

## 2011 ASCO/AACR Methods in Clinical Cancer Research Workshop

### Biographical Profiles of Faculty Members

**Stacy L. Berg, M.D.**, is Professor in the Department of Pediatrics, Section of Hematology/Oncology, and Associate Dean for Research Assurances at Baylor College of Medicine; and the Director of Clinical Research at the Texas Children's Cancer Center. Dr. Berg completed her residency training at the Children's Hospital of Pittsburgh, after which she completed a fellowship at the National Institutes of Health. In addition, Dr. Berg is a member of the Developmental Therapeutics Steering Committee of the Children's Oncology Group. Dr. Berg's primary area of interest is pharmacology and experimental therapeutics, with a special emphasis on the development of new anticancer drugs for children. In the laboratory, her interests include preclinical investigation of the pharmacokinetics of new agents. Drug concentrations are determined by high-pressure liquid chromatography or other appropriate methods. Data are analyzed with a variety of computer modeling strategies. These data facilitate the development of new therapies of children with cancer. In addition to these research interests, Dr. Berg also has a strong interest in clinical trial design, biomedical ethics, and the incorporation of palliative care principles into pediatric oncology practice. This is Dr. Berg's second year serving on the Vail Workshop faculty.

**Specialty Preferences:** Pediatric oncology; biomedical ethics; palliative care



**Michael R. Bishop, M.D.**, received his M.D. from the University of Illinois in 1985. He was an assistant professor of medicine at the University of Kentucky Medical Center from 1991 to 1992 and an associate professor of medicine at the University of Nebraska Medical Center from 1992 to 1999, where he served as director of the Leukemia and Allogeneic Stem Cell Transplantation Programs. Dr. Bishop joined the National Cancer Institute in March 1999 to serve as the Clinical Head of the Stem Cell Transplantation Program. In 2003, he received the National Institutes of Health Distinguished Clinical Teacher Award. He received tenure as Senior Investigator at NIH in 2007. Dr. Bishop currently serves as Head of the Hematologic Malignancies Section in the Division of Hematology and Oncology at the Medical College of Wisconsin/Froedtert Hospital in Milwaukee. Dr.

Bishop's research focuses on the development and conduct of novel clinical trials in hematopoietic stem cell transplantation. Particular areas of interest within his program include the therapeutic use of T cells to accentuate graft-versus-tumor. In addition, the program focuses on methods to prevent and treat recurrent disease following allogeneic stem cell transplantation, with primary focus on B cell malignancies and leukemias. Dr. Bishop has authored or co-authored over 140 peer-reviewed articles and over 20 book chapters relative to the fields of hematologic malignancies and stem cell transplantation. This is Dr. Bishop's first year serving on the Vail Workshop faculty.

**Specialty Preferences:** Hematopoietic stem cell transplantation/adoptive cellular therapy; prevention and treatment of recurrence following stem cell transplantation; non-Hodgkin's lymphoma/B cell malignancies; leukemia



**A. William Blackstock, M.D.**, is Professor and Chair of Radiation Oncology at the Wake Forest University School of Medicine. Dr. Blackstock completed his residency training in radiation oncology at the University of North Carolina at Chapel Hill. He then completed an NCI-funded three-year fellowship focused on laboratory and clinical research in the area of radiation modifiers. He currently serves as the Vice Chair of the Radiation Oncology and Gastrointestinal Committees within the Cancer and Leukemia Group B (CALGB) Cooperative Group. Dr. Blackstock has also served on numerous grant review committees, including the NCI Clinical Oncology study section (full member), the ASCO grants review committee, and the Michael Smith Foundation for Health Research-Canada. While at the University of North Carolina and more recently at Wake Forest University, he has remained

involved in the training of medical students, residents, and fellows, and is the clinical director of an NCI training grant (T-32) focused on translational research in radiation oncology. Dr. Blackstock serves on the Editorial Board

for several journals, including the *Journal of Clinical Oncology*, and is an ad hoc reviewer for numerous journals. He is serving his fifth year on the Vail Workshop faculty.

**Specialty Preferences:** Phase I/II chemoradiation trial design; preclinical chemoradiation trials; chemoradiation translational studies



**Rick J. Chappell, Ph.D.**, is Professor of Biostatistics and Medical Informatics and of Statistics at the University of Wisconsin-Madison School of Medicine and Public Health, Madison, Wisconsin. Dr. Chappell received his Ph.D. from the Department of Statistics at the University of Chicago in 1990, studying under Paul Meier. Since then he has been Assistant, Associate, and now Full Professor at Wisconsin. Methodologically, he is currently interested in noninferiority trials, issues in fitting radiobiologic models to clinical data, the design of phase I cancer studies, survival analysis, and other aspects of the design and analysis of clinical trials. He is statistician for a large number of phase I, II, and III clinical trials for the University of Wisconsin Cancer Center, Institute on Aging, and other investigators in the U.W. Medical School, as well as private industry and numerous governmental organizations. Dr. Chappell is a founding member and consulting statistician for the Hong Kong Nasopharyngeal Carcinoma Study Group; he has designed and is analyzing three large multicenter clinical trials for them. He is or has been a member of the FDA's Cellular, Tissue and Gene Therapy Advisory Committee, several NIH Scientific Review Committees, the U.W. Human Subjects Committee, the U.W. Cancer Center's Protocol Review Committee, and many data safety monitoring boards. He is a fellow of the American Statistical Association, on the Board of Directors of the Society for Clinical Trials, and an Associate Editor for *JCO*. Dr. Chappell teaches graduate-level courses on statistical methods in clinical trials, epidemiology, generalized linear models, and statistical consulting, as well as instructional seminars for clinicians. He is serving his fifth year on the Vail Workshop faculty.

**Specialty Preferences:** Statistics; goals and aims (primary/secondary); power/sample size calculations; analysis plans; noninferiority trials; radiation oncology; phase I clinical trial design



**Gary M. Clark, Ph.D.**, is Vice President of Biostatistics & Data Management at Array BioPharma, Inc. in Boulder, Colorado. He is actively involved in the development of targeted therapies for various cancers. His areas of expertise and interest include the identification and evaluation of prognostic and predictive biomarkers for breast cancer, lung cancer, pancreatic cancer, and other solid tumors. Prior to joining Array BioPharma in 2008, he was Vice President of Biostatistics & Data Management at OSI Pharmaceuticals, Inc., in Boulder, Colorado, where he helped develop and was instrumental in the regulatory approval of a small molecule inhibitor of EGFR tyrosine kinase. Prior to joining OSI Pharmaceuticals in 2002, he served at Baylor College of Medicine in Houston, Texas (1999-2002), as Professor of Medicine and Associate Director of the Breast Center, Director of Tissue Resources, and Director of Informatics, and at the University of Texas Health Science Center at San Antonio, Texas (1980-1999), where he was Professor of Medicine in the Division of Medical Oncology and Director of the Biostatistics, Data Management & Data Processing Shared Resource of the San Antonio Cancer Institute. He was co-director of the ASCO/AACR Workshop on Methods in Clinical Cancer Research in Vail, Colorado, from 1996 to 2000; co-director of the FECS/AACR/ASCO Workshop on Methods in Clinical Research in Flims, Switzerland, from 1999 to 2005; and faculty member of the Australia and Asia Pacific Clinical Oncology Research Development Workshop (ACORD) since 2008. He returned to the Vail Workshop as a faculty member in 2010.

