Partners in Progress: Cancer Patient Advocates and FDA Workshop
Speakers-Panelists Biographical Information

Organized by FDA

with support from: American Association for Cancer Research (AACR), American Society of Clinical Oncology (ASCO) & American Society of Hematology (ASH)

November 13, 2017

Speakers and Panelists

Heather Benz, PhD., Medical Device Fellow, Center for Devices and Radiological Health (CDRH), FDA
Dr. Benz conducts research on patient preferences in the Office of the Center Director in support of the Center strategic priority "Partnering with Patients," with a focus on the application of patient preference information to neurological device review. She also collaborates with researchers in the Center's Office of Science and Engineering Laboratories on the development of patient-centered outcome measures. She serves on the Medical Device Innovation Consortium Science of Patient Input Committee. Dr. Benz received a B.S. in Biomedical Engineering from Case Western Reserve University and a Ph.D. in Biomedical Engineering from Johns Hopkins University School of Medicine.

Vishal Bhatnagar, MD, Medical Officer, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), FDA
Dr. Bhatnagar 's work focuses on the evaluation of investigational new drugs and marketing applications for drugs for the treatment of malignant hematologic disorders. His regulatory interests include patient preference and incorporation of patient experience in oncology trials. He also serves as a scientific liaison for multiple myeloma, which involves engagement with the multiple myeloma community. Dr. Bhatnagar received his BA in Political Science and his medical degree at the George Washington University. He completed his internal medicine residency and hematology/oncology fellowship at the University of Maryland.

Gideon M. Blumenthal, MD, Acting Deputy Office Director, Office of Hematology and Oncology Products (OHOP), CDER, FDA
Dr. Blumenthal is a medical oncologist and serves as the associate director of precision therapeutics in OHOP. He is board certified in internal medicine, medical oncology, and hematology by the American Board of Internal Medicine. He earned his undergraduate degree from Washington University in St Louis and his medical degree from University of Maryland School of Medicine. He completed an internal medicine residency at University of Maryland, followed by a hematology/oncology fellowship at the National Cancer Institute. Dr. Blumenthal previously worked as a medical officer, clinical team leader in thoracic oncology and head and neck cancer, and scientific liaison for lung cancer at FDA. He was an associate investigator on several phase 1 and phase 2 clinical trials as a fellow and then as an adjunct attending physician in the thoracic malignancy branch of the NCI. Dr. Blumenthal serves as the OHOP scientific liaison to the American Society for Clinical Oncology, is a member of the Foundation for the NIH Biomarker Consortium Cancer Steering Committee, and served on the White House Cancer Moonshot Liquid Biopsy Blood Profiling Atlas in Cancer (Blood-PAC) committee. His research has focused on investigating novel intermediate endpoints and biomarkers to better inform oncology drug and diagnostic development and clinical trial design.

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Najat Bouchkouj, MD, Medical Officer, Clinical Hematology Branch, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research (CBER), FDA

Dr. Bouchkouj received her MD at the University of Damascus, Faculty of Medicine. She completed her residency in Pediatrics at the State University of New York, Downstate Medical Center. Subsequently, Dr. Bouchkouj completed her fellowship at the Children's National Medical Center in Pediatric Hematology and Oncology and was a guest researcher at the National Cancer Institute. Prior to Joining the FDA, Dr. Bouchkouj worked at Georgetown University Hospital as a faculty member and attending physician at the Division of Pediatric Hematology Oncology at the Department of Pediatrics; where she continues to hold her academic appointment as an Assistant Professor of Pediatrics.

Annie Ellis, Patient Advocate

Annie Ellis is a survivor of recurrent ovarian cancer and early stage breast cancer. In addition to serving as an FDA Patient Representative, Annie serves as a patient advocate member with the NCI Gynecologic Cancer Steering Committee, CDMRP Ovarian Cancer Research Program (OCRP) programmatic panel and the Ovarian Cancer Research Fund Alliance Scientific Advisory Committee. Annie has provided the patient perspective at various meetings and event and has participated in the American Association for Cancer Research (AACR) Scientist↔Survivor Program (AACR SSP) and the Biennial Cancer Survivorship Research Conference Survivor-Researcher Mentor Program. Annie provides peer support through SHARE's Ovarian Helpline and New York Presbyterian-Columbia's Woman to Woman Program.

