

# Getting the Dose Right: Optimizing Dose Selection Strategies in Oncology An FDA-ASCO Virtual Workshop May 3 and 5, 2022

## Biographies – Day 2

### Welcome to the Workshop



**R. Donald Harvey, PharmD**  
**Professor, Hematology and Medical Oncology**  
**Emory University School of Medicine**

R. Donald Harvey, PharmD, is Professor in the Department of Hematology and Medical Oncology with a joint appointment in the Department of Pharmacology and Chemical Biology at Emory University School of Medicine. A board-certified oncology pharmacist, Dr. Harvey serves as director of Winship Cancer Institute's Phase I Clinical Trials Unit and as Medical Director of Winship's Clinical Trials Office, where he works to ensure the quality and compliance of clinical research practices at all Winship locations. He is a Fellow of the American College of Clinical Pharmacy and a Fellow of the Hematology/Oncology Pharmacy Association. Dr. Harvey has also active nationally and internationally in several cancer and pharmacology professional organizations. He is also a past president of the Hematology and Oncology Pharmacy Association, an international professional organization. Dr. Harvey obtained his BS Pharmacy and Doctor of Pharmacy degrees at the University of North Carolina at Chapel Hill (UNC).



**Mirat Shah, MD, MHS**  
**Medical Oncologist, Office of Oncologic Drugs**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

Mirat Shah, MD, MHS is a medical oncologist on the Breast, Gynecologic, and Supportive Oncology team within the Office of Oncologic Diseases at the FDA. She also serves as Clinical Lead for FDA Oncology Center of Excellence's Project Optimus which is an initiative to reform the dose selection paradigm for oncology drugs. She completed her internal medicine residency at Vanderbilt University Medical Center. She completed her medical oncology and clinical pharmacology fellowship at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, including one year as chief oncology fellow. She obtained a master's degree in health sciences through the Johns Hopkins

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Bloomberg School of Public Health. Her main interests are improving dose selection for oncology drugs and providing medical education in regulatory science. She currently maintains a supportive oncology clinic at Johns Hopkins.

### Session 3a: Opportunities to Improve Dose Optimization: Designing Trials and Applying Pharmacometrics

**Mirat Shah, MD, MHS (Moderator)**  
**Medical Oncologist, Office of Oncologic Drugs**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**  
See biography above

#### Presenters:



**Liz Garrett-Mayer, PhD, FSCT**  
**Vice President, Center for Research and Analytics (CENTRA),**  
**American Society for Clinical Oncology**

Dr. Garrett-Mayer joined ASCO in 2017 as CENTRA's Division Director for Biostatistics and Research Data Governance and became CENTRA's first Vice President in 2022. CENTRA leads ASCO's research efforts, including the TAPUR Study, ASCO's COVID-19 Registry, and research projects aimed at dose optimization and increasing minority enrollment in clinical trials. Prior to joining ASCO, she served on the faculty in the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in the Department of Oncology, and then joined the faculty of the Medical University of South Carolina (MUSC) and established the Biostatistics Shared Resource at the Hollings Cancer Center (HCC). She earned her bachelor's degree from Bowdoin College in Math and Economics, and a PhD in Biostatistics from Johns Hopkins Bloomberg School of Public Health. Her publication record includes more than 280 peer-reviewed publications, primarily in early phase clinical trial design methods and clinical cancer research. She has been a member of numerous NIH grant review committees, Data Safety Monitoring Boards for NIH-supported clinical trials and serves on the editorial board of three peer-reviewed journals (*Clinical Trials*, *Cancer*, and the *Journal of the National Cancer Institute*), and was faculty on the ASCO/AACR Methods in Clinical Cancer Research Workshop for over a decade.

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**Bernd Meibohm, PhD, FCP, FAPPS**  
**UTHSC Distinguished Professor of Pharmaceutical Sciences**  
**Associate Dean for Research and Graduate Programs**  
**The University of Tennessee Health Science Center**

Bernd Meibohm, Ph.D. is a UTHSC Distinguished Professor of Pharmaceutical Sciences and Associate Dean for Research and Graduate Programs at the College of Pharmacy, The University of Tennessee Health Science Center, Memphis, Tennessee, USA. He also serves as Chair of the University of Tennessee Department of Pharmaceutical Sciences and holds the Harriet S. Van Fleet Endowed Professorship in Medicinal Chemistry and Pharmaceutics.