**Specialty Preferences:** Identification and evaluation of prognostic and predictive biomarkers for breast cancer; lung cancer and other solid tumors; and the design and analysis of phase I, II, III clinical trials of targeted therapies



**Laura G. Cleveland** started advocating for patients when she initiated patient-centered meetings for people diagnosed with chronic lymphocytic leukemia. What she thought would be a backyard cookout for 20 people turned out to be a conference for over 250 patients and their family members. Laura began serving on the CALGB Leukemia and Leukemia Correlative Science Committees as a research advocate and now co-chairs the Patient Advocate Committee within CALGB. She has been involved in a broad spectrum of cancer research advocacy on many levels. She serves locally as the Research Subject Advocate for patients on phase I gene therapy transfer trials at The Ohio State University's James Cancer Center. Laura also volunteers for the Leukemia and Lymphoma Society's

First Connection patient matching program. She is the patient advocate on The Ohio State University's Comprehensive Cancer Center's Leukemia SPORC's External Advisory Committee. Nationally, Laura has spoken at the ASCO Annual Meeting and to many patient groups in the United States and Canada, the CLL Consortium's Data and Safety Monitoring Committee, and The Coalition of Cancer Cooperative Group's Patient Advisory Board. Prior to her service as an advocate, Laura worked as an educator and educational administrator for almost twenty years. She is the mother of three and lives with her husband and children near Columbus, Ohio. This is Laura's fourth year to serve as faculty for the Vail course and considers this position to be one of the most meaningful of all of her advocate roles.

**Specialty Preferences:** Leukemia; patient and research subject advocacy



**Angelo M. De Marzo, M.D., Ph.D.**, is Professor of Pathology, Oncology, and Urology and is a member of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. He received his M.D. and Ph.D. from the University of Colorado Health Sciences Center in Boulder, Colorado, and completed his residency in anatomic pathology at The Johns Hopkins University School of Medicine in 1997. He then completed a research fellowship with Donald S. Coffey, Ph.D., before joining the faculty in 1998. Dr. De Marzo is a urological pathologist whose clinical practice has focused extensively on prostate cancer. His research laboratory group interacts extensively with a number of other JHU and outside research groups. Their work is focused on developing new insights into the molecular

pathobiology of prostate cancer. For example, using human tissue specimens, genetically engineered mouse models, and cell culture systems, his group is interested in determining the molecular mechanisms involved in neoplastic transformation and disease progression in the prostate, with a particular emphasis on the role of the *MYC* oncogene. His laboratory also studies the role of inflammation and infection in prostate carcinogenesis. Finally, the group performs translational research in which they analytically validate and interrogate biomarker expression in human prostate tissues, where such biomarkers are used to help pathologists in rendering a diagnosis, help predict outcome, determine whether a given pathway alteration is present, or determine whether a drug has hit its target. This is Dr. De Marzo's third year to serve on the Vail Workshop faculty.

**Specialty Preferences:** Pathology; prostate cancer; biomarkers



**Mary L. (Nora) Disis, M.D.**, is the Associate Dean for Translational Health Sciences in the University of Washington School of Medicine, Professor of Medicine, and Adjunct Professor of Pathology/Obstetrics and Gynecology at UW and a Member of the Fred Hutchinson Cancer Research Center. She is the Director of the Institute of Translational Health Science and the Center for Translational Medicine in Women's Health. Dr. Disis received her M.D. from the University of Nebraska and completed a residency and Chief Residency in Internal Medicine at the University of Illinois. She completed a fellowship in Oncology at the University of Washington/Fred Hutchinson Cancer Research Center where she has remained on faculty. Dr. Disis is an expert in breast and ovarian cancer immunology and translational research. Her research interest is in the discovery of new

molecular immunologic targets in breast and ovarian cancer for the development of vaccine and cellular therapy for the treatment and prevention of those malignancies as well as other solid tumors. In addition, her group evaluates the use of the immune system to aid in the diagnosis of cancer and develops novel assays and approaches to quantitate and characterize human immunity. She holds several patents in the field of targeted

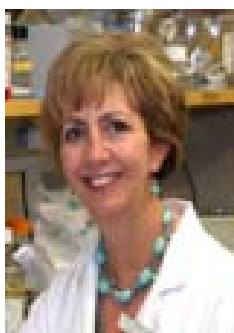
cancer therapy and cancer diagnostics. This is Dr. Disis' ninth year serving on the Vail Workshop faculty, and second year serving as a Course Director.

**Specialty Preferences:** Breast and ovarian cancer; tumor immunology; translational oncology; biomarkers



**Chaitanya Divgi, M.D.**, is Professor and Vice-Chair, Research, Department of Radiology and Director, PET/Nuclear Medicine Division at Columbia University, New York. A graduate of Bangalore University, he completed his residency in nuclear medicine at Memorial Sloan-Kettering Cancer Center, New York. Some of his current and previous positions and responsibilities have included Deputy Editor, Academic Radiology; Member, Clinical Oncology Study Section, NCI; member of the Cancer Steering Committee, Biomarkers Consortium, NIH; member of the Cancer Immunology program project at Memorial Sloan-Kettering Cancer Center, and Head of the Cyclotron/Radiochemistry Program at the University of Pennsylvania. Dr. Divgi is serving his first year on the Vail Workshop faculty.

**Specialty Preferences:** Renal cancer; ovarian cancer; antibodies in cancer imaging and therapy; PET; radiochemistry



**S. Gail Eckhardt, M.D.**, is Professor and Division Head, Medical Oncology, and Director, Phase I and Developmental Therapeutics Programs at the University of Colorado Cancer Center. Dr. Eckhardt obtained her medical degree from the University of Texas Medical Branch in Galveston followed by an internship and residency at the University of Virginia Medical Center. Following fellowship, Dr. Eckhardt joined the faculty of the Cancer Therapy and Research Center, Institute for Drug Development in San Antonio, Texas, where she held the position of Associate Director of Clinical Research. In 1999, Dr. Eckhardt joined the faculty of the University of Colorado to set up a phase I program, and in 2006 became the Division Head of Medical Oncology. Dr. Eckhardt has served on numerous committees/study sections, including the ASCO Molecular Oncology Task Force, the ASCO

Board of Directors, the FDA Oncology Drugs Advisory Committee, the NCI Developmental Therapeutics Study Section, and the NCI Cancer Centers Study Section. She is also a member of the NCI Colon Cancer Task Force. She has served as Vail faculty for many years, and was a Course Director from 2007 to 2009. Dr. Eckhardt is the Principal Investigator on grants involving early clinical trials and colorectal cancer research and has conducted numerous phase I and II clinical trials. Her area of interest is in the preclinical and clinical development of combinations of molecularly targeted compounds, with a laboratory focus on colorectal cancer and melanoma. This is Dr. Eckhardt's ninth year serving on the Vail Workshop faculty.

