

WINTER 2005

THE GOG NEWSLETTER

2005
SILENT AUCTION
DONATION FORMS!

THE GYNECOLOGIC ONCOLOGY GROUP
FOUR PENN CENTER
1600 JFK BOULEVARD, SUITE 1020
PHILADELPHIA, PA 19103

CHAIR'S CORNER

Philip J. DiSaia, MD



Overall accrual to GOG protocols has diminished modestly over the last six months because of the closure of some very large accruing studies such as Protocol 182. Several new protocols are nearing activation and have been delayed by a variety of administrative issues. Some of them involve new and exciting biologics which has required detailed negotiations with pharmaceutical and biotechnical companies. I'm confident that in the not too distant future we will have a menu of protocols that are appealing and at the same time yielding better compensation to our investigators. In the interim, I encourage all members to utilize the remaining active protocols, such as Protocol 210, to their fullest extent.

On a lighter note, I would like to congratulate a long-time active member of our Group, David Alberts, on his appointment as Director of the Arizona Cancer Center. David is a Regents Professor of Medicine, Pharmacology, Nutritional Science, and Public Health at the University of Arizona. He joined the University of Arizona in 1975 and he has served as Director of the Cancer Prevention and Control Program at that institution since 1989. Between 1988 and 1996, he served as Deputy Director of the Cancer Center and between 1996



and 2002 he served as Associate Dean for Research in the College of Medicine at the University of Arizona. Since 1987, David has served as a Principal Investigator with the University of Arizona. Between 1988 and 1996, he served as Deputy Director of the Cancer Center and between 1996 and 2002 he served as Associate Dean for Research in the College of Medicine at the University of Arizona. Since 1987, David has served as a Principal Investigator with two NIH-funded cancer prevention program project grants: the Colon Cancer Prevention Program Project and the Chemoprevention of Skin Cancer Program Project. The emphasis of his laboratory-based and clinical research has been the pre-clinical screening and clinical trials of chemical and biologic agents for chemoprevention of pre-cancerous lesions. He currently serves on a National Cancer Institute Board of Scientific Advisors and he's been Chairman of the Cancer Prevention Committee of the Gynecologic Oncology Group since its inception in 1994. We're very proud to have David as a member of our family.

A TRIBUTE TO "JACK"

MY FRIEND IN PHILADELPHIA

John Blessing, PhD

I remember when Dr. Lewis informed me that he had hired Jack Kellner to head the GOG Administrative Office. His predecessor in that position had not been particularly collegial, so naturally I was curious about Jack and cautiously optimistic. We met for lunch in the Spring of 1981 in Westwood Village near UCLA. Within minutes we had each inadvertently exposed the same idiosyncrasy and both laughed hysterically. At that time, I instinctively knew that we would work well together. In 1981 the staff of both offices numbered 10, an-

nual accrual was 1,526, and the highest numbered GOG study was Protocol 50. Obviously, the GOG has grown significantly over the ensuing 24 years! During that time, Jack and I strove to make the growing staffs of the two offices a cohesive group. Communication was stressed and interaction thrived. We developed one rule of thumb: we might disagree in the hall or on the phone, but we'd work it out and go into any meeting on the same page.

In the early years, we traveled together frequently. (At that time Jack had hair and mine was dark.) On one memora-

ble trip to Salt Lake City, Jack let me pick the hotel and I let him pick the restaurant. After closet hotel rooms and inedible food, we decided that we'd each better stick to our strengths. Other episodes regarding water slides, "Bo concerts", valet parking, and stress management come to mind, but I'll leave those for Jack to tell.

One of the best fringe benefits of GOG involvement has always been the treasured ongoing relationships which are developed while performing important work. For 24 years I've had the pleasure of sharing that with Jack Kellner!

TRANSITION

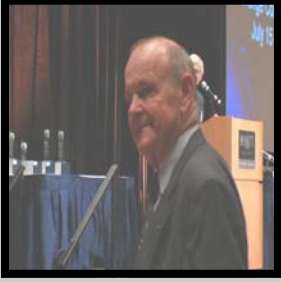
Frederick Stehman, MD

After twenty-four years of working with the Gynecologic Oncology Group, Jack R. Kellner will be retiring this year. Fortunately he won't be leaving altogether; we will still have access to his expertise and experience in a consultant role. But it will be the end of an era as we transition to new leadership in the Philadelphia Administrative office.

When Jack first came to the GOG, he immediately had a calming influence on what had previously been a not-very-stable office. Working closely with Dr. George Lewis he was involved from the ground floor in the major transition of changing the Gynecologic Oncology Group from being sponsored by Jefferson Medical College in Philadelphia to being sponsored by the American College of Obstetricians and Gynecologists. We have since split from ACOG, but that transition was a major

step forward and a considerable advantage for the GOG at the time. It also provided an avenue to make major savings in indirect costs and to make these dollars available for Institutional Investigators to use.