Dr. Meibohm received his pharmacy degree and doctorate in pharmaceutics from Technical University Carolo-Wilhelmina, Braunschweig, Germany. After completion of a clinical pharmacology research fellowship at the University of Florida in 1997, he joined the faculty of the University of South Carolina, and in 1999 the University of Tennessee.

Dr. Meibohm's scientific interests include bacterial and viral infectious diseases, pediatric pharmacotherapy and the application of quantitative modeling and simulation techniques in preclinical and clinical drug development, with specific focus on therapeutic proteins. His research has resulted in over 190 scientific papers and book chapters (>10,000 citations; *h*-index 51), three textbooks, 180 abstracts, and over 200 invited scientific presentations to national and international audiences.

Dr. Meibohm is a Fellow of the American Association of Pharmaceutical Scientists (AAPS) and the American College of Clinical Pharmacology (ACCP). He was the President of ACCP 2014-2016 and served on its Board of Regents 2008-2018. He also served as 2010 Chair for the 'Pharmacokinetics, Pharmacodynamics and Drug Metabolism' section of AAPS, as 2016-2019 Member-at-Large on the Board of Directors of AAPS, and currently as member of the Board of Directors of the International Society of Pharmacometrics. Dr. Meibohm is also serving as associate editor for *The AAPS Journal* and is a member of the editorial advisory boards of 7 other peer-reviewed publications.

**Panelists:**

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**Akintunde Bello, PhD**  
**Head- Clinical Pharmacology and Pharmacometrics**  
**Bristol Myers Squibb**

Akintunde (Tunde) Bello is Head of Clinical Pharmacology and Pharmacometrics at BMS supporting the therapeutic areas of Oncology, Hematology, Cell Therapy, Immunology, Fibrosis, CV and Neuroscience. Tunde has more than 25 years of experience in preclinical and clinical drug development. He started his career at Rhone Poulenc Rorer (Sanofi) in the UK and moved to the US to join BMS in 1998 and spent 5 years working on the development of anti-infective and oncology therapeutics. Following an 11-year stint at Pfizer, as a clinical pharmacology group leader, Tunde rejoined BMS in 2015 to head up clinical pharmacology and pharmacometrics for oncology.

In his current role, Tunde also has quantitative systems pharmacology (QSP), physiologically based PK (PBPK), model based meta-analysis (MBMA), clin pharm analysis and reporting (CPAR) and clin pharm data sciences (DS) functions within his organization. Over the course of his career, Tunde has played key roles in the development, approval and life cycle management of more than 6 marketed drugs in the oncology, pain management, inflammation and infectious disease TAs. He oversaw the clinical pharmacology teams that supported the development and approval of multiple sBLAs for nivolumab and ipilimumab, as well as the BLA for elotuzumab. At Pfizer, Tunde managed the clinical pharmacology group and was a core member of the crizotinib (xalkori) development team.

Tunde has a BSc in Medical Laboratory Sciences (Biomedical Sciences) from Portsmouth University (UK), an MSc in Instrumentation and Analytical Sciences from the University Of Manchester Institute Of Science and Technology (UMIST, UK) and a PhD in Pharmaceutical Sciences from King's College, University of London (UK).

Tunde has authored and co-authored more than 70 peer reviewed abstracts and journal manuscripts, he is a member of the American Society of Clinical Pharmacology and Therapeutics (ASCPT), the American Association of Pharmaceutical Scientists (AAPS) and the American Society of Clinical Oncology (ASCO).

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**Jill Feldman**  
**Lung Cancer Patient and Advocate**

Jill Feldman is a lung cancer patient and advocate. When Jill was 13 years old, she lost her dad and two grandparents to lung cancer and then her mom and close aunt died of lung cancer when she was in her 20's. In 2009, at 39 years old with four small children, Jill herself was diagnosed with EGFR positive lung cancer.

Jill is committed to understanding and promoting patient-centered research as Chair of IASLC's patient advisory board, member of the programmatic panel for the Department of Defense Lung Cancer Research Program, a member of the the ECOG-ACRIN Research Group's patient advocate committee and thoracic committee and as the patient advocate on the National Lung Cancer Round Table steering committee. She is a co-founder of the EGFR Resisters, a grassroots, patient-driven community committed to accelerating research that will prolong and better the lives of people diagnosed with EGFRm lung cancer.