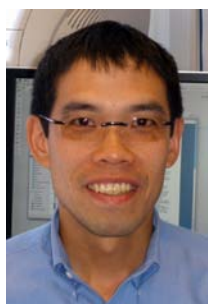
**Specialty Preferences:** Early clinical trials; colorectal cancer research; preclinical and clinical development of molecularly targeted compounds; melanoma; predictive biomarkers



**Lee M. Ellis, M.D.**, holds a dual appointment as Professor in the Departments of Surgical Oncology and Cancer Biology at the University of Texas MD Anderson Cancer Center, and currently serves as Chair, Ad Interim, Department of Cancer Biology, University of Texas MD Anderson Cancer Center in Houston. Dr. Ellis is also director of the Metastasis Research Center and the Colorectal Cancer Translational Research Program at MD Anderson Cancer Center. Dr. Ellis graduated from the University of Virginia School of Medicine in 1983, and completed his residency in surgery at the University of Florida in 1990. He went on to complete a surgical oncology fellowship at the MD Anderson Cancer Center (MDACC), where he has been on the faculty since 1993. Dr. Ellis has a clinical practice in surgical oncology, focused on patients with colorectal cancer and liver metastases. Dr. Ellis has established a reputation for expertise in the area of angiogenesis and growth factor receptors in gastrointestinal malignancies and is funded by several grants for research in this area. He has served on numerous NIH study sections and is a consultant to the National Cancer Institute. In 2000, Dr. Ellis was awarded the Faculty Scholar Award from the MDACC, and he was also the inaugural recipient of a grant from the

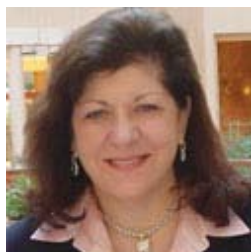
George and Barbara Bush Endowment for Innovative Cancer Research. In 2007, he was awarded the William C. Liedtke Jr., Chair in Cancer Research. Dr. Ellis serves on numerous Editorial Boards, including *Journal of Clinical Oncology*, *Cancer Research*, and *Clinical Cancer Research* (Senior Editor). He has also authored over 200 peer-reviewed publications, 100 invited reviews and editorials, three books, and 30 book chapters. In addition, he has published important editorials in journals such as *Nature*, *NEJM*, *Cell*, *Cancer Cell*, *Nature Medicine*, *JNCI*, *JCO*, and *The Lancet Oncology*. He is co-chair of the largest clinical angiogenesis meeting in the world held in January/February annually. Dr. Ellis serves in a leadership role in the major cancer societies and has served on numerous committees. He was chair of the 2007 GI Cancers Symposium. In 2011, he was a Program Committee Co-Chair and Education Committee Co-Chair of the 2011 AACR Annual Meeting, a member of the ASCO Cancer Education Committee, and leader for the Tumor Biology track. He is a former student of the Vail Workshop. This is Dr. Ellis' second year serving as a Course Director and fifth year to serve on the Vail Workshop faculty.

**Specialty Preferences:** Biomarkers; targeted therapies; angiogenesis; surgical oncology; GI cancers



**Lawrence H. Fong, M.D.**, is an Associate Professor of Medicine at the University of California, San Francisco. His research interests are in developing immunotherapies for cancer and he has been involved in clinical studies with sipuleucel-T and anti-CTLA4 antibodies. Dr. Fong leads the immunotherapy program within the GU Oncology Group at UCSF and also leads a research lab studying T cell activation and antigen-specific recognition of tumors in both mouse models and clinical trials. Dr. Fong performed his postdoctoral fellowship at Stanford University and at present serves as a Member of the NIH, NCI CONC Study Section as well as an Ad Hoc Member of the NIH, NCI Special Emphasis Panels - Clinical P01 and the NIH, NCI CII Study Section. He is on the Editorial Board of the *Journal of Clinical Oncology* and has received numerous honors for his work, including an American Society of Clinical Oncology Young Investigator Award, an American Cancer Society Post-Doctoral Fellowship Award, and an American Association for Cancer Research Scholar-in-Training Award. He has authored or co-authored over 50 publications and is today a Principal Investigator for an NIH/NCI-funded research initiative, the goal of which is to develop immunomodulatory treatment for prostate cancer by with CTLA4 blockade. This is Dr. Fong's second year serving as a Vail Workshop faculty member.

**Specialty Preferences:** Prostate cancer; cancer immunotherapy



**Margaret Foti, Ph.D., M.D. (h.c.)**, is the Chief Executive Officer of the American Association for Cancer Research (AACR). Located in Philadelphia, Pennsylvania, the AACR is the oldest and largest cancer organization in the world dedicated to the conquest of cancer. Dr. Foti holds a B.A., M.A., and Ph.D. from Temple University in Philadelphia, and has been awarded Honorary Doctorate degrees; one in Medicine from the University of San Pablo CEU in Madrid in June 2009, another in Medicine and Surgery from the University of Catania, Catania, Italy in July 2008, and a third in Medicine and Surgery from the University of Rome in 2003 for contributions to cancer research worldwide. She previously served as the Managing Editor of the *Cancer Research* journal and as Publisher for AACR for many years. Active in a wide variety of professional publishing organizations, Dr. Foti is a Past President of the Society for Scholarly Publishing and the Council of Science Editors. During Dr. Foti's tenure, AACR has developed a dynamic and vibrant membership of over 33,000 members in more than 90 countries. She contributes to numerous cancer organizations and is a member of the Executive Committee for the Friends of Cancer Research; Council Member for the European Association for Cancer Research; and Past President of the National Coalition for Cancer Research. Dr. Foti has received numerous national and international awards for her contributions to cancer research, including: the European CanCer Organisation Lifetime Achievement Award for outstanding contributions to cancer; the Inaugural Kripke Legend Award for significant contributions to the advancement and promotion of women in the cancer field; and ASCO's Special Recognition Award for her instrumental role in the development of this important Workshop as well as providing vital links between translational scientists and clinicians. In 2008, Dr. Foti expanded the role of the AACR as a grant giving organization and scientific partner for Stand Up To Cancer, a national, translational cancer research initiative. Most recently, Dr. Foti has been

named the recipient of the Raymond and Beverly Sackler Award for Sustained National Leadership, and locally as the recipient of the prestigious Pinnacle Award for her extraordinary accomplishments in the field of cancer research. Dr. Foti has served on the Vail Workshop Faculty since its inception, and worked with Dr. Daniel D. Von Hoff, Past President of AACR and Founder of the Vail Workshop, to help develop his concept for this Workshop, which has trained over 2,100 clinical researchers in clinical trial design in the United States and abroad.

**Specialty Preferences:** Association management; publishing; government relations; foundation support; administration



**Elizabeth Garrett-Mayer, Ph.D.**, is Director and Associate Professor of Biostatistics at the NCI-Designated Hollings Cancer Center (HCC) at the Medical University of South Carolina. She is a graduate of Bowdoin College and Johns Hopkins Bloomberg School of Public Health. Dr. Garrett-Mayer served for seven years as a member and for one year as the chair of the Scientific Clinical Review Committee for the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. She has been a member of the Protocol Review Committee for more than four years and Co-Chair of the Data Safety and Monitoring Committee at HCC. She serves as Co-Chair of Biostatistics for the Translational Breast Cancer Research Consortium. She has co-authored more than 150 peer-reviewed papers, mostly in cancer research. Her research interests are in adaptive designs in phase I studies and phase II studies. She recently co-edited a book, “Principles of Anti-Cancer Drug Development,” with other current and former Vail faculty members Gail Eckhardt, Manuel Hidalgo, and Neil Clendenin. This is Dr. Garrett-Mayer’s ninth year as a faculty member at the Vail Workshop and she served as Course Director for three years (2008-2010).

**Specialty Preferences:** Biostatistics; predictive models; phase I and phase II study designs; power and sample size



**Mithat Gönen, Ph.D.**, is an Associate Attending Biostatistician at Memorial Sloan-Kettering (MSK) Cancer Center, New York. He is a member of the American Statistical Association, Society for Clinical Trials, and International Biometric Society. He has been serving on various NIH panels and data safety monitoring boards. He is also on the Editorial Board of *Clinical Trials: Journal of the Society for Clinical Trials* and *Gastrointestinal Cancer Research*, the official journal of the International Society of Gastrointestinal Oncology. He will be the program chair for the 2012 meeting of the Society for Clinical Trials. He has interests in imaging studies, clinical trial design, cancer staging, and predictive modeling. Dr. Gönen is serving his fifth year on the Vail Workshop faculty and his first as a co-director.