One area where Mr. Kellner has added a high degree of professionalism and sophistication to the GOG has been the area of Group Meetings arrangements and planning. As the group has grown, he has been able to plan ahead and compete for excellent facilities at



Reasonable rates, even though we have restricted him to a limited number of dates in mid-July and mid-January. Unfortunately, he has not been able to do anything about the weather we experienced in Phoenix, or in Charleston in July, but the room rates were good!

In the late 1980's and the early 1990's, the Group converted to the current per capita reimbursement arrangement. Many people were actively involved in this transition including Drs. Robert Park, John Blessing, and my late chairman, Dr. Clarence Ehrlich. But all those changes, all those spread sheets, all the commotion was centered in Jack Kellner's office. I think it is reasonable to say we would have not been the first cooperative group to have per capita reimbursement system if it wasn't for Jack's efforts.

Over the twenty-four years that Jack has been with the Gynecologic Oncology Group, the Group has experienced a virtual explosion in growth. During Mr. Kellner's leadership the GOG has initiated collaboration in new drug development, with industry, Phase I trials, Quality of Life trials, Prevention and Control trials, and translational science. The GOG was involved in none of these areas before Jack came, and all these areas have required a lot of adjustment in the administrative office.

The GOG will certainly miss Jack Kellner. While we look forward to new leadership in the post, it will never be quite the same GOG with Jack retiring.

Developmental Therapeutics Committee (DTC)

The GOG DTC is responsible for development and prioritization of a large number of early-phase clinical trials, including Group-wide phase II , limited access phase II, phase I (through the Phase I Working Group), and vaccines. Although many studies are conducted in collaboration with the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute, an increasing number of studies with novel agents involve collaboration and financial support from the pharmaceutical industry. In addition, many studies have incorporated exploratory laboratory correlates for analysis of pharmacokinetics and molecular markers. Successful development involves close collaboration between the study chairs, sponsors, Administrative Office, Statistical and Data Center, and participating local institutions. Responsibilities for commercial studies may also include contract development, filing of Investigational New Drug (IND) applications, and reporting to regulatory agencies.

Phase II Studies

Most phase II studies are activated Group-wide for patients with recurrent disease after completion of primary therapy. However, due to the large number of interesting biologic and cytotoxic agents available, a few strategies have been implemented to maximize participation and expand the number of studies that can be conducted simultaneously by the Group and offered to our patients. First, the entire GOG membership has been divided into teams (A and B), permitting selected phase II studies for each disease site to be independently activated within each team. In addition, a process was developed for simultaneous activation of biologic and cytotoxic studies for each disease site. Finally, in ovarian cancer, a small number of studies have allowed multiple prior therapies. Thus, for an individual patient with ovarian cancer, it is possible to participate in a phase II biologic (170 series), followed by a phase II cytotoxic (126 or 146 series), and a phase II third-line cytotoxic (186 series).

In addition to providing more opportunities for our patients, we hope that this new and evolving structure will encourage local institutional participation in an expanded menu of phase II studies. In the past, some institutions have limited their participation in our phase II program due to rapid study turn-over and the challenges of timely regulatory review, which we hope to address through this revised structure.

Almost all phase II studies utilize a two-stage design with early-stopping criteria based on efficacy and toxicity. This two-stage process can be confusing at the local level, as it has been common practice for GOG to activate a new study (or re-activate an old study) after first-stage accrual has been completed, and the study has been suspended. This policy helps to maintain an active study for each patient population while allowing sufficient time for ongoing treatment, data collection, and study chair review. Even though we switch from one suspended study to another, we make a concerted effort to avoid competing trials for the same patient population to minimize the risk of selection bias, and there should only be one cytotoxic phase II study open within each disease site (or team). The majority of phase II studies are eventually closed after completion of the first stage due to lack of efficacy, although a number of important compounds have emerged with sufficient activity to justify second-stage accrual and incorporation in front-line therapy. This has been an important resource for the Group, and recognized in the context of the recent GOG grant submission.

Any GOG member can submit concepts for new phase II studies, using investigational or commercial agents. Due to the number and diversity of studies, there are many opportunities for members to serve as study chairs, or co-chairs, and become familiar with the GOG protocol development process. However, due to the complexities of new drug development in oncology, not every approved concept becomes a full study, and not all studies are eventually activated for patient accrual. We have recently appointed section heads for each of the major disease sites, including ovary (Bob Burger), endometrium (Scott McMeekin), cervix (Peter Rose), and sarcoma (Greg Sutton), and members are urged to discuss potential concepts and roles with the appropriate section head. Contact information and a list of current studies under development can be obtained through the Developmental Therapeutics Committee section on the GOG website.