Jill also continues to share her story in the media and at various events and participates in countless advocacy opportunities to shine a light on lung cancer to end the stigma associated with it and to embed a health equity lens in all aspects of research and care.



**Gregory Friberg, MD**  
**Vice President, Medical Affairs (ELMAC Region)**  
**Amgen**

Greg Friberg MD serves as Vice President, Medical Affairs for Europe, Latin America, Middle East, Africa, and Canada (the ELMAC Region), having taken on the role in the Summer of 2021.

Greg joined Amgen in Medical Sciences in 2006, first serving as an early development lead and then as Oncology Therapeutic Area (TA) head for the early pipeline. Starting in 2012, Greg served as the interim Global Development co-TA head for Oncology, overseeing the initial regulatory approvals for blinatumomab and talimogene laherparepvec. Greg then served for two years as Global Product General Manager for blinatumomab and the early hematology BITE portfolio. Starting in 2018, Greg became the Global Development TA Head for Hematology/Oncology and Bone. He helped build the development team over the next 4 years and to usher romosozumab, blinatumomab for MRD and sotorasib to their first approvals. Of note, sotorasib was the first KRAS G12C inhibitor approved in the US, with under three years from first patient dosed to FDA approval.

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Greg received his A.B. from Middlebury College and M.D. from New York Medical College. He completed his residency in internal medicine at Dartmouth-Hitchcock Medical Center and his fellowship in hematology and oncology at The University of Chicago Medical Center. He joined the faculty of the University of Chicago thereafter as a member of the Phase I, Gastrointestinal, and Gynecologic oncology teams and an investigator for early phase clinical trials.



**Jonathon Vallejo, PhD**  
**Lead Mathematical Statistician, Division of Biometrics IX**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

Jonathon Vallejo is a lead mathematical statistician in Division of Biometrics IX at FDA. Jonathon earned his PhD in statistics from Baylor University and joined FDA in 2016. His team supports the Division of Hematologic Malignancies I, which reviews protocols and applications in AML, MDS, ALL, and related diseases. Jonathon is involved in regulatory initiatives involving trial design and dose optimization. In addition, Jonathon's research interests include biomarkers, meta-analysis, and statistical issues in pediatric oncology.

### **Session 3b: Opportunities to Improve Dose Optimization: Assessing Safety and Tolerability**

**Mirat Shah, MD, MHS (Moderator)**  
**Medical Oncologist, Office of Oncologic Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration**  
See biography above

#### **Presenters:**

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**Sophie Postel-Vinay, MD, PhD**  
**Physician Scientist, Drug Development Department, Goussave Roussy**

Sophie Postel-Vinay (MD, Ph.D), is currently Physician Scientist at the Drug Development Department (where she is Senior Medical Oncologist) and U981 INSERM research unit (Group Leader) at Gustave Roussy.

She received her medical degree from the Université Paris XI in 2010 and joined the faculty in November 2013 after completion of her PhD performed at the Institute of Cancer Research (London), which focused on DNA repair and synthetic lethality. Specialized in Drug Development and early phase clinical trials, she completed her medical oncology residency training in Paris, and spent 18 months at the Royal Marsden Hospital of London at the Drug Development Unit. Dr Postel-Vinay is member of ESMO, AACR and ASCO. She was the head of the Phase 1 committee between 2020 and 2022 and is particularly interested in novel designs and dose-definition in phase 1 trials.

Thanks to her Physician Scientist position, Dr Postel-Vinay also has a fundamental and translational research activity within the INSERM Unit 981. She obtained in 2017 the ATIP-Avenir “Young Group Leader” grant from INSERM, and in 2019 the ARC Fundamental Research label, which allowed her to develop her own independent group. She was granted the “Prix Irène Joliot-Curie” from the French Academy of Sciences in 2019 for her scientific research work, and the “Prix Gallet et Breton” from the French Medicine Academy for her clinical research. Her current research activity focuses on chromatin remodeling and its interplay with DNA repair and immune modulation in solid tumors. Her research interests include DNA repair, chromatin remodeling, synthetic lethality, lung, sarcoma, predictive biomarkers and drug development.