**Specialty Preferences:** Clinical trials with imaging endpoints; surgical oncology clinical trials; staging and prognosis, general biostatistics



**Ana Maria Gonzalez-Angulo, M.D., M.Sc.**, is an Associate Professor of Medicine in the Departments of Breast Medical Oncology and Systems Biology at The University of Texas MD Anderson Cancer Center. Dr. Gonzalez-Angulo attended medical school at the Universidad del Cauca in Colombia and moved to the U.S. to continue her training. She completed a residency in Internal Medicine at the Mount Sinai Medical Center in Miami, and a Fellowship in Medical Oncology at the Ochsner Clinic Foundation in New Orleans. She then went to the University of Texas MD Anderson Cancer Center to specialize in breast cancer as she was selected as the Susan G. Komen Breast Cancer Fellow. She stayed at MD Anderson as faculty and works exclusively with breast cancer patients and in breast cancer research. She is interested in aggressive types of breast cancer including triple receptor-negative disease. Her research focuses on mechanisms of resistance to standard breast cancer therapies, and on the development of markers to predict

response to treatments using functional proteomics. She is funded by the NCI, ASCO, Komen for the Cure, AACR (SU2C), and the Commonwealth Foundation for Cancer Research. She is the Chair of the Endocrine Resistance Working Group and a member of the Correlative Sciences Working Group for the Translational Breast Cancer Research Consortium, and a member of the Breast Cancer Committee of SWOG and of the BIG-NABG Triple Negative Working Group. She serves as a member of the steering committee of The United States–Middle East Partnership for Breast Cancer Awareness and Research and the Partnership for Breast Cancer Awareness and Research of the Americas. Dr. Gonzalez-Angulo is serving her first year as a Vail Workshop faculty member.

**Specialty Preferences:** Triple-negative breast cancer; mechanisms of resistance to standard breast cancer therapies; development of biomarkers in breast disease



**Stuart A. Grossman, M.D.**, is Director of Neuro-Oncology, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, and Professor of Oncology, Medicine, and Neurosurgery at The Johns Hopkins University School of Medicine, Baltimore, Maryland. He also directs the Adult Brain Tumor Consortium funded by the NIH to conduct phase I/II clinical trials and an NIH funded neuro-oncology training program. A graduate of the University of Rochester Medical School, he completed his Internal Medicine Internship and Residency at Strong Memorial Hospital and his medical oncology training at Johns Hopkins. Dr. Grossman is a member of the American Society of Clinical Oncology (ASCO), and is a member and past president of the Society of Neuro-Oncology. He serves on the Editorial Boards of the *Journal of Supportive Care in Cancer*, the *Journal of Clinical Oncology and Neuro-Oncology*, and is a member of the NCI's Brain Malignancy Steering Committee. In addition, he is the founder and co-director of the Cancer Pain Service at Johns Hopkins and is actively involved in research to improve cancer pain treatment in the United States and developing countries. Dr. Grossman is serving his fourth year on the Vail Workshop faculty.

**Specialty Preferences:** Primary brain tumors; CNS metastases; cancer pain; clinical trial design and conduct



**Sandra J. Horning, M.D.**, Senior Vice President, Global Head of Clinical Development for Hematology/Oncology Product Development, joined Genentech/Roche in late 2009 where she became a member of the Development Senior Staff, responsible for leading the medical and scientific strategies for the global clinical development portfolio in oncology and leading and managing the team of oncology clinical scientists. Dr. Horning is an internationally recognized oncologist who has made significant contributions to the classification, understanding, and treatment of lymphoma. She is a tenured Emeritus Professor of Medicine (Oncology) at Stanford University School of Medicine and joined Genentech/Roche after more than 25 years as a practicing oncologist, investigator, and professor at Stanford University. Dr. Horning has also held many significant leadership roles within the oncology community, most notably as President of ASCO in 2005-2006. This is Dr. Horning's third year serving on the Vail Workshop faculty.

**Specialty Preferences:** Burkitt's lymphoma (hematology and medical oncology); Hodgkin's disease (blood and marrow transplant and medical oncology)



**Judith E. Karp, M.D.**, is a Professor of Oncology and Medicine and Director of the Leukemia Program at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore, Maryland. Dr. Karp received her medical degree from Stanford University School of Medicine, completed her internship and residency at Stanford University Hospital and Johns Hopkins Hospital, and completed her Oncology Fellowship at the Johns Hopkins University School of Medicine. Her research interests focus on the experimental therapeutics of acute leukemias, including development of timed sequential therapy, new biology agents for older adults with acute leukemias, and new approaches to the treatment of refractory acute leukemias, including secondary leukemias that evolve from

myelodysplasia or from prior cytotoxic chemotherapies. Dr. Karp is serving her fourth year on the Vail Workshop faculty.

**Specialty Preferences:** Acute leukemias; signal transduction; cell kinetics



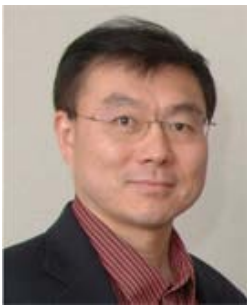
**Mark D. Krailo, Ph.D.**, is the Associate Group Statistician of the Children's Oncology Group (COG) and a Professor in the Department of Preventive Medicine at the Keck School of Medicine, University of Southern California, Arcadia, California. In his role as a statistician with COG, Dr. Krailo is responsible for over 150 phase I, II, and III clinical trials of pediatric cancer. His methodological interests include the statistical evaluation of phase I studies, the statistical implications of unequal randomization in clinical trials, and practical concerns of differential follow up in interim monitoring of clinical trials. A graduate of the University of Waterloo, this is the sixth year Dr. Krailo has served on the faculty of the Vail Workshop.

**Specialty Preferences:** Statistical design; data collection; interim monitoring



**Daniel H. Laheru, M.D.**, is an Associate Professor of Oncology, and Co-Director, Skip Viragh Center for Pancreas Cancer Clinical Research and Patient Care at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. He is Clinical Director of GI Oncology and holds the Ian T. MacMillan Professorship in Pancreas Cancer Clinical Research. He specializes in gastrointestinal oncology with a specific focus in pancreatic cancer. His clinical research interests are in developing and testing new therapies for the treatment of pancreatic cancer.

**Specialty Preferences:** Gastrointestinal oncology; specifically pancreatic and colon cancer



**Ming Lei, Ph.D.**, is Chief of the Cancer Training Branch in NCI's Center for Cancer Training. The Cancer Training Branch develops, administers, and manages NCI's grant-supported research training and career development programs. Dr. Lei received his Ph.D. from and conducted postdoctoral research at Cornell University. He was an associate professor in the Department of Microbiology and Molecular Genetics at the Medical College of Wisconsin, where his research laboratory studied regulation of DNA replication and chromatin assembly. Dr. Lei served as a program director at the National Science Foundation before joining NCI in 2008. As Chief of the Cancer Training Branch, Dr. Lei oversees national strategies for training and career development of basic, clinical, and population-focused cancer researchers, and fosters education, outreach, and curriculum

development activities in fields that support cancer research. He was a Vail workshop faculty member in 2010.