GOG Winter Symposium

January 13, 2005 - Sponsored by the GOG Educational Underwriters

"Scientific Priorities and Future Directions in Gynecologic Malignancies"



▲ Dr. Michael Bookman (right) with the winner of the Investigational Drug Survivor William McGuire, MD (left) of Franklin Square Hospital.

More than 400 people registered for the GOG Winter Symposium, which included a range of scientific sessions to address antiangiogenesis, targeting of growth factor receptors, novel cytotoxic agents, recent developments with platinum, and clinical trial design. There was considerable interest in the presentation by Dr. Rakesh Jain regarding "Interactions of Antiangiogenic Therapy with Cytotoxic Therapy" in view of the development of GOG0218, our front-line ovarian cancer trial, which will evaluate chemotherapy in combination with bevacizumab. In addition, at the end of the session, there was a competition for development of new investigational drugs. Three well-known clinical investigators from GOG (William McGuire, Robert Mannel, and Gini Fleming) were each charged with creating a successful development plan for a new drug in ovarian cancer. The plans were reviewed and rated by an Industry panel, as well as a panel representing the (ODAC), which provides advice to the FDA on new drug applications. While all three contestants provided entertaining and innovative plans for drug development, the panel selected William McGuire, MD as the "winner" for the overall competition.

Semi-Annual Meeting & Symposium Highlights

San Diego, California
January 13-16, 2005
Manchester Grand
Hyatt Hotel





SILENT AUCTION

Friday, July 8, 2005



On Friday, July 8, 2005, during the Semi-Annual meeting in Baltimore, Maryland, GOG will host a Silent Auction for its membership. Auction proceeds will help fund the upcoming special projects associated with research activities. Donated items will appear on our website prior to the auction. Information on the items and the donor will also appear. Donated items will be displayed outside the registration area. Interested members and guests will enter the auction area and be issued a catalog with a bidder number. Bidders will enter their bid on the items bid sheet and may be raised anytime prior to the items table closing Friday evening. The evening of the auction, the table closings will be posted and participants will be given the opportunity to increase their bid. The highest bidder at the time of closing will be awarded the item. The official GOG auctioneer (to be announced) acknowledges the winner. The GOG hopes that this event will be a fun-filled and be enjoyed by all. Please plan to attend. We will have plenty of food, drink, music, and good old-fashioned FUN!

Just take a look at what we have to offer!

Sports Trivia



Dallas Cowboy autographed photo of Pete Hunter

Redskins QB—autographed photo of Patrick Ramsey

Ravens autographed football autographed by Head Coach Brian Billick

San Diego Chargers official "Throw Back Jersey" from Carlos Bradley

Vacation Packages



Stay at a Marriott Hotel of your choice within the US

The Inn At Henderson's Wharf—2 night stay

Hampton Inn Baltimore—Enjoy a weekend off. 2night stay.

Many more packages, trips, outings, etc. to come. See our website for complete details.

SILENT AUCTION DONATION

2005

If you would like to make a donation, please complete this form and return it to the GOG Development office. Auction items or cash donations, must be received by JUNE 15, 2005, to ensure that your donation and name appears in the program. A tax acknowledgment will be mailed to you for tax purposes.

Name: _____

Address: _____

Phone: _____ E-mail: _____

YES, COUNT ME IN! I WILL MAKE A DONATION OF AN ITEM.

YES, ENCLOSED IS MY MONETARY GIFT.

Description of item as it should appear in the program and our website. Please use detailed terminology, so that the time can be fully described in the catalog and website. Cash contributions will be acknowledged in the catalog as well as the website. A tax acknowledgment letter will be mailed to each individual donating an item or making a monetary gift. Please send all donations to GOG, Kathy Shumaker, Development Manager, 2127 Espey Court, #104, Crofton, Maryland 21114. If you have any questions, please contact Kathy Shumaker at 410-721-7126 or Kshumaker@gog.org.

Description:

FINANCIAL GIFTS

Supporting the GOG financially helps provide the much-needed financial resources with will allow GOG to develop and deliver essential research tools to enrich our efforts in the quality of life aspects to our trials as well as in basic research activities.

The following gifts were made to the GOG in memory of a loved one:

Contributor

Kim Etcheberry & Family
Mt. Kisco Elementary School
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Bobby Bryden
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Karen Matkovic
Mike Beukema

Kenneth Beukema
Patricia Miner

In Loving Memory of:

Joyce Ingebretsen
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Maria Ceglio-Miglino
Pauline Bryden
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Maria Ceglio-Miglino
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Ken & Connie Beukema &
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