**Vishal Bhatnagar**  
**Associate Director for Oncology Patient Outcomes**  
**Oncology Center of Excellence**  
**U.S. Food and Drug Administration**

Vishal Bhatnagar is a medical oncologist and Associate Director of Oncology Patient Outcomes at the Oncology Center of Excellence (OCE) at the U.S. Food and Drug Administration. He has a clinical focus in multiple myeloma and plasma cell disorders. His current regulatory work focuses on management of the OCE’s patient-focused drug development program. His interests include patient-reported outcomes, patient preference, and incorporation of patient experience in oncology trials. Dr. Bhatnagar received his B.A. in Political Science and his M.D. at the George Washington University. He completed his internal medicine residency and hematology/oncology fellowship at the University of Maryland.

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**Jeanne Fourie Zirkelbach, PhD**  
**Team Lead Clinical Pharmacologist, Cancer Pharmacology II**  
**Office of Clinical Pharmacology**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

Jeanne Fourie Zirkelbach, PhD, is a Team Lead Clinical Pharmacologist at the Office of Clinical Pharmacology, Division of Cancer Pharmacology II, at the U.S. Food and Drug Administration. Dr. Fourie Zirkelbach is actively engaged in research on patient reported outcomes (PRO) symptom data to complement traditional exposure-response analysis for dose optimization within the Oncology Center of Excellence (OCE) Project Patient Voice and on early dose optimization initiatives within OCE's Project Optimus. Following her PhD, she, served as a Postdoctoral Fellow at the University of Alabama, Birmingham, Department of Pharmacology and Toxicology and Comprehensive Cancer Center, and subsequently, completed her Research Fellowship at the Department of Molecular Pharmacology and Experimental Therapeutics at the Mayo Clinical Cancer Center, Rochester. Dr. Fourie Zirkelbach joined FDA as a senior clinical pharmacology reviewer in 2008.

### Panelists:

**Akintunde Bello, PhD**  
**Head of Clinical Pharmacology and Pharmacometrics**  
**Bristol Myers Squibb**  
See biography above

**Jill Feldman**  
**Lung Cancer Patient and Advocate**  
See biography above

**Gregory Friberg, MD**  
**Vice President, Medical Affairs (ELMAC Region)**  
**Amgen**  
See biography above

**Jonathon Vallejo, PhD**  
**Lead Mathematical Statistician, Division of Biometrics IX**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**  
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## Session 4: The Path Forward to Optimizing Dose Selection in Oncology

**R. Donald Harvey, PharmD (Moderator)**

**Professor, Hematology and Medical Oncology, Emory University School of Medicine**

See biography above

### Panelists:



**Percy Ivy, MD**

**Associate Chief, Investigational Drug Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute**

S. Percy Ivy, MD is the Associate Chief (2005-present) of the Investigational Drug Branch (IDB) which is part of the Cancer Therapy Evaluation Program (CTEP) (1997-present) in the Division of Cancer Treatment and Diagnosis of the National Cancer Institute. She received her medical and subspecialty training at Tulane University Medical School, Vanderbilt University Medical Center, and the National Cancer Institute, respectively. During her fellowship she worked in the Molecular Pharmacology Section, Medicine Branch, NCI which focused on the molecular mechanisms of drug resistance mediated by the ABC transporter genes in models of breast cancer and carcinogenesis. She is also currently an Adjunct Professor of Pediatrics at the George Washington University School of Medicine on the faculty at Children's National Medical Center where she attends in the leukemia clinic.

In her role as Associate Chief of IDB she has supervised nine Senior Investigators and multiple fellows in the Developmental Chemotherapy Section which became Experimental Therapeutics Section I with a focus on inhibitors of DNA repair and damage response including PARPi, Wee1, DNA-PKi, angiogenesis inhibitors, heat shock protein 90 inhibitors and inhibitors of receptor:ligand interactions including dysregulated cancer stem cell embryonic signaling pathways for hedgehog, notch, wnt and others. She has received 15 NIH Merit Awards for her work on specialized studies in patients with hepatic and renal dysfunction using cancer investigational therapeutics, use of novel imaging techniques for the evaluation of investigational agents in early clinical trials and most recently for assisting the in the implementation of the Investigational Drug Steering Committee (IDSC) which is part of the Clinical Trials Working Group, an NCI initiative for improving NCI-sponsored clinical trials in the US. She serves on the IDSC coordination team as well as starting the angiogenesis task force and NCI chairing the Clinical Trial Design and Pharmacology Task Forces for Early Clinical Trials.