**Specialty Preferences:** National management of grant-supported research training; training and career development of cancer scientists; DNA replication and genome stability



**Barbara K. LeStage, M.H.P.**, is a breast cancer survivor and an advocate for more than 30 years. She served as president of the American Cancer Society's local unit and chair of the Massachusetts Executive Committee and Board of Directors. She was a member of the ACS National Board of Directors from 1988-1999. She served on three ACS national extramural research committees and the Council for Extramural Grants. She is past chair of the NCI Director's Consumer Liaison Group and past member of NCI's Central IRB, Advisory Committee to the Director and Informed Consent Template Update Working Group. She currently serving on NCI's Concise Informed Consent Document Planning Committee and the Clinical Imaging and Patient Advocate Steering Committees. Barbara

chaired the Patient Advocacy Committee of the American College of Radiology Imaging Network (ACRIN) for seven years. She was also a member of ACRIN's Steering Committee and protocol teams for two trials. She was a faculty member of the 2006 Clinical Trials Methodology Workshop conducted by the Radiological Society of North America and a member of the American College of Radiology's 2006 Blue Ribbon Panel on Radiation Dose in Medicine. Barbara received a B.S. from Denison University and a Master of Health Professions degree from Northeastern University's Bouvé College of Pharmacy and Health Sciences. She is a graduate of the National Breast Cancer Coalition's Project LEAD and the American Cancer Society's Stakeholder Training. She twice attended the American Association for Cancer Research's Scientist-Survivor program. This is her first year as a member of the Vail Workshop faculty.

**Specialty Preferences:** Patient advocacy; breast cancer; clinical imaging



**Wendy B. London, Ph.D.**, is Associate Professor of Pediatrics, Harvard Medical School, Harvard University; Director of Biostatistics and Director of the Clinical Translational Investigation Program in the Division of Pediatric Hematology/Oncology of Children's Hospital Boston and Dana-Farber Cancer Institute; and, Member, Biostatistics Core of the Dana-Farber Harvard Cancer Center. In the Children's Oncology Group (COG), she is the Lead Statistician and Executive Committee member of the Neuroblastoma Committee, and Executive Committee member, COG Phase II/III Data Safety Monitoring Committee. A graduate of Purdue University and Virginia Commonwealth University's Medical College of Virginia, she has held positions at Pharmaceutical Research Associates, Inc. (PRA), United Network for Organ Sharing (UNOS), and University of Florida. Some of her current and previous positions and responsibilities have included: Chair, Statistics Committee of the International Neuroblastoma Risk Group (INRG) Task Force; Member, Clinical Oncology Study Section, NCI; Ad-hoc Member, Subcommittee H Study Section, NCI; Member, Advisory Board of the Advances in Neuroblastoma Research Association; and Assistant Editor, Medical and Pediatric Oncology. Dr. London is serving her first year on the Vail Workshop faculty.

**Specialty Preferences:** Neuroblastoma; prognostic stratification; clinical trials design



**Patricia LoRusso, D.O.**, is a Professor of Medicine at Wayne State University, Division of Hematology/Oncology, and Faculty of the Karmanos Cancer Institute, Detroit, Michigan. Her primary interest is experimental therapeutics with a focus on phase I clinical research and novel trial designs. She currently directs one of only 14 National Cancer Institute (NCI) U01-funded phase I sites in North America. Dr. LoRusso serves as co-chair of the NCI Cancer Therapy Evaluation Program (CTEP) Investigational Drug Steering Committee. She has also served on the education and scientific committees of the American Society of Clinical Oncology (ASCO), the scientific committee of the American Association for Cancer Research (AACR), and as a parent member of the NCI's Quick Trials Clinical Subcommittee. She has served either ad hoc or as an appointed member on multiple study sections, including Subcommittee D of the Program Projects Grants, and Small Business Innovation Research (SBIR) and Department of Defense (DOD) study sections. She is a third year faculty member of the Methods in Clinical Cancer Research Workshop in Flims, Switzerland. In 1999, Dr. LoRusso was awarded the Hero of Breast Cancer award and in 2004 the Bennett J. Cohen Educational Leadership Award for Medical Research. She received the Marygrove College Distinguished Alumni Award and was named one of Crain's Detroit Business Health Care Heroes. She was also recognized with the 2008 Michaele C. Christian Oncology Drug Development Award and Lectureship from NCI CTEP. This is her fifth year on the Vail faculty.

**Specialty Preferences:** Phase I; breast cancer



**Vicki A. Morrison, M.D.** is an Associate Professor of Medicine at the University of Minnesota, and Staff Physician in the Sections of Hematology/Oncology and Infectious Disease at the Veterans Affairs Medical Center, Minneapolis. Dr. Morrison earned her M.D. at the University of Wisconsin Medical School. She completed a basic medicine internship, internal medicine residency, and senior residency at the Naval Regional Medical Center, Portsmouth, Virginia. She then completed an infectious diseases fellowship at Bethesda (MD) Naval Hospital, followed by a medical oncology fellowship at the University of Minnesota. Dr. Morrison has been a principal investigator on numerous research projects and has lectured nationally on lymphoproliferative disorders, fungal infections, and infections in immunocompromised patients. Dr. Morrison has co-authored

numerous articles, book chapters, and abstracts, and is a reviewer for the *Journal of Clinical Oncology* and *Clinical Infectious Diseases*. Dr. Morrison is a member of several committees, including the Lymphoma and Elderly Working Committees of the Cancer and Leukemia Group B (CALGB) and is head of the VA Field Advisory Group for Hematology/Oncology and Clinical Oncology Research Network (VA-CORNET). Her current clinical research interests include: 1) infectious complications of oncology patients, to include a) infectious complications of patients treated with nucleoside analogues, b) mucosal immune function in patients with CLL and multiple myeloma, c) neutropenic prophylaxis in patients receiving cyclical myelosuppressive therapy; 2) invasive fungal infections in solid organ and stem cell transplant recipients; 3) varicella zoster infections in older patients - approaches to prevention; 4) transplant-related lymphoproliferative disorders (evaluation, therapy), 5) therapy of non-Hodgkin's lymphoma; 6) therapy and complications of chronic lymphocytic leukemia; 7) cancer in the older population. This is Dr. Morrison's second year serving as a Vail Workshop faculty member.

**Specialty Preferences:** Lymphoma; non-Hodgkin's lymphoma; bone marrow transplant; infectious complications of oncology patients



**Katherine S. Panageas, Dr.P.H.**, is Associate Attending Biostatistician, Department of Epidemiology and Biostatistics, Memorial Sloan-Kettering Cancer Center (MSKCC), New York. She received her doctorate in biostatistics at Columbia University. Her research interests are principally in the analysis of cluster correlated data, primarily in the context of volume-outcome studies. She is currently involved in the assessment of appropriate endpoints for trials involving brain tumor patients and is evaluating the effects of interval censored data in phase II and III clinical trials with progression-free survival as a primary endpoint. Dr. Panageas works with the Clinical Immunology, Melanoma, and Neurology Services to design and analyze prospective and retrospective studies to evaluate treatment strategies including immunotherapies, explore various biomarkers, develop prediction

models, and develop models to estimate the risk of developing distant metastasis or local recurrences. Dr. Panageas is serving her first year on the Vail Workshop faculty.

