or parts of the body, but the fact that it is always unpleasant makes it an emotional experience as well.

The consequences of inadequate pain relief are suffering, anxiety, fear, depression, anger, immobility, and isolation. Any or all of these experiences can result in a reduction of the patient's quality of life. Also, many patients view pain as a worsening of their physical status. It is, however, estimated that pain can be controlled in 90% to 99% of patients.

The therapeutic goal of pain control is not simply to reduce pain, but to prevent pain. The key to effective pain management is constant reassessment and appropriate treatment modifications. Pain management is achieved through nonpharmacologic approaches, pharmacologic approaches, or a combination of these. Examples of nonpharmacologic approaches are surgery, neurosurgery, radiation, anesthesiology procedures and psychological procedures. In most cases pharmacologic approaches are used first.

Narcotic analgesics, which bind to specific opioid receptors in the brain

and spinal cord, are used for moderate to severe pain. Other central nervous system effects of narcotic analgesics are respiratory depression, drowsiness, sedation, change in mood, mental clouding, euphoria, dysphoria, nausea, and vomiting (stimulation of chemoreceptor trigger zone or CTZ). It is important to note that there is no set or optimal dose of narcotic analgesics. The correct dose is the one that controls pain without excessive or intolerable adverse effects.

Nausea, vomiting, and constipation can be the most distressing side effects of the narcotic analgesics. Phenothiazines can be used to prevent the nausea and vomiting associated with narcotics. Examples include prochlorperazine (Compazine) and perphenazine (Trilafon). Constipation from narcotic analgesics is caused by the inhibition of peristalsis. To treat constipation caused by narcotics, stimulant laxatives must be used. Senna, bisacodyl, and cascara are three examples of this type of laxative. A good rule of thumb to counteract narcotic-induced constipation is to use one Senakot tablet for every 30 mg of morphine equivalent.

Tolerance and addiction are significant concerns for patients, families, and clinicians and are often obstacles in the achievement of adequate pain control. Neither of these aspects of narcotic usage, however, presents a real problem in patients with advanced cancer. Properly treated, these patients do not become addicted to narcotic analgesics. Another concern of family

members is that narcotic use hastens death. This is simply not the case. Continued use of narcotics simply assures that death will be as peaceful and painless as possible.

Non-narcotics, such as acetaminophen and NSAIDs, are good for treating mild to moderate pain or as adjuncts to narcotics. NSAIDs are especially effective for bone pain caused by primary tumor or bone metastases since bone pain is caused by prostaglandins mediating pain, and NSAIDs work by inhibiting prostaglandin biosynthesis. Non-narcotics, however, have a ceiling effect above which increased doses have no additional analgesic effect.

Other adjuvant drugs include the tricyclic antidepressants, good for neuropathic pain. These drugs achieve analgesia at doses lower than those required for depression. Pamidronate, a bisphosphonate, is currently being used to treat osteolytic bone pain in multiple myeloma patients and in metastatic breast cancer patients with bone metastases. The current dose being used is 60 mg every four weeks in multiple myeloma and 90 mg every three to four weeks in metastatic breast cancer.

Treating advanced cancer pain can be difficult and frustrating both for the patient and the clinician. Nevertheless, pain can be controlled in the majority of these patients. With a better understanding of the range of options that are available, health care professionals can be certain that their patients are as comfortable and free of pain as possible.

Ashburn M and Lipman A. Management of pain in the cancer patient. *Anesth. Analg.* 1993;76:402-416.

Levy M. Pain management in advanced cancer. *Seminars in Oncology*. Vol. 12, No 4(Dec.), 1985: 394-410.

American Pain Society. *Principles of Analgesic Use in the Treatment of Acute Pain and Chronic Cancer Pain*. 2nd edition. Clinical Pharmacy. Vol. 9 1990:601-611.

Haviley C et al. Pharmacological management of cancer pain. *Cancer Nursing*. 15(5): 1992; 331-346.

