For nearly four decades, since the signing of the 1971 Cancer Act that gave National Cancer Institute special authority and made the NCI Director a presidential appointee, prominent individuals in the cancer field were solicited as a committee to select the NCI Director. That tradition was broken when former President George W. Bush appointed urologist Andrew von Eschenbach as Director of the NCI, and then as Head of the FDA. Following Dr. Eschenbach, Dr. John Niederhuber became the Director and is the current Director. President Obama has not elected to resume the tradition of a “Blue Ribbon” selection committee, and has delegated the selection of the new NCI Director to the NIH Director, Dr. Francis S. Collins. President Obama appointed Dr. Collins as the NIH Director in August of 2009 when the search for NCI Director has already begun. Dr. Collins appears to be managing the recruitment with the advice of select individuals and without the traditional search committee process. The NIH Director and the NCI Director are Presidential appointments, but unlike the NIH Director, the appointment of the NCI Director does not require Senate confirmation. It had been a tradition for the NIH Director to resign before the end of the presidential term, but the NCI Director has always stayed on for an additional year. Dr. Niederhuber’s stay has now exceeded that year.

The NCI currently has a budget of about $5 billion, a 2.9 percent increase over the previous year. Most of the pressure on that budget appears to be to increase the research grant pay line from its current 15 percent. President Obama’s budget proposed a release of $2.2 billion on research project grants, which makes up just under half of the total NCI budget. In addition to these pressures, the new
May 2009 the NCI’s Cancer Therapy Evaluation Program (CTEP) rolled out the C-PIRAT initiative: CIRB Process for Initial Reviews of Adult Trials. The information was provided to all CIRB participating institutions at the time of the roll-out. The following synopsis is presented in this forum as a follow-up for all GOG member institutions.

The NCI CIRB worked closely with NCI, CTEP in order to revise the process for the initial review of Adult Phase III GOG trials. This was done in an effort to make these important trials available to investigators as quickly as possible, with a continued focus on the thorough and rigorous scientific and ethical reviews that are completed by CTEP and the CIRB respectively.

The sequence of review was redesigned such that final CTEP approval is no longer contingent upon CIRB review and approval. CTEP provides approval, and the trial is forwarded simultaneously to the CIRB and the GOG. The CIRB conducts its review of the trial at the same time that the GOG works to complete its final preparation for activation of the trial.

It was anticipated that by allowing the GOG to make final preparation for study activation while the CIRB conducts its review, the total time to activation of Adult Phase III trials could be shortened. Additionally, the new process allows for the CIRB to have its own version of the informed consent document (ICD). The CIRB’s own version of the ICD is based on the GOG’s model consent.

Revised Process for Initial Review
If the GOG completes final preparation and is ready to activate the trial prior to CIRB approval, GOG may proceed with activation of the trial. In this event, notification is posted to the CIRB website indicating the CIRB meeting date for review of the study as well as an anticipated CIRB approval date.

Impact on CIRB Participants
• If the CIRB has completed its review of the trial prior to GOG activation, the trial will be CIRB-approved at time of activation and the CIRB’s review may be used in a similar manner as per the current process. It is the goal of the CIRB Operations Office to have study approval available to local IRBs and research staff at the time the trial is distributed by the GOG.
• In the event that the GOG activates the trial prior to completion of CIRB review, local IRBs who wish to use the CIRB’s review must wait until they are notified by the CIRB of study approval. A notification is posted to the CIRB website, on the study-specific Web page, indicating the CIRB meeting date for review of the study as well as the anticipated CIRB approval date. When the study has been CIRB approved, local IRB and research staff is notified via email of the approval and the documents are posted on the CIRB website, per the usual processes.
• If the protocol was changed during CIRB review, the GOG will distribute an amendment encompassing all of the modifications that occurred during CIRB review. Sites with local IRB approval of the study (i.e. sites that did not wait for CIRB approval or are not enrolled in the CIRB) must submit this amendment to their local IRB for review. Sites enrolled in the CIRB Initiative are encouraged to wait for CIRB approval and use the CIRB’s review as per the current process.

CIRB’s Version of the Informed Consent Document
Starting May 1, 2009, trials approved by the CIRB have the CIRB’s own version of the informed consent document (ICD). The CIRB’s own version is based on the GOG’s model however it will reflect changes that may have been made by the CIRB to increase study participant protections. All changes appearing in the CIRB’s own version will have prior approval by the study’s lead cooperative group. Local IRBs who have accepted facilitated review of the study should download and use the CIRB’s version of the ICD from the CIRB website. The CIRB’s version of the ICD will also be available on the CTSU website. Previously, local IRBs and research staff were advised to use the informed consent document posted to the GOG website; this is no longer the case.