**Specialty Preferences:** Clinical trial design, melanoma; immunotherapy; neuro-oncology



**Edith A. Perez, M.D.**, is Professor of Medicine at Mayo Medical School in Rochester, Minnesota. She is the Director of the Breast Clinic and the Cancer Clinical Study Unit at Mayo Clinic in Jacksonville, Florida, as well as a member of the Mayo Clinic Women's Cancer Program Steering Committee. Dr. Perez received her medical degree from the University of Puerto Rico School of Medicine in San Juan and completed her residency in Internal Medicine at the Loma Linda University Medical Center in California. She served as a general internist in the Division of National Health Services Corps (Los Angeles), and as a fellow in Hematology/Oncology at Martinez Veterans' Administration Medical Center at the University of California Davis School of Medicine. She is the Chair of the Breast

Committee for the North Central Cancer Treatment Group (NCCTG) and is also a member of the Clinical Trials Working Group, National Policy Forum of the Institute of Medicine Committee, and the Board of Scientific Advisors to the National Cancer Institute (NCI). Dr. Perez has developed and is involved in a wide range of clinical trials exploring the use of new therapeutic agents for the treatment and prevention of breast cancer. She

also has recently developed studies to evaluate the role of genetic markers in the development and aggressiveness of breast cancer. She has authored more than 150 research articles in journals and books. Dr. Perez is a recipient of the Breast Cancer Research Foundation Research Grant Award (1998-2006) and the 2002 Horizon Achievement Award in Cancer Research presented by Bristol-Myers Squibb Oncology and the Susan G. Komen Breast Cancer Foundation. She has been a member of the Mayo Clinic Institutional Review Board and the National Cancer Institute (NCI) Central Institutional Review Board. She is an active member of ASCO, AACR, and the American Association for the Advancement of Science, and serves on the editorial boards of multiple journals. Dr. Perez is serving her seventh year on the Vail Workshop faculty.

**Specialty Preferences:** Breast cancer; targeted therapies; translational clinical trials



**Alfred W. Rademaker, Ph.D.**, is Professor, Department of Preventive Medicine, Northwestern University Feinberg School of Medicine, Director, Division of Biostatistics, Director, Biostatistics Core Facility, The Robert H. Lurie Comprehensive Cancer Center and Director, Biostatistics Collaboration Center, Feinberg School of Medicine, Chicago, Illinois. A graduate of the Pennsylvania State University (Ph.D., Statistics), Dr. Rademaker is a member of The American Statistical Association, The Biometric Society, Society of Clinical Trials, and the American Speech-Language-Hearing Association. He currently serves as co-chair of the Cancer Center's Scientific Review Committee. He has served on data and safety monitoring committees in breast cancer and ophthalmology. He is a co-investigator on several NCI and other NIH grants. He is the biostatistician for

Northwestern's Center for Cancer Nanotechnology Excellence, Clinical Translational Science Award and Cognitive Neurology and Alzheimer's Disease Center. This is Dr. Rademaker's sixth year to serve on the Vail Workshop faculty.

**Specialty Preferences:** Early phase cancer clinical trial design; sample size determination; statistical methods for diagnostic testing; cluster randomized clinical trials



**Meredith M. Regan, Sc.D.**, is Associate Professor of Medicine, Department of Biostatistics & Computational Biology, Dana-Farber Cancer Institute and Harvard Medical School. Dr. Regan received her doctoral degree at the Harvard School of Public Health. Dr. Regan collaborates with the Dana-Farber/Harvard Cancer Center Genitourinary Oncology Programs, including as Biostatistics & Computational Biology Core Director for the Prostate Cancer SPORE and as Data Coordinating Center Director for the PROST-QA Consortium, a multicenter longitudinal cohort study assessing health-related quality of life among men undergoing primary local therapy for prostate cancer. She also collaborates with the DF/HCC Breast Oncology Program and is Group Statistician for the International Breast Cancer Study Group. Dr. Regan is a member of the NCI Breast Cancer Steering Committee.

Dr. Regan's research focuses on clinical and translational research to inform patient care, specifically biological features of the patient and tumor as predictors of treatment responsiveness. This is Dr. Regan's fourth year to serve on the Vail Workshop faculty.

**Specialty Preferences:** Biostatistics and outcomes research; particularly applied in breast, prostate, renal, and bladder cancers



**Brian I. Rini, M.D., FACP**, is Associate Professor of Medicine at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University in Cleveland, Ohio. A staff member of the Department of Solid Tumor Oncology at the Cleveland Clinic Taussig Cancer Institute, Dr. Rini's work focuses on genitourinary malignancies. Dr. Rini received his Bachelor of Arts degree from The University of Notre Dame and earned his medical degree at The Ohio State University College of Medicine. Dr. Rini's primary research has been in renal cell carcinoma (RCC) with special focus on antiangiogenic therapy and immunotherapy. Dr. Rini has been involved in the initial and ongoing development of

targeted agents for metastatic RCC, and was an integral investigator in the clinical development of these agents, which are now FDA approved. Dr. Rini is also Director of the Experimental Therapeutics Fellowship Program at The Cleveland Clinic. Dr. Rini has authored over 155 peer-reviewed articles and 14 book chapters. He is the Section Editor for Genitourinary Cancer for the journal *Cancer*, and a member of the editorial boards of *Journal of Clinical Oncology*, *Lancet Oncology*, *Cancer*, *Clinical Genitourinary Cancer*, *Kidney Cancer Journal*, *British Journal of Urology*, and *HemOnc Today*. This will be Dr. Rini's first year serving as faculty of the Vail Workshop.

**Specialty Preferences:** Genitourinary malignancies; renal cell carcinoma; antiangiogenic therapy; immunotherapy



**Karl L. Schwartz, M.F.A.**, makes his home in Riegelsville, Pennsylvania. He is a graduate of Maryland Institute of Art and Brooklyn College where he received his M.F.A. in Fine Arts. He is a caregiver to his spouse, a fourteen-year survivor of lymphoma. He is the co-founder and president of Patients Against Lymphoma, a nonprofit group founded in 2004. He is the lead author of [www.lymphomation.org](http://www.lymphomation.org), which provides support and evidence-based information on lymphoma and its treatments. Mr. Schwartz has served as patient representative and consultant to the FDA since 2002 and has participated in four advisory committee (ODAC) deliberations. He was an invited participant in the NCI Progress Review Group for Blood Cancers in 2001, NCI Biospecimen Best Practices workshops, and the NCI Technical Evaluation Panel: "Development of a Common Biospecimen Coordination System and Informatics Infrastructure for NCI Prostate SPORE." He has served as a faculty member in a workshop sponsored by FDA, NCI, ASCO, and Duke University: "Accelerating Anticancer Agent Development and Validation Workshop." He has presented to patients, the CALGB CARE subcommittee, the drug industry, and to FDA patient representatives on a variety of clinical trial topics. His report on "Interest, Attitudes and Participation in Clinical Trials among Patients with Lymphoma" was published by ASCO in 2009. Mr. Schwartz is serving his first year as a member of the Vail Workshop faculty.

**Specialty Preferences:** Patient advocacy; lymphoma; FDA consulting and patient representatives programs



**Mary J. Scroggins, M.A.**, is a writer, editor, and educator who was diagnosed with ovarian cancer in 1996. She is a Co-Founder and President of In My Sister's Care, an organization focused on eliminating health disparities and on improving gynecologic cancer awareness and care for medically underserved women. Ms. Scroggins holds an M.A. in writing from Johns Hopkins University. She is Chair of the Gynecologic Oncology Group's Patient Advocate Committee and a member of the GOG Ovarian, Operations, Protocol Development, and Rare Tumor Committees. She is also a member of the Gynecologic Cancer Steering Committee and the Patient Advocate Steering Committee of the National Cancer Institute (NCI); a certified Prostate Cancer Community Awareness Educator; a grant application reviewer for the U.S. Health Resources and Services Administration; and a past panelist in the Department of Defense Ovarian Cancer Research Program. She was a roundtable participant in the NCI Progress Review Group on Gynecological Cancers. She has published essays and articles on cancer survivorship and health disparities and fiction focused on social justice issues; served on the charter Editorial Board of *CR*, the American Association for Cancer Research (AACR) consumer magazine; and served on the faculty of the American Society of Clinical Oncology (ASCO) Clinical Trials Workshop for the Community Oncology Team in 2005. Her advocacy work is driven by a commitment to improved awareness, access, care, quality of life, and survival rates for all women. This is Ms. Scroggins' third year of service on the Vail Workshop faculty.