PROTOCOL UPDATES

u Protocol Activations

u 12/15/96

CALGB 8892: Phase III Trial of Orchiectomy/LHRH Analog + Flutamide + Suramin + Hydrocortisone vs. Orchiectomy/LHRH Analog + Flutamide in Patients with Metastatic Prostate Cancer. Study Chair: Nancy Dawson, M.D.

CALGB 9670: Barriers to Participation of Older Women with Breast Cancer in Clinical Trials: A Pilot Study. Study Chair: Margaret M. Kemeny, M.D.

u 1/15/97

CALGB 9663: Androgen Receptor Mutations in Hormone Refractory Prostate Cancer (Mandatory Companion to CALGB 9583 and Optional Companion to CALGB 9480 and CALGB 9680). Study Chair: Mary-Ellen Taplin, M.D.

u 2/15/97

CALGB 9621: Phase I Study of MDR Modulation with PSC-833 with a Pilot Study of Cytogenetic Risk-Adapted Consolidation Followed by a Phase II Pilot Study of Immunotherapy with rIL-2 in Previously Untreated Patients with AML < 60 Years. Study Chair: Jonathan Kollitz, M.D.

u Protocol Closures

CALGB 9294: Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil vs. 5-Fluorouracil and Levamisole in Selected Patients with Completely Resected Colon Cancer. Study Chair: Robert J. Myerson, M.D. (12/17/96)

CALGB 9493: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy. Study Chair: Parvesh Kumar, M.D. (1/1/97)

CALGB 9211: A Phase II Trial of 2-Chlorodeoxyadenosine in B-Cell Chronic Lymphocytic Leukemia Patients who have Previously Failed Therapy with Fludarabine Phosphate. Study Chair: Lawrence Piro, M.D. (12/18/96)

CALGB 9393: Prospective Randomized Trial of Postoperative Adjuvant Therapy in Patients with Completely Resected Stage II and Stage IIIa Non-Small Cell

Lung Cancer. Study Chair: Leslie Kohman, M.D. (2/4/97)

CALGB 9483: Phase III Randomized Trial of Pre-Operative vs. Post-Operative Combined Modality Therapy for Resectable Rectal Cancer. Study Chair: Joel Tepper, M.D. (2/14/97)

CALGB 9590: Phase II Study of VIP (Etoposide, Ifosfamide, and Cisplatin) in Treatment of Invasive Thymoma. Study Chair: Joseph Aisner, M.D. (2/27/97)

u 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.: 2° Prim. Tmrs (NSCLC) (MDAnderson)
- 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
- 9380 Thoracoscopic Staging for Esophageal Cancer
- 9399 Prostate Cancer Prevention Trial (SWOG 9217)
- 9411 Econ Analysis/Modeling of Costs of Care for CALGB 9111
- 9473 Trial of Omega 3 Fatty Acids for Cancer Cachexia
- 9481 FUDR, LV + Dex vs. 5-FU, LV Colorectal Ca Hep Met
- 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
- 9670 Barriers to Part of Older Women in Breast Ca Trials

For more information, contact:
Mary Sherrell
CALGB Financial Officer
(773)702-9856.

Ocular Toxicity Associated with Tamoxifen Therapy

A previously undescribed ocular toxicity associated with tamoxifen has been detected as a result of an NSABP trial designed to evaluate side-effects of tamoxifen on the eye. NSABP trial P-1E, an ancillary study to NSABP B-14, evaluated a total of 303 women. The women comprised three groups: those who had never taken tamoxifen (Tam-None); those who had taken tamoxifen for an average of 4.8 years and were off tamoxifen for an average of 2.7 years (Tam On-Off); and those who had taken tamoxifen for an average of 7.8 years (Tam-Cont). The results demonstrated no vision-threatening ocular toxicity among tamoxifen-treated patients. There was a trend toward an increasing frequency of intraretinal crystals reported with tamoxifen use; reports were more frequent in those women who had taken tamoxifen for the longest period of time (Tam-Cont). The overall rate of occurrence of cataracts was similar for the placebo and the tamoxifen-treated groups (40% vs. 43%, respectively). However, the incidence of one particular type of cataract appeared to be increased. In women who had never taken tamoxifen (Tam-None), 2.5% of the women had posterior subcapsular opacities, as compared with 9.2% in the Tam On-Off group and 9.3% in the Tam-Cont group.