Local IRBs and research staff from institutions using the CIRB’s reviews, as evidenced by submission of the Facilitated Review Acceptance Form, should use only the CIRB’s version of the Informed Consent Document as posted to the CIRB website. Revising the CIRB’s version of the ICD to accommodate local context concerns is still permissible and the revisions should comply with cooperative group guidelines pertaining to revising the ICD.

Additional Support for CIRB Participants
The CIRB and CTSU are taking action to ensure that local IRBs and research staff can find the CIRB status easily for any new trial distributed by a cooperative group. These actions include the following:

• CIRB-approved trials appear with all review documents readily available and are included on the study menu on the Participant’s Side of the CIRB’s website at www.ncicirb.org. New trials still in CIRB review appear with the date of CIRB review and an estimated CIRB approval date.
• If CIRB approval occurs after GOG has distributed the trial to investigators; the CIRB will notify all local IRB and research staff included in their database through a study specific email. As usual, the bi-monthly Study Activity Update will include the listing of documents that have been posted in regards to the study recently approved.
• The CTSU will provide information on its website if CIRB approval is pending for a new trial at time of activation by the Group.
William T. Creasman, MD, Professor of Obstetrics and Gynecology at the Medical University of South Carolina (MUSC) College of Medicine, was recently designated an MUSC Distinguished University Professor by its Board of Trustees. Dr. Creasman’s career accomplishments were regarded as “nothing short of remarkable,” and that “we are fortunate at MUSC to have such a distinguished clinician scientist on our faculty.”

Distinguished University Professor status is given by the MUSC Board of Trustees to individuals who have excelled in their own field, and have contributed substantially to the MUSC and to society in areas that superseded their own academic field. Additionally, the major contributions of the individual to their field of scholarship should have been made during their time at the MUSC. Fewer than thirty individuals have received this honor in the history of the institution.

Dr. Creasman was formally recognized by the MUSC Board of Trustees at a February 12, 2010 meeting.

Memorial University Medical Center in Savannah, GA, announced that Curtis and Elizabeth Anderson made a $2.5 million donation to the cancer treatment facility that is named in their honor. The Curtis and Elizabeth Anderson Cancer Institute at Memorial University Medical Center was given the gift in order to expand its clinical care and research services.

In 2001, the Andersons donated funds to help establish the ACI. In 2006, they helped fund the William and Iffath Hoskins Center for Biomedical Research at Memorial University Medical Center. Curtis Anderson is a retired investment banker.

Memorial University receives $2.5 million gift for Center

Dr. William Creasman named MUSC Distinguished University Professor

Dr. Parviz Hanjani honored at dedication

Parviz Hanjani, MD, Director of the Gynecologic Oncology Institute at Abington Memorial Hospital, Abington, PA, was recently honored during a dedication ceremony at the hospital’s Rosenfeld Cancer Center. The ceremony was in recognition of the new Hanjani Institute for Gynecologic Oncology at the hospital, named in honor of Dr. Hanjani.
GOG’s inaugural satellite symposium a success

The Gynecologic Oncology Group (GOG) held its first ever satellite symposium at the January 2010 Semi-annual Meeting. The satellite symposium entitled “Practice Challenges and Novel Targeted Therapies for Gynecologic Cancers: Ovarian, Endometrial, Uterine, and Cervical” was chaired by Bradley J. Monk, MD, FACOG, FACS from the University of California Irvine Medical Center. The faculty presenters included Carol A. Aghajanian, MD from Memorial Sloan-Kettering Cancer Center, Robert A. Burger, MD from Fox Chase Cancer Center, and Krishnansu S. Tewari, MD, FACOG, FACS from University of California Irvine Medical Center. Participation was a huge success with 293 attendees.

The focus of the satellite symposium was on current and emerging evidence demonstrating the clinical potential of targeted agents in the treatment of gynecologic cancers. The program included a review of agents spanning the continuum care from initial diagnosis through resistant and recurrent disease. Case-based discussions were utilized to apply the presented concepts to clinical practice.