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She serves as the program director for the Experimental Therapeutics Clinical Trials Network (ETCTN) which is funded by NCI. She is also Program Director for the Drug Resistance and Sensitivity Network and the Create Access to Targeted Cancer Therapy for Underserved Populations (CATCH-UP.2020). She served on the Scientific Committee for the AACR-NCI-EORTC Molecular Targets Conference and for the Experimental Therapeutics Section for ASCO and AACR. She has presented both nationally and internationally on topics related to early therapeutics development, early phase clinical trial design, biomarker development, the role of anti-angiogenic agents in cancer therapy, clinical trials for patients with hepatic and renal dysfunction.

She has participated in the development of over 60 investigational agents, co-developed and monitored greater than 100 early phase clinical trials, established the NCI organ dysfunction working group that has evaluated 20 plus drugs, co-authored or authored >225 manuscripts and 15 book chapters in her areas of interest in experimental therapeutics. She has received the Margaret B. and Cyril A. Shulman Distinguished Service Award for starting the general pediatric clinic for medically indigent children at Bread for the City/Zaccheus Free Clinic and supports Doorways for women and children who are victims of abuse and established the Woody and Mickey Healthy Pet Fund that supports the Animal Welfare League of Arlington, VA.



**Olga Kholmanskikh, MD, PhD**  
**Member, EMA/CHMP Oncology Working Party**

Olga Kholmanskikh, MD, PhD, has been appointed as a member of the EMA/CHMP Oncology Working Party since 2019. Dr. Kholmanskikh has extensive scientific and regulatory experience as a clinical assessor of anticancer medicines at European and national levels. She joined the Belgian Federal Agency for Medicines and Health Products (FAMHP) in 2012, where she leads and oversees the day-to-day activities of a team of clinical assessors involved in regulatory review procedures of anticancer medicines throughout their lifecycle. She is trained as a medical doctor and pursued research in tumor biology and immunology at Ludwig Institute for Cancer Research, Brussels Branch. She holds a PhD in Biomedical and Pharmaceutical Sciences from the Catholic University of Louvain (UCL).

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**Shing Lee, PHD**  
**Associate Professor of Biostatistics**  
**Columbia University Irving Medical Center**

Shing M. Lee, PhD is an Associate Professor of Biostatistics at Columbia University Irving Medical Center (CUIMC) and Director of the Biostatistics, Epidemiology and Research Design Resource of the Irving Institute for Clinical and Translational Research at CUIMC. Her research interests are in the development of methods that improve the understanding of the toxicity and the tolerability of cancer treatments. She is particularly interested in the design and conduct of dose-finding cancer clinical trials and has developed various methods that incorporate adverse event types, grades, late onset toxicities, and patient-reported outcomes. She is also interested in developing methods to facilitate the implementation of novel designs and for analysis, summary, and visualization of adverse event data in clinical trials that better reflect the global toxicity burden of patients.



**Jeffrey Peppercorn, MD, MPH**  
**Medical Oncologist, Director of Supportive Care and Survivorship,**  
**Massachusetts General Hospital**  
**Associate Professor of Medicine, Harvard Medical School**

Dr. Jeffrey Peppercorn, MD, MPH is a medical oncologist specializing in breast cancer, Director of Supportive Care and Survivorship for the Massachusetts General Hospital Cancer Center, and Associate Professor of Medicine at Harvard Medical School. He is a graduate of Harvard Medical School, Harvard School of Public Health, and the Harvard Bioethics Fellowship. His research focuses on the intersection of clinical care and clinical research in oncology and has addressed ethics and policy issues related to costs of care, informed consent, research biopsies, and doctor-patient communication. He chairs the Ethics committee of the Alliance for Clinical Trials in Oncology, serves on the ASCO research committee and has served as Chair of the ASCO Ethics Committee. He has chaired a recent ASCO taskforce on initial dose selection in the setting of metastatic disease and has participated in research with the Patient-Centered Dosing Initiative. He is an alumnus of the Greenwall Faculty Scholars Program in Bioethics and has published over 150 papers related to bioethics, policy, and patient care in oncology.