Based on the findings of NSABP P-1E, an evaluation was undertaken of cataract data from the Breast Cancer Prevention Trial (BCPT) in October 1996. Women in the tamoxifen group who reported having a cataract before entering the BCPT had a slightly higher incidence of cataract surgery.

As a result, changes will be made to currently active CALGB protocols and consent forms (CALGB 9082, 9343, and 9344) that include tamoxifen as part of the treatment plan. In addition, women who have received tamoxifen on a CALGB protocol must be notified that there is a slightly increased risk of developing cataracts, and that they might require cataract surgery if they had a cataract before beginning tamoxifen. Patients currently taking tamoxifen will be asked to sign an Information Update at the time of their next scheduled visit. Patients who are currently being followed on trials involving tamoxifen, but are no longer taking tamoxifen, will be notified of this new potential toxicity, but signed receipt of this information will not be required.

Further information regarding tamoxifen-associated ocular toxicity, as well as a sample Information Update, will be forthcoming in a monthly protocol mailing from the Central Office.

CALGB 1997 TENTATIVE SPRING GROUP MEETING SCHEDULE

FRIDAY, JUNE 20, 1997

Data and Safety Monitoring Board*	1:00 pm	-	5:00 pm
Oncology Nursing Core Committee*	2:00 pm	-	5:00 pm
Pathology Committee	2:00 pm	-	3:00 pm
Surgical Pathology Subcommittee	3:00 pm	-	5:00 pm
Hematopathology Subcommittee	3:00 pm	-	5:00 pm
Extended Executive Committee*	5:00 pm	-	9:00 pm
SoCRA Certification Examination	6:00 pm	-	9:30 pm
Data Audit Committee*	8:00 pm	-	10:00 pm

SATURDAY, JUNE 21, 1997

Registration	7:00 am	-	6:00 pm
Foundation Board of Trustees*	7:00 am	-	8:30 am
GI Surgery Subcommittee	7:30 am	-	9:00 am
9334 Workshop for CRAs & Physicians	8:00 am	-	9:00 am
Respiratory Committee & Thoracic Surg. Subcommittee	8:30 am	-	12:30 pm
Soy Study	9:00 am	-	11:00 am
Leukemia Committee	9:00 am	-	12:00 Noon
CRA Committee	9:00 am	-	12:00 Noon
GI Committee	9:00 am	-	12:00 Noon
Health Outcomes Research Council	11:00 am	-	1:00 pm
9270 CAPS Workshop	11:30 am	-	1:00 pm
Constitution Committee*	12:00 Noon	-	1:00 pm
Plenary Session	1:00 pm	-	3:00 pm
Membership Committee*	3:00 pm	-	4:00 pm
PET Committee	3:00 pm	-	6:00 pm
Oncology Nursing Committee	3:00 pm	-	6:00 pm
Prostate Committee and Prostate Surg. Subcommittee	3:00 pm	-	6:00 pm
Correlative Sciences Leukemia/Lymphoma Committee	3:00 pm	-	6:00 pm
Surgery Committee	3:00 pm	-	6:00 pm
CRA Continuing Education Workshop	3:00 pm	-	6:30 pm
Epidemiology Working Group	4:00 pm	-	6:00 pm
CCOP/CGOP Committee	4:00 pm	-	6:00 pm
Reception	6:30 pm	-	10:00 pm