Dr. Monk had the following comments regarding the symposium:

“Ovarian cancer is the most common cause of death from gynecologic malignancies. Despite encouraging recent data on both diagnostics and therapeutics, treatment of ovarian cancer remains a challenge, with many clinical debates remaining. The resolution of these debates will greatly impact the interdisciplinary approach to ovarian cancer treatment. In addition, a new version of the NCCN guidelines was released in 2010. Therefore, it is critical for medical oncologists, gynecologic oncologists, and other caregivers to be aware of the issues and understand the newly available data to support optimal clinical decision-making.”

While the majority of the participants were gynecologic oncologists (62%), medical oncologists, radiation oncologists, and OB/GYN MDs, others were invited to attend as well (Figure 1).

Prior to the satellite symposium, the GOG membership was invited to participate in a practice patterns survey (PPS) (22 questions) so the chair and faculty could understand participants’ preferences of their treatment strategies for gynecologic tumors. One hundred and seventy one individuals participated in this research. Out of the 171 participants of the survey, 117 were U.S. gynecologic oncologists (gyn onc) and medical oncologists (med onc). About half who participated reported they practiced in an academic medical center and the other half in community-based centers (Figure 2).

SYMPOSIUM continued on next page
SYMPOSIUM  continued from previous page

An analysis of the data from the survey revealed significant disagreement about optimal treatment of ovarian, endometrial/uterine, and cervical cancers. Examples of two of the results are shown in Figure 3 and 4. As shown in Figure 3, there is still debate regarding the route of administration of the chemotherapy (via intravenous or intraperitoneal administration) and which agents to use for optimal front-line treatment of ovarian/primary peritoneal/fallopian tube cancer.

In addition, physicians reported utilizing bevacizumab in a variety of ways to treat ovarian/primary peritoneal/fallopian tube cancer (Figure 4). Although most physicians (52%) preferred to utilize bevacizumab in combination with at least one cytotoxic agent in most situations, they also utilized bevacizumab as a single agent (18%) or only in the setting of a clinical trial (27%). Three percent reported that they never utilize bevacizumab.

The full results of this survey will be emailed to those who participated in the satellite symposium.

Attendee evaluations of the GOG’s January 2010 symposium reflect its success at educating physicians and changing practice. For example:

82.4% of the attendees who completed an evaluation reported that “I gained new strategies, skills, or information that I can apply to my area of practice” (n=126)

Specific practice changes planned by attendees were: Increase bevacizumab use, increase use of targeted agents in general, increase referrals to clinical trials, and better educate patients on available therapies.

Approximately 80% of attendees thought that the program met the stated learning objectives.

The data from the practice patterns research and the participants’ evaluations highlight the critical need to educate GOG oncologists in order to resolve their disagreement and augment their understanding of optimal therapies and the use of targeted agents for gynecologic malignancies. It is important that the GOG membership participate in future satellite symposiums during the GOG meetings and participate in practice patterns research so that we can better understand the needs of our group and address any educational gaps there are in treatment methodologies.

CHAIR  from  page 1

NCI Director will have to deal with the Institutes’ Intramural programs and the NIH Clinical Center itself.

It remains to be seen what NIH Director Collins decides regarding the appointment of the NCI Director. It is obvious that there will be many challenges and a rather flat budget. I am hopeful an increase in the Cooperative Group budget will take place under a new director, but that may not be realistic, and our partnerships with industry need to continue or even advance.
George C. Lewis, Jr., M.D. (1919-2010) passed away April 3, 2010 at Bryn Mawr Hospital, Bryn Mawr, PA, of pulmonary emboli. He was 91. Dr. Lewis was preceded in death by his wife of 65 years, Elizabeth “Betty” Glenn Zipf Lewis.

Dr. Lewis was born in Williamsburg, KY and reared in Bryn Mawr, PA. He attended Haverford Prep School, and graduated from Haverford College and the University of Pennsylvania School of Medicine.

While attending the University of Pennsylvania, he served in the Army Student Training Program and was commissioned a Lieutenant in the Army Medical Corps upon graduation. He served in the Army until 1947, wherein he returned to Pennsylvania and completed his residency at the University of Pennsylvania Hospital, and served as Assistant Professor of Obstetrics and Gynecology at Penn until 1962. He then held the position of Chairman of the Department of Obstetrics and Gynecology at the Hahnemann University of Health Sciences, Philadelphia, PA. He was Professor of Obstetrics and Gynecology at the Thomas Jefferson University, Philadelphia, PA, from 1973 until his retirement.