**Specialty Preferences:** Health disparities; community partnerships; vulnerable populations; informed consent; quality of life



**Westley Sholes, M.P.A.**, is a 14-year prostate cancer survivor and a consumer advocate for cancer issues in general and prostate cancer issues in specific, with an emphasis on health disparities in minority populations. He earned his B.S. at Xavier University and a Master of Public Administration at the University of Southern California. His professional career has been mainly in health care, starting as a biochemical medical technologist in 1960 until his retirement in 1993 as Deputy Director, Administrative Services, Los Angeles County Department of Health Services. During that period he held positions of Associate Hospital Administrator, Hospital Administrator, and Director of Budget & Legislation. Since 1993 he has been the Principal in Sholes & Associates, a management and strategic planning company focusing on health care-related projects. He is currently

Chairman of the SRO Housing Corporation Board of Directors, a homeless housing agency; and, a member of the Board of Directors for California Prostate Cancer Coalition, the Intercultural Cancer Council, National Organization of Black County Officials, and National African American Tobacco Prevention Project. He also serves on the National Institute of Health's Consumer Advocates in Research & Related Activities Council, is a Consumer Peer Review Panelist for the Department of Defense (DOD) Prostate Cancer Research Program, as is on the Integration Panel for the DOD. This is Mr. Sholes' third year on the Vail faculty.

**Specialty Preferences:** Patient advocacy issues; health care management; prostate cancer



**Yu Shyr, Ph.D.**, is Professor and Chief of the Division of Cancer Biostatistics and Director of the Vanderbilt Center for Quantitative Sciences, Vanderbilt University School of Medicine. He completed his doctoral training in the Department of Biostatistics at the University of Michigan. He has been on the faculty at Vanderbilt University School of Medicine since 1994. He has served on numerous NCI study sections, is currently a member of the NCI SPORE review panel, and is a voting member of the FDA external advisory board. Dr. Shyr has assisted investigators in developing clinical research protocols and has developed several biostatistical methodology papers. He has delivered more than 160 abstracts to professional meetings and published more than 250 peer-reviewed papers in a variety of journals. Dr. Shyr has received numerous awards, including the American Statistical Association Chapter Service Recognition Award and the Vanderbilt University

School of Medicine Master of Science in Clinical Investigation Program Excellence in Teaching Award. This is Dr. Shyr's eighth year in serving as Vail Workshop faculty.

**Specialty Preferences:** Biostatistics; bioinformatics; trial design



**George W. Sledge, Jr., M.D.**, is the Ballve-Lantero Professor of Oncology at Indiana University Simon Cancer Center. He also serves as a Professor of Pathology and Laboratory Medicine at that institution. He received his undergraduate degree from the University of Wisconsin, and his medical degree from Tulane University. He completed his residency at St. Louis University and his fellowship at the University of Texas, San Antonio. He has been at Indiana University since 1983. Dr. Sledge has held numerous leadership roles at both AACR and ASCO. He is currently serving as ASCO President. This is Dr. Sledge's second year of service on the Vail Workshop faculty.

**Specialty Preferences:** Molecular and tumor biology, growth factors, and antiangiogenic therapy related to breast cancer



**Franklin O. Smith, III, M.D.**, currently holds the Marjory J. Johnson Endowed Chair and is Professor of Pediatrics and Medicine at the University of Cincinnati College of Medicine and Cincinnati Children's Hospital Medical Center (CCHMC). He currently directs the Bone Marrow Transplantation Program in the Division of Hematology/Oncology within the Department of Internal Medicine at the University of Cincinnati. Previously, Dr. Smith served as the Director of the Division of Hematology/Oncology at CCHMC and as the Vice-Chair of the Children's Oncology Group. Dr. Smith received his B.S. from Wofford College and his M.D. from the University of South Carolina School of Medicine. He was a resident in pediatrics at the University of Florida College of Medicine and did fellowship training in pediatric hematology/oncology at the University of Washington and the Fred Hutchinson Cancer Research Center. Dr. Smith has clinical expertise in hematopoietic stem cell transplantation and research interests in acute myeloid leukemia and Fanconi anemia. This is his first year to serve on the faculty at the ASCO/AACR Workshop.

**Specialty Preferences:** Hematology/oncology; pediatric oncology; hematopoietic stem cell transplantation; acute myeloid leukemia; Fanconi anemia



**Anil K. Sood, M.D.**, is Professor and Vice Chair for Translational Research, Department of Gynecology Oncology and has a joint appointment in the Department of Cancer Biology at University of Texas MD Anderson Cancer Center in Houston. He is also Co-Director, Center for RNA Interference and Non-Coding RNA and Director of the Blanton-Davis Ovarian Cancer Research Program. He completed his residency at the University of Florida and his Fellowship in Gynecologic Oncology at the University of Iowa Hospitals and Clinics. Dr. Sood received the Gynecologic Cancer Foundation/Margaret Greenfield/Carmel Cohen, M.D. Excellence in Ovarian Cancer Research Award, James F. Nolan Award, and the Charles A. Hunter, Jr. Prize Thesis Award. He is a member of several organizations, including the AACR, ASCO, the Society of Gynecologic Oncologists, and has been elected to the American Society for Clinical Investigation. A graduate of the University of North Carolina, he is serving his third year on the Vail Workshop faculty.

**Specialty Preferences:** Gynecologic oncology; novel therapeutics; angiogenesis



**Steven P. Stratton, Ph.D.**, is Associate Professor of Medicine at the Arizona Cancer Center, Tucson, Arizona. He graduated from the University of Arizona with his Ph.D. in Pharmacology and Toxicology. Dr. Stratton serves as a member of the Society of Toxicology, the Association of Clinical Research Professionals, the American Association for the Advancement of Science, and the American Society of Preventive Oncology. He is a reviewer for *Clinical Cancer Research*, *Cancer Epidemiology Biomarkers & Prevention*, *Journal of Cellular Biochemistry*, *Journal of Pharmacology and Experimental Therapeutics*, *Cancer Chemotherapy and Pharmacology*, and *Breast Cancer Research and Treatment*. He is Chairman of the Arizona Cancer Center Scientific Review Committee, Co-Director of the Analytical Chemistry Shared Service, and Co-Director of the Prostate Cancer Prevention Program. Dr. Stratton is serving his seventh year on the Vail faculty.

**Specialty Preferences:** Cancer chemoprevention; skin cancers; preclinical drug development; protocol review and monitoring; pharmacokinetics; prostate cancer



**Lisa L. Taylor**, Patient Advocate, serves as a patient representative to the Gynecologic Oncology Group's (GOG) Developmental Therapeutics Committee and to its Uterine Corpus Committee. She also serves as a member of the Data Safety Monitoring Board for a Phase II therapeutic vaccine trial in cervical intraepithelial neoplasia. Her involvement in advocacy is driven by personal loss of family members and friends. Professionally, she is President and Founder of Packers Falls Group, Inc., a small consultancy which focuses on commercial development for both small and large biopharmaceutical companies. She received her A.B. in Human Biology at Stanford University, and an M.B.A. from Harvard University. Ms. Taylor is serving her first year on the Vail Workshop faculty.