SUNDAY, JUNE 22, 1997

Registration	7:00 am	-	2:00 pm
Institutional Performance Evaluation Committee*	7:00 am	-	9:00 am
9082 Monitoring Committee*	8:00 am	-	9:00 am
Minority Issues Committee	8:00 am	-	10:00 am
Pharmacy Core Committee*	8:00 am	-	10:00 am
Radiation Oncology Committee	8:00 am	-	11:00 am
Psycho-Oncology Committee	8:00 am	-	11:00 am
Breast Committee	8:00 am	-	12:00 Noon
Lymphoma Committee	9:00 am	-	12:00 Noon
Conflict of Interest Committee*	12:00 Noon	-	1:30 pm
Membership Committee*	12:00 Noon	-	2:00 pm
Cancer Control Committee	1:00 pm	-	3:00 pm
AIDS Malignancies Working Group	1:00 pm	-	3:00 pm
Breast Surgery Subcommittee	1:00 pm	-	3:00 pm
Pharmacy Committee	1:00 pm	-	3:00 pm
Cancer in the Elderly Working Group	1:00 pm	-	3:00 pm
Study Chair Workshop	1:00 pm	-	4:00 pm
Solid Tumors Correlative Sciences	1:00 pm	-	4:00 pm
Board of Directors*	4:00 pm	-	7:00 pm

*closed meeting

CALGB SPRING MEETING INFORMATION

Queen Elizabeth Hotel - 900 Rene Levesque Boulevard West, Montreal, Quebec, Canada H3B 4A5
June 20 - 22, 1997

• INFORMATION ON MONTREAL

A mountain in the middle of an island...in the middle of a river that flows to the Atlantic Ocean more than 1,000 miles away. It's a cultural hub, a cosmopolitan city, and an international meeting place. It's Montreal, the site of the CALGB Spring Group Meeting. You need not leave North America to experience the ambiance of a European city. Montreal, the world's second-largest French-speaking city, is rich with a cultural diversity and international flavor that make it a unique meeting destination. Cobblestone streets dotted with specialty shops, boutiques and an assortment of cuisines for even the most discriminating diner, are within walking distance of the Queen Elizabeth Hotel, the CALGB's host hotel. The hotel is conveniently located downtown and is connected to Montreal's underground city—a below-ground network of boutiques, restaurants, theaters, and train and bus stations.

Hailed as a city with a spirited nightlife, Montreal offers an abundance of live entertainment for every taste, such as the Montreal Casino, which is among the 10 largest casinos in the world. Free continuous shuttle service is available from the Queen Elizabeth Hotel to the Casino daily.

Diehard shoppers will not only appreciate Montreal's reputation as a shopping Mecca, but will also be pleased that the U.S. dollar, with its current exchange rate of 35%, gives shoppers a lot for their money.

Montreal has long been recognized for its vibrant cultural scene, as well. On Sherbrooke Street, you can visit the McCord Museum, the Montreal Museum of Fine Arts, or the Canadian Centre for Architecture. Montreal is also home to Les Grands Ballets Canadiens and the Montreal Symphony Orchestra.

• TRAVELING TO CANADA

Proof of U.S. citizenship is required when traveling between Canada and the United States. Travelers are strongly advised to carry a current passport. Although U.S. citizens may prove citizenship with a driver's license and voter's registration card, we recommend that you not rely on this form of identification, but use either a passport, birth certificate, or U.S. citizenship documents.

As a visitor to Canada, you may claim a refund for some of the tax you pay on accommodation, providing your stay is less than one month. You may also claim a tax refund for eligible goods you take home. This includes refunds for the Goods and Services Tax (GST) and Provincial Sales Taxes paid in the provinces of Quebec and Manitoba. You may apply for all three tax refunds using the same application form. The current Goods and Services Tax is 7%, Quebec Sales Tax is 6.5%, and Manitoba Sales Tax is 7%. You may obtain your tax refund at any participating Canadian duty-free shop (for a cash refund of up to a maximum of \$500CAN) or by completing and mailing an application to Revenue Canada. You qualify for a tax refund

if you are not a resident of Canada, you have the original receipt, and your total refund claim is for a minimum of \$14CAN for each tax you are claiming and for eligible goods. Each individual receipt must be a minimum of \$3.50CAN for each tax you are claiming.

• 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:** \$40 (for registrations received before May 30, 1997); \$65 (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 May 30, 1997. After this date, we will be unable to accept substitutions.