Paul G. Kluetz, MD, Acting Associate Director of Patient Outcomes, Oncology Center of Excellence, FDA

Dr. Kluetz joined FDA in 2010 focusing on genitourinary cancers. From 2014-2015, he served as Acting Deputy Director of OHOP, helping to develop and support regulatory science and strategic policy initiatives. Dr. Kluetz has an interest in defining clinical benefit in oncology trials, the use of expedited programs such as accelerated approval and breakthrough therapy, and the opportunities and challenges associated with patient reported outcomes (PRO) data, wearable technologies, and other methods to obtain data on the patient experience both in the clinical trial and "real-world" settings. He is currently serving in the newly formed Oncology Center of Excellence leading a team to develop regulatory science and policy initiatives to advance patient-focused drug development in cancer trials.

Dr. Kluetz is a board certified medical oncologist and internist. He completed a medical oncology fellowship at the National Cancer Institute (NCI) in Bethesda, MD and continues to see patients and teach medical house staff as an attending physician at the Georgetown University Hospital.

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Aviva Krauss, MD, Medical Officer, Office of Hematology and Oncology Products, CDER, FDA
Dr. Krauss is a pediatric hematologist/oncologist. Her professional interests include the treatment of hematologic malignancies, patient advocacy engagement and toxicity assessment. She serves as the scientific liaison for pediatric hematopoietic stem cell transplantation. Dr. Krauss received her BA in Philosophy and Judaic Studies from Stern College for Women of Yeshiva University and her medical degree from Albert Einstein College of Medicine. She completed her residency at the University of Medicine and Dentistry of New Jersey in Newark, NJ, and her fellowship in pediatric hematology/oncology at Children's National Medical Center in Washington, DC. Her professional interests include the treatment of hematologic malignancies, patient advocacy engagement and toxicity assessment. She serves as the scientific liaison for pediatric hematopoietic stem cell transplantation.

Virginia Kwitkowski, MS, ACNP-BC, Associate Director for Labeling, Division of Hematology Products, Office of Hematology and Oncology Products, CDER, FDA.
Ms. Kwitkowski is responsible for coordinating, planning, evaluating, overseeing and managing all labeling activities within the Division of Hematology at the U.S. Food and Drug Administration (FDA). She also leads a team of clinical reviewers who review investigational new drug applications and new drug applications for benign and malignant hematology indications. She is a Patient Reported Outcomes Lead for the division. Prior to joining the FDA, Kwitkowski was a nurse practitioner in the Medicine Branch of the National Cancer Institute

Steven Lemery, MD, MHS, Associate Division Director, Division of Oncology Products 2 (DOP2), Office of Hematology and Oncology Products, CDER, FDA.
Prior to serving as the Associate Division Director, Dr. Lemery was the Team Leader for the gastrointestinal oncology team within DOP2. Dr. Lemery joined the FDA after completing his fellowship in hematology and oncology at the National Institutes of Health (NHLBI). Recent activities within the Agency have included work on tissue agnostic drug development and on biosimilar products.

Suzanne M. Leous, MPA, Director of Government Relations and Practice, American Society of Hematology (ASH)
With nearly 30 years of experience and extensive work in health policy, Suzy has a wealth of knowledge of the legislative and regulatory process related to biomedical research and clinical practice issues. As Director of Government Relations and Practice, Ms. Leous is responsible for working with ASH members, department directors, and the executive leadership in planning and implementing Society activities related to the government affairs, practice, and scientific priorities as directed by the ASH Executive Committee. She also represents ASH's policy positions to Members of Congress, Federal Agencies, advocacy-related coalitions, and patient groups. Prior to her current role, Suzy was ASH's Senior Manager for Quality and Practice and focused on policy issues related to practice of hematology

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including physician reimbursement, quality metrics, drug cost and access, laboratory testing, and the impact of evolving health care systems on hematologists.
Before coming to ASH, Suzy was the Manager of Public Affairs at the American Society for Microbiology (ASM) for more than a decade. During her time at ASM, Suzy focused on developing public and scientific policy on issues related to clinical laboratory practice and responding to Federal legislation and regulations. Prior to ASM, Suzy worked at the Bureau of Health Professions in the Health Resources and Services Administration of the U.S. Department of Health and Human Services where she managed outreach with medical professional associations. She also analyzed policy and coordinated advocacy efforts for the American College of Preventive Medicine and the American Dental Education Association. Prior to this work, she was Legislative Assistant to former Congressman Thomas H. Andrews (ME-1).

Ms. Leous has a bachelor of arts degree with a concentration in political science from Saint Michael's College in Colchester, VT and earned her master's degree in public administration from George Mason University in Fairfax, VA. She serves on the Board of Directors for the Coalition for Health Funding and the Alumni Board of Directors for Saint Michael's College.

Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, FDA
Dr. Marks received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.

Deborah Miller, PhD, RN, Patient Liaison Program, Office of Health and Constituent Affairs, FDA
Dr. Miller recruits and trains cancer patient representatives for the Oncologic Drugs Advisory Committee panels and for the Office of Hematology and Oncology Product's divisional assignments; talks to patients, families, advocacy groups, and healthcare providers about clinical trials, expanded access, and personal importation; and is the editor of the biweekly FDA Patient Network Newsletter.

Carol Pamer, MS, Research Program Lead, Office of Surveillance and Epidemiology, Regulatory Science Staff, CDER, FDA
Carol Pamer earned her B.S. degree in Pharmacy from the Ohio State University and her M.Sc. in Epidemiology and Preventive Medicine from the University of Maryland, Baltimore. She is a Principal Investigator for the FDA-PatientsLikeMe Research Collaboration Agreement. Carol has dedicated most of her federal career to pharmacovigilance and drug safety at FDA.

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Richard Pazdur, MD, Director, Oncology Center of Excellence (OCE), FDA
OCE leverages the combined skills of FDA's regulatory scientists and reviewers with expertise in drugs, biologics and devices to expedite the development of novel cancer products. In his role as director of the OCE, Pazdur is responsible for leading the effort to develop and execute an integrated regulatory approach to enhance the cross-center coordination of oncology product clinical review.
Dr. Pazdur previously served as the director of the Office of Hematology and Oncology Products (OHOP) in the FDA's Center for Drug Evaluation and Research. This Office was formed in 2005 to consolidate the review of drugs and therapeutic biologics for the diagnosis, treatment, and prevention of cancer, as well as the review of drugs and therapeutic biologics for hematologic diseases and for medical imaging. As director of OHOP, Pazdur facilitated coordination of oncology activities across all FDA Centers and ensured an ongoing outreach and collaboration between FDA, the National Cancer Institute, and other cancer-related organizations within and outside of the government. Pazdur was the director of the Division of Oncology Drug Products from September 1999 to May 2005.

Prior to joining the FDA, Pazdur was professor of medicine at The University of Texas M.D. Anderson Cancer Center in Houston, Texas. During his tenure at M. D. Anderson Cancer Center, from 1988 to 1999, Pazdur held administrative positions of assistant vice president for academic affairs, associate director of clinical trials administration (Division of Medicine) and director of educational programs (Division of Medicine). Pazdur served on the faculty of Wayne State University, Detroit, Michigan, from 1982 to 1988.

Pazdur received his bachelor's degree from Northwestern University (Evanston, Illinois), his M. D. from Loyola Stritch School of Medicine (Maywood, Illinois), and completed clinical training at Rush-Presbyterian St. Luke's Medical Center (Chicago, Illinois) and the University of Chicago Hospitals and Clinics.

Pazdur has published more than 600 articles, book chapters and abstracts. In 2015, Fortune magazine named Pazdur as one of the 50 World's Greatest Leaders. The American Association for Cancer Research recognized Pazdur with its Distinguished Public Service Award (2015) and the American Society of Clinical Oncology recognized him with the Service Recognition Award (2009) and the Public Service Award (2013.) In 2015, Pazdur also received the Public Service Leadership Award from the National Coalition for Cancer Survivorship and the Face of Hope Award from the LUNGevity Foundation. In 2016, Pazdur was named to Massachusetts General Hospital Cancer Center's "The One Hundred" list.

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Jon Retzlaff, MBA, MPA, Chief Policy Officer and Vice President, Science Policy and Government Affairs, American Association for Cancer Research

Mr. Retzlaff directs and oversees the science policy and government affairs activities for the American Association for Cancer Research (AACR) in Washington, D.C. In this role, Mr. Retzlaff (and his team of ten) works with the AACR Science Policy and Government Affairs Committee to devise and implement strategies to influence important biomedical research-related public policy issues with the end goal of accelerating the prevention and cure of all cancers. The office also works to foster more efficient and effective communication among legislators, regulators, scientists, and the public.

Before joining the AACR in 2010, Mr. Retzlaff led the health and biomedical practice for a government relations firm in D.C. Prior to that, he served as legislative director for the Federation of American Societies for Experimental Biology from 2004-2007.