From 1975 through 1989, Dr. Lewis served as Group Chair for the Gynecologic Oncology Group (GOG). He authored or co-authored over 80 major articles and was a frequent lecturer in the U.S. and abroad. He continued working with the GOG as a consultant until 2008.

We have lost a dear friend in Dr. Lewis and he will be sadly missed.

In lieu of flowers, Dr. Lewis’ family requests that donations be made to GOG’s New Horizons GYN Cancer Research Fund, “In Memory of Dr. George C. and “Betty” Lewis Lectureship Fund.”

Donations can be made by going to www.gog.org, under the heading “support,” then to “Help Support GOG.” Complete the contribution information on pages 8-9, and then forward that along with your donation to:

Finance Office
Gynecologic Oncology Group
2127 Espey Court #100
Crofton MD 21114

The GOG would like to thank the following individuals and families for their generous contributions to the New Horizons GYN Cancer Research Fund:

Doris Porter
CJ Brown
Yvonne Levermore
Donna Fortune
Arilma St Clair

In Memory of Connie Taylor
Anonymous

In Memory of Renee Fitzke
Gary Fitzke
Melissa Fricke
Ricky J Soll

Four River Sportsmen’s Club
Irene Utecht
Donna Davis
Harvey and Helen Soll
William and Diane McLeod
Don and Phyllis O’Dey

In Memory of Barbara LoMenzo
Roger LoMenzo
John G Smith
Melissa LoMenzo

Jack and Jan Kellner Memorial Fund
Dr. Paula M Fracasso
Dr. George C Lewis

Contributions on behalf of Terra Draper’s “Pump & Run” scheduled on Sept. 17, 2010
Ralph and Carrie Robertson
BJ’s Restaurants Foundation
Joan and Terry Dykstra
Elizabeth Dykstra
It's Spring and “Chasing the Cure” advocacy, awareness and fundraising ideas are blooming all over the place!

Two of the latest Spring fundraising “blooms” include a “Chasing the Cure” race hosted by Terra Draper on September 18, 2010, in Sturgis, Michigan. In the past, Terra has been active organizing breast cancer awareness races. But since ovarian cancer has sadly touched the life of a loved one, Terra has dedicated this “Chasing the Cure” race to her Aunt Joan who is battling the disease. Terra has done a great job with organizing this race, and we are very grateful for the many “helpful hints” that she has shared with us regarding fundraising races. We look forward to attending this race, and helping make it a success. Thanks Terra, for your consideration of the Gynecologic Oncology Group (GOG) as the benefactor of your race.

Our next exciting news involves the Zeta Phi Beta Sorority, located in Washington, DC. The Zeta Phi Beta is one of the largest black sororities in the United States. Sorority sisters Bumi Gbadamosi and Krystal Hamlet have decided that a “Steppin’ Out Strut” race would be a great event to raise awareness, educate and have some fun as a sorority project. Bumi and Krystal have done a beautiful job with their brochure, and we are in the process of deciding what topics are going to be covered at their educational seminar being held prior to the race.

Another exciting addition is a New Horizons’s Web site where advocacy, awareness and fundraising information will be available. This site will have important upcoming clinical trial information, and will have testimonials from women who have participated in a clinical trial. Debbie Miller has worked diligently to get the advocacy part of the website started, and has contributed many ideas on how this website can be an outreach to women. The GOG and New Horizons are also very grateful to Mary Jackson Scroggins and the GOG Patient Advocates for their assistance in advocacy and awareness issues.

After our last GOG Semi-Annual Meeting in San Diego, there were a number of inquiries from attendees about hosting a fundraising race, similar to Ashton Doane’s “Steppin’ Out Strut” race. In June 2010, Ashton will be competing for the Miss Tennessee title...Go Ashton! Please let us know if you have an interest in following her “footsteps” by hosting a race and we will help you along the way.

Hope to see you in Boston... until then have a wonderful Spring!!!
SAVE THE DATE
NEW FOR GYNECOLOGIC ONCOLOGY GROUP 81ST SEMI-ANNUAL MEETING

Dinner Satellite Symposium for Health Care Professionals
Friday, July 16, 2010
6:30 – 9:30 pm
Sheraton Hotel
Boston, Massachusetts

Breakfast Satellite Symposium for Registered Nurses and Data Managers
Saturday, July 17, 2010
7:00 – 10:00 am
Sheraton Hotel
Boston, Massachusetts

Please check http://www.GOG.org in the coming weeks for more information.