• TRANSPORTATION

Airline: The CALGB has appointed I.T.S. (International Travel Service) as the official air travel coordinator for our 1997 Meeting. I.T.S. provides attendees with personalized, unbiased airline reservations and ticketing at the lowest available fare with one easy, toll-free call. I.T.S. will provide the following:

- Meeting discounts on American Airlines; 10% off unrestricted coach fares or 5% off lowest applicable fares, including first class.
- Guaranteed lowest available air fare.
- Full mileage credit for all frequent flyer club members.
- Easy payment by all major credit cards.

Call I.T.S. toll-free 1-800-621-1083 (Mon. - Fri., 8:00 am - 5:00 pm Central Time) or you may call American Airlines at 1-800-433-1790 and reference star file #S0367 MD.

Please Note: Your institution may not use PHS grant funds to reimburse you for airline expenses that you incur using a non-U.S. airline (e.g., Air Canada) to attend our Group Meeting. The requirement to use a U.S. flag air carrier may not be disregarded due to factors of cost, convenience, or personal travel preference.

Ground Transportation: The least expensive fares and most

CALGB SPRING MEETING INFORMATION

convenient and reliable service can be found with Airport Express (approximately \$9.00CAN one-way to the Queen Elizabeth Hotel; \$16.50CAN round trip). Service is available every half-hour. Airport Express is located at the baggage claim area at the Dorval Airport. Travel time from the airport to the hotel is about 20–25 minutes.

• HOTEL RESERVATIONS

• Rates:

Standard Category

\$124CAN single occupancy (**\$92 USD***)
\$159CAN double occupancy (**\$117 USD***)

Deluxe Category

\$144CAN single occupancy (**\$106 USD***)
\$179CAN double occupancy (**\$132 USD***)

Entree Gold (Concierge Level)

\$174CAN single occupancy (**\$129 USD***)
\$209CAN double occupancy (**\$155 USD***)

* Approximate current exchange rate conversion to U.S. dollars.

Room rates are subject to 7% Goods and Services Tax and 6.5% Provincial Sales Tax. Nonresidents of Canada are eligible for rebate on guest room taxes.

• **Hotel Check-in/Check-out Times:** Check-in is 3:00 pm; check-out is 12:00 Noon.

• **Reservations Deadline:** May 30, 1997. Reservations received after the cutoff date will be accepted on a space-available basis only.

• **Deposits:** A \$100.00 US deposit will be required when making your reservation. Should you fail to cancel your reservation 48 hours before arriving, your deposit will be forfeited. (Note: your room will be guaranteed for late arrival when reservation is accompanied by a deposit, payable either by check or credit card.)

• **Phone Reservations:** Call the Queen Elizabeth Hotel at (514) 861-3511 and request the Reservations Department, or call Central Reservations at 1-800-441-1414. Be sure to identify yourself as a Cancer and Leukemia Group B attendee in order to receive the special convention rate, and have your credit

card available when you call.

• **Fax Reservations:** (514) 954-2256. Fax the completed copy of the Hotel Reservation Form from this newsletter directly to the hotel. Be sure to include your credit card information, including the expiration date, on the form.

• **Reservations by Mail:** Send the completed Hotel Reservation Form from this newsletter directly to the hotel. If using the mail-in method, be aware of your mailing date. Reservations should be received at the hotel by May 30 to ensure availability.

Cancellations: If you must cancel your reservation, be sure to notify the hotel 48 hours **before your 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 located in the lower level.

(Note: You will find that hotel business center prices are typically quite costly.)

• CALGB RECEPTION

Saturday, June 21, 1997

6:30 pm - 10:00 pm

Any registered CALGB attendee may participate in the reception at no charge. This is a good opportunity to network with your colleagues in a relaxed atmosphere.

• 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 (note: a good rule of thumb is that a slide, when held at arm's length, 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:
Elmetrica Holman (773) 702-9163.