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**Atik Rahman, PhD**  
**Division Director, Cancer Pharmacology II**  
**Office of Clinical Pharmacology**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

Nam Atiqur Rahman, Ph.D., is the Director of the Division of Cancer Pharmacology II within the Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, US Food and Drug Administration (USFDA). The Division includes clinical pharmacology reviewers who are involved in the development, review, approval, and life cycle management of the drugs and therapeutic biologics for solid tumors. Prior to joining FDA, Dr. Rahman earned his doctorate degree from the Washington State University and completed post-doctoral training in Molecular Pharmacology and Pharmacogenomics at the St-Jude Children’s Research Hospital, Memphis, Tennessee.

Dr. Rahman’s interest includes immuno-oncology, dose optimization, and application of modeling and simulation in cancer drug development. Dr. Rahman’s interest also includes the application of pharmacogenomics to promote personalized medicine for cancer patients. He supports the review staff who facilitates innovation in drug development and drug approval from Clinical Pharmacology perspectives through interaction with the pharmaceuticals. In addition, Dr. Rahman is working with national organizations, such as, American Society for Clinical Oncology, Patient Advocacy Groups, Friends of Cancer Research to modernize the eligibility criteria for entry of patients in clinical trial for drug development.

Dr. Rahman received over 40 FDA level awards, published 55 articles in peer review journals and authored 6 book chapters. He has given over 50 presentations in national and international meetings, workshops, and symposiums. He is currently a member of American Society of Clinical Oncology.



**Mace Rothenberg, MD**  
**Medical Oncologist**  
**Independent Board Member at Tango Therapeutics, Surrozen, and**  
**Aulos Bioscience**

Mace L. Rothenberg, MD is a medical oncologist with more than 30 years of experience spanning government, academia, and industry. Dr. Rothenberg served as Chief Medical Officer of Pfizer from 2019 to 2021. During this time, the company initiated, completed, and obtained emergency use authorization for its COVID-19 vaccine. Prior to that role, Mace led Clinical Development for Oncology at Pfizer from 2008 to 2018. Over that 10 year period, his organization developed and obtained regulatory approval for 11 new cancer medicines. Prior to joining Pfizer, Dr.

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Rothenberg was Professor of Medicine at Vanderbilt University and Ingram Professor of Cancer Research at the Vanderbilt-Ingram Cancer Center from 1998 to 2008. From 1991 to 1998, Mace was Associate Professor of Medicine at the University of Texas Health Science Center at San Antonio and Executive Officer of the Southwest Oncology Group. Dr. Rothenberg is board-certified in Internal Medicine and Medical Oncology and is a Fellow of the American College of Physicians and the American Society of Clinical Oncology.

**Mirat Shah, MD, MHS**  
**Medical Oncologist**  
**Office of Oncologic Drugs**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**  
See biography above



**Peggy Zuckerman, Patient Advocate**  
**KidneyCAN**  
**Kidney Cancer Association (KCA)**  
**SWOG Cancer Research Network**

Peggy Zuckerman, diagnosed in 2004 with Stage IV kidney cancer, began her patient advocacy at her first patient support group. Little education and less hope for patients was shocking, so Peggy and others started an RCC group. She was German major and teacher by background, so ‘translated’ ongoing research for others. “Education empowered the patient,” leading to better outcomes, in treatments and trials.

Peggy has become an ‘expert patient’, now serving her 5<sup>th</sup> year as the renal cancer research advocate for the SWOG Clinical Trial Network. In addition, she is active with multiple kidney cancer organizations, KidneyCan, KCCure, Kidney Cancer Association, IKCC, the Judy Nicholson Kidney Cancer Foundation, SmartPatients and others. She has reviewed grants for the Congressionally Directed Medical Research Program, Rising Tide Foundation and PCORI since 2011.

Interested in misdiagnosis, she is part of the Society for Improved Diagnosis in Medicine and wrote the Patient ToolKit to help patients to seek a rationale for the working diagnosis and subsequent treatment. Her work with the Scientific Ethics Advisory Group for Roche, and the Society for Participatory Medicine, Peggy advocates for access to all patient data, including trial results, and genetic or genomic data, ‘actionable’ or not.

Peggy writes a blog about kidney cancer and maintains and shares a large library of medical articles about RCC for other patients. It is her great joy to see the improvement of

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care for kidney cancer patients but notes that the lack of biomarkers is a major impediment to successful treatments.

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