**Specialty Preferences:** Ovarian cancer, uterine cancer, cervical cancer, prostate cancer



**Charles Richard Thomas, Jr., M.D.**, is Professor and Chair, Department of Radiation Medicine and Professor of Hematology/Oncology in the Department of Medicine at The Oregon Health & Science University in Portland, Oregon. He is also an active member of the Knight OHSU Cancer Institute. Dr. Thomas has received triple-board certification in Radiation Oncology (American Board of Radiology), Medical Oncology and Internal Medicine (American Board of Internal Medicine). He has an interest in cancer disparities and was one of the editors for the special edition on cancer disparities that was published in *The Journal of Clinical Oncology* in 2006. He is also active in protocol development within the U.S. cooperative group mechanism, with a focus on novel therapeutic translational clinical research on GI and thoracic malignancies. Currently, Dr. Thomas is the Chair of the Radiation Oncology Committee of the American College of Surgeons Oncology Group (ACOSOG). He has served on the Editorial Boards of the *JCO*, *Diseases of the Esophagus*, *Radiographics*, and *CA: A Cancer Journal for Clinicians*. Dr. Thomas has served as an oral and written examiner for the GI section of The American Board of Radiology Certification Examination, as well as on multiple committees within ASCO and ASTRO. He is the author or co-author of over 120 journal articles and is a co-editor of multiple textbooks including *Mediastinal Tumors* (Springer-Verlag, 1995), *Biliary Tract & Gallbladder Cancers: Diagnosis and Therapy* (Demos Medical Publishing, 2008), and *Esophagus Cancers: Practice and Principles* (Demos Medical Publishing, 2009). A former student at the Workshop, this is Dr. Thomas' third year to serve on the Vail Workshop faculty.

**Specialty Preferences:** Radiation oncology/thoracic focus; radiation oncology/GI focus



**Miguel A. Villalona-Calero, M.D.**, is Professor, Departments of Internal Medicine & Pharmacology, Director of the Division of Medical Oncology at The Ohio State University College of Medicine and Public Health, Columbus, Ohio, and Section Chief of the Arthur James Cancer Hospital. He is also Director of Solid Tumor Experimental Therapeutics at The Ohio State University Comprehensive Cancer Center and Principal Investigator of the OSUCCC N01 contract for phase II trials with the National Cancer Institute (NCI). Dr. Villalona-Calero is a member of the NCI Investigational Drug Steering Committee, Co-Chair of the IDSC DNA Repair Task Force, Council Member of AACR Minorities in Cancer Research, member of the American Society of Clinical Oncology, Cancer and Leukemia Group B (Thoracic Core Committee) and others. He is on the Editorial Board of the *Journal of Clinical Oncology*, *Clinical Cancer Research*, and *Journal of Cancer Chemotherapy and Pharmacology*. This is Dr. Villalona-Calero's fourth year to serve on the Vail Workshop faculty.

**Specialty Preferences:** Phase I trials; EGFR pathway; lung cancer; DNA repair



**Jamie H. Von Roenn, M.D.**, is a Professor of Medicine in the Division of Hematology/Oncology at Northwestern University, and the Medical Director of the Northwestern Memorial Hospital Hospice Program. She is a board-certified medical oncologist and palliative medicine specialist. She has been practicing in breast oncology for more than 25 years. Dr. Von Roenn has a longstanding interest in palliative care and the integration of palliative care principles into standard oncology care. She developed a course in supportive care and symptom management for house officers and fellows. She initiated the analgesic dosing service, a multidisciplinary pain service for the inpatient oncology unit, to improve the management of pain for inpatients and to improve training in pain management. Dr. Von Roenn's interest in the supportive care of oncology patients has led to the initiation of a standard psychosocial/symptom assessment program for all new patients seen in the outpatient setting. She is committed to increasing the visibility and integration of palliative care practices and principles into the practice of oncology on a local, national, and an international level. She has participated in the development of educational content and training programs for physician trainees and practicing oncologists. She served as the chair of the ASCO Task Force on Pain and Symptom Management, as a member of the board of directors of both ASCO and the American Academy of Hospice and Palliative Medicine, and as a member on the ABMS board for development of the oncology board certification examination. Dr. Von Roenn is the principal investigator of both local and national trials in palliative care, including trials evaluating innovative approaches to fatigue and cachexia, and is an integral member of the program developing trials in chemotherapy-induced peripheral neuropathy. Her research has been awarded long-term funding from a variety of sources, including the National Institutes of Health. This is Dr. Von Roenn's second year on the Vail faculty.

**Specialty Preferences:** Palliative care; chemotherapy; symptom management



**Nu Viet Vu, Ph.D.**, is Professor and Director of the Unit of Development and Research in Medical Education at the University of Geneva Faculty of Medicine in Geneva, Switzerland. A graduate of Southern Illinois University in Educational Psychology (Learning, Testing and Measurement), her expertise and areas of research, development, and responsibilities are in curriculum design and development, problem-based learning, faculty development, program evaluation, students' assessment, performance-based testing with standardized-simulated patients, and clinical teaching and reasoning. Recently, she has pilot tested and worked with the Swiss Department of Public Health in the concept, design, and development of the new Licensing Swiss Federal Examination in Human Medicine which is administered for the first time in 2011. Dr. Vu serves on the Editorial Boards of and as a reviewer for: *Medical Education*; *Teaching and Learning in Medicine: An International Journal*; *Advances in Health Sciences Education: Theory and Practice*; and *Education for Health: Change in Training and Practice*. Dr. Vu has been involved with the Vail Workshop for 11 years.

**Specialty Preferences:** Educational testing and evaluation; development of clinical knowledge; assessment of clinical reasoning and competence; program evaluation



**Vivian K. Weinberg, Ph.D.**, is Principal Statistician in the UCSF Helen Diller Family Comprehensive Cancer Center Biostatistics Core, San Francisco, California. Dr. Weinberg received her Ph.D. in biostatistics from Yale University and has over 25 years of experience in cancer clinical trials research, including experience in both the cooperative group setting with Cancer and Leukemia Group B and the individual institution environment. She has over 140 peer-reviewed papers. Prior to joining the UCSF Cancer Center, Dr. Weinberg was the biostatistician for the UCSF General and Pediatric Research Centers. She has focused her statistical support in the area of prostate cancer as well as providing research support to investigators in the areas of nonprostate genitourinary diseases, gynecology, head and neck, ophthalmology, and pediatric cancer. She has a major commitment with the Department of Radiation Oncology where she lectures and mentors residents and fellows. She is responsible for the statistical activities of the UCSF Cancer Center Prostate Program and for the UCSF Prostate Tissue Core as well as serving on the UCSF Data Safety and Monitoring Committee. This is Dr. Weinberg's fifth year to serve on the Vail Workshop faculty.

**Specialty Preferences:** Biostatistics; clinical trials; prostate cancer; other GU cancers; survival analysis



**Heidi L. Weiss, Ph.D.**, is Professor of Biostatistics at the Markey Cancer Center of the University of Kentucky in Lexington. A graduate of the University of South Carolina with her Ph.D. in Biostatistics, she completed her postdoctoral training at the Comprehensive Cancer Center, University of Alabama Birmingham (UAB) and held faculty positions both at the UAB Cancer Center and the Dan L. Duncan Cancer Center at Baylor College of Medicine. Dr. Weiss is a past member of the Clinical Oncology Study Section (CONC) in the Center for Scientific Review at NIH/NCI and has participated in several NCI special emphasis panel review committees. She is also a member of the American Association for Cancer Research, the American Statistical Association, and the Society for Clinical Trials. This is Dr. Weiss' fifth year to serve on the Vail Workshop faculty.

**Specialty Preferences:** Biostatistics; design and analysis of cancer immunotherapy trials; design and analysis of cancer chemoprevention trials; Bayesian interim monitoring methods in early phase trials