If you have questions about reimbursement, contact Braunda Ridley (773) 702-9775.
For other meetings-related questions, contact Helen Pollard, Meetings Manager (773) 702-4129.

WORKSHOP INFORMATION

9270 (CAPS) WORKSHOP

CALGB Spring Group Meeting
Sunday, June 22, 1997
11:00 am - 1:00 pm

Protocol 9270, the colorectal adenoma prevention study (CAPS) using aspirin, is an important study for the CALGB. The Division of Cancer Prevention and Control (DCPC) is working with the CALGB on ways to increase accrual to this Intergroup study. In addition to a newsletter devoted entirely to CALGB 9270, the CALGB holds workshops at its biannual Group Meetings. Please Note: There will not be a separate 9270 workshop this year; participants from other cooperative groups will be invited to attend our Montreal Meeting. We urge those who work with this study to attend this session where you can meet with and discuss this trial with your peers.

4 Please indicate your attendance on the registration form on the last page of this newsletter.

Tentative Schedule*:

- NCI DCPC Report
- Overview of CALGB 9270
- Speaker—to be announced
- Question and Answer Session

* An e-mail broadcast will be sent prior to the Group Meeting once the schedule is finalized.

STUDY CHAIR WORKSHOP

CALGB Spring Group Meeting
Sunday, June 22, 1997
1:00 pm - 4:00 pm

The Study Chair has numerous responsibilities connected with the design, analysis, and reporting of a study. Anyone who is currently a Study Chair must attend a Study Chair Workshop at least every four years. New Study Chairs are required to attend the Workshop, which is regularly offered during the Spring Group Meeting.

4 Please indicate your attendance on the registration form on the last page of this newsletter.

Topics to be covered at the Study Chair Workshop include the following:

- Resources Needed
 - Adequate office facilities to collect, organize, and store incoming data
 - Support staff
 - E-mail capabilities
- Protocol Development
 - Present concept to Disease Committee
 - Write first draft of protocol
 - Follow protocol through development process
- Form Development
 - Advise Data Coordinator and Statistician on form content for new and revised forms
 - Participate in form review and approval process
- Active Protocol Monitoring Responsibilities
 - Respond to medical questions from institutions and study team
 - Review case records to confirm eligibility
 - Review Adverse Event Reports for trends in toxicity
 - Complete Case Evaluation Forms for patients on treatment studies who have met a protocol endpoint
 - Approve copy of study reports for CALGB Agenda Book
- Publication of Results
 - Manuscript due within six months after final analysis of a study

QUEEN ELIZABETH HOTEL
RESERVATION FORM
Cancer and Leukemia Group B (CALGB)
1997 Spring Group Meeting
June 20, 1997 - June 22, 1997

Note: Hotel Reservation Deadline is May 30, 1997. Reservations received after this date will be accommodated on a space-available basis.

Please Print or Type:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Daytime Tel. No.: _____

Arrival Day/Date: _____ Departure Day/Date: _____

(Check-in time is 3:00 pm)

(Check-out time is 12:00 noon)

Name of person(s) sharing Accommodations: _____

Standard Category:

\$124CAN single occupancy (\$92 USD*)

\$159CAN double occupancy (\$117 USD*)

Deluxe Category:

\$144CAN single occupancy (\$106 USD*)

\$179CAN double occupancy (\$132 USD*)

Entree Gold (Concierge Level)

\$174CAN single occupancy (\$129 USD*)

\$209CAN double occupancy (\$155 USD*)

* Approximate current exchange rate conversion to U.S. dollars.

Room rates are subject to 7% Goods and Service Tax and 6.5% Provincial Sales Tax. Nonresidents of Canada are eligible for rebate on guest room taxes.

I request a nonsmoking room

I request a handicapped-accessible room
please describe handicap: _____

Room rates are in effect for the entire duration of your stay, based on availability.

Please enclose a check or money order for \$100.00 US or provide credit card information below to guarantee your room. Be advised that credit card will be immediately charged toward 1st night's deposit.

Make your check payable to: Queen Elizabeth Hotel

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:

Queen Elizabeth Hotel
900 Rene Levesque Blvd. West
Montreal, Quebec, Canada H3B 4A5
ATTN: Reservations
FAX: (514) 954-2256

CALGB SPRING MEETING BULLETIN BOARD

The Plenary Session for the Spring 1997 CALGB Group Meeting will be held on June 21, 1997, from 1:00 pm - 3:00 pm. The scheduled speaker and the topic of her address is:

"Recruiting Women and Minorities into Clinical Trials"
G. Marie Swanson, Ph.D., M.P.H., Director
Cancer Center, Michigan State University

Topic for the CRA Continuing Education Workshop on Saturday, June 21 from 3:00 pm - 6:30 pm will be "Diagnosis and Multimodality Treatment of Breast Cancer"

There will be a SoCRA Certification Examination Session available on Friday, June 20 from 6:00 pm - 9:30 pm. The session will be limited to the first 25 registrants. Please contact Patti Wingate, CCRA, at (401) 444-6217 to register.

The Study Chair Workshop will be held Sunday, June 22 from 1:00 pm - 4:00 pm. All new Study Chairs are required to attend this Workshop.

Please Note: There will be no Clinical Trials Management for Beginner Clinical Research Associates Workshop at the Spring Group Meeting.

There will not be a Genetics Workshop at the Spring Group Meeting, but one will be held at the Fall Group Meeting.

CONTINUING MEDICAL EDUCATION CREDITS

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

The University of Chicago has approved cosponsorship of the CALGB's Spring Group Program. The University of Chicago is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians. Approval of approximately 18.5 credit hours in Category I of the Physician's Recognition Award of the American Medical Association has been granted.

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

The Illinois Nurses Association has approved Continuing Education Credit (approx. 22.8 contact hours) for nurses.

After participating in this activity, nurses should be able to:

- 1) Summarize the role of multidrug resistance in the therapy for cancer patients;
- 2) Identify side effects of PSC-833 and nursing management issues;
- 3) Identify and discuss nursing implications related to patients receiving irinotecan;
- 4) List nursing interventions to manage diarrhea; and
- 5) Exchange information and enhance peer support through networking with fellow oncology nurses.

C.C.R.A.s

An application for approval of approximately 7.5 CEUs has been submitted to the Society of Clinical Research Associates.

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

CALGB Group Meeting Registration Form

Event: 1997 Spring Group Meeting
June 20-22, 1997
Montreal, Quebec, Canada

MEMBER INFORMATION

Name: _____ SS#: _____
Institution: _____ Phone: _____
Address: _____ Fax: _____

REGISTRATION

Registration Date:

Advance Registration Deadline is May 30, 1997
Must be postmarked by deadline

Please check off the event(s) you wish to attend and fill in the appropriate fee(s).

Group Meeting
\$40 advance/\$65 on-site

\$

Study Chair Workshop
No Charge

CAPS Workshop
No Charge

Agenda Book Only
\$30 advance only

Donation to CALGB Foundation
I wish to make a tax-deductible donation in the following amount:
You will receive an acknowledgment from the Foundation by mail.

Total Due: \$

IMPORTANT

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 the advance registration deadline.

AGENDA BOOKS: The registration fee for the meeting includes (1) Agenda Book. However, we cannot guarantee that the Agenda Books will be available if you register after the advance registration deadline. If you cannot attend the meeting and wish to obtain an Agenda Book, return this form (see above) with a check for \$30 made payable to the University of Chicago/CALGB by the advance registration deadline.

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 the University of Chicago/CALGB to:

Cancer and Leukemia Group B
Attn: Elmetrica Holman
208 S. LaSalle St., Suite 2000
Chicago, IL 60604-1104

ACKNOWLEDGMENTS

We wish to add to the list published in our last issue of the Cal Gab the following individuals who also generously supported the CALGB Foundation during 1996.

Robert Cooper, M.D.
Herbert Maurer, M.D.
Bruce Peterson, M.D.
Ted Szatrowski, M.D.