Additionally, he previously worked (from 1993-2004) for the National Institutes of Health (NIH), first as a program analyst within the NIH Office of the Director's legislative office; then as a senior legislative advisor to the National Institute of Neurological Disorders and Stroke; and finally as the Executive Officer of the National Library of Medicine. During his time as an NIH employee, Mr. Retzlaff was "detailed" to the House (1998) and Senate (2000-2001) appropriations subcommittees on labor, health and human services, education and related agencies on health research funding issues, as well as within the Office of the Secretary for Legislation at the Department of Health and Human Services. He entered the Federal Government as a Presidential Management Intern in 1993 and completed a rotation in the Office of Senator Herb Kohl (D-Wis.) during his two-years of formal training.

Mr. Retzlaff earned a Bachelor of Science degree from the University of Minnesota in 1989, a master's degree in public administration from Indiana University in 1993, and a master's degree in business administration from the Massachusetts Institute of Technology

Tara Ryan, MD, MS, MBA, Acting Clinical Deputy Director, Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices, CDRH, FDA.

Dr. Ryan has worked at FDA in the Center for Devices and Radiological Health for more than 20 years. She has extensive experience with a wide variety of therapeutic and diagnostic and therapeutic medical devices. Her expertise is in both clinical trial design and engineering device test qualification/methodologies. She earned her medical degree from George Washington University School of Medicine, a master's degree in biomedical engineering from Rensselaer Polytechnic Institute and a Master of Business Administration from the University of Maryland. She is a board-certified internist and continues to practice hospitalist medicine at two hospitals in Maryland.

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Shimere Williams Sherwood, PhD, Associate Director, NIH and FDA Advocacy, American Society of Clinical Oncology (ASCO)

Dr. Sherwood manages the ASCO NIH and FDA regulatory portfolio, tracking, developing, and responding to policy initiatives on behalf of ASCO and its members. Her portfolio includes policies related to clinical research and drug development while working with the ASCO Policy and Advocacy team to help guide the ASCO policy activities and strategies. Shimere also has over ten years of experience in science and health policy including serving as a Professional Committee Staff member of the House Science and Technology Committee of the U.S. House of Representatives. She earned a Bachelor of Science degree in Civil and Environmental Engineering and a Doctor of Philosophy in Pharmacology and Neuropharmacology. She is the proud wife of a U.S. Marine Corp officer and mother of a beautiful toddler.

Jeannine Salamone, Director, Patient Advocacy, Communications and Patient Information, American Society of Clinical Oncology (ASCO)

Jeannine Salmone is a 17-year, two-time breast cancer survivor who has been active in patient advocacy since her initial diagnosis in May 2000. She began her advocacy work as a volunteer for the Young Survival Coalition and the Virginia Breast Cancer Foundation. After advancing to leadership roles and serving as a member of the Board of Directors for both organizations, Jeannine completed patient advocacy training through the National Breast Cancer Coalition's Project LEAD program. In 2004, she decided to devote herself full time to patient advocacy and began working at the American Society of Clinical Oncology, where she leads the patient advocacy team in developing and managing programs and activities that aid patient advocates in attaining the education, knowledge, and skills essential to their participation and engagement in patient advocacy and cancer research. Jeannine also serves as a founding member of Georgetown Breast Cancer Advocates, providing input into the design and implementation of the research goals, observational studies, and clinical trials carried out at Georgetown-Lombardi Comprehensive Cancer Center. She represents Georgetown as a patient advocate on the Translational Breast Cancer Research Consortium.

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Jeffrey Shuren, MD, JD, Director of the Center for Devices and Radiological Health (CDRH), FDA
Dr. Shuren previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, Dr. Shuren joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. From 1998 to 2003, he served as a Staff Volunteer in the National Institutes of Health's National Institute of Neurological Disorders and Stroke Cognitive Neuroscience Section supervising and designing clinical studies on human reasoning. Dr. Shuren returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009.

Patty Spears, Research Advocate
Patty Spears is an 18-year breast cancer survivor and cancer research advocate. Ms. Spears has extensive clinical trial advocacy experience having served as an advocate on the Translational Breast Cancer Research Consortium (TBCRC) and NCI Breast Cancer Steering Committee (BCSC). She is currently serving as Co-Chair of the Patient Advocate Committee of the Alliance for Clinical Trials in Oncology. She is a Komen Scholar, serves as Vice Chair on the Komen Advocates in Science Steering Committee and is an FDA Patient Representative. She also has an interest in Patient Reported Outcomes (PROs) in drug development. Ms. Spears is currently working as a scientific research manager and patient advocate at UNC Lineberger Comprehensive Cancer Center.

Joohee Sul, MD, Medical Officer, Division of Oncology Products 2, Office of Hematology and Oncology Products, CDER, FDA
Dr. Sul serves as the brain and CNS malignancies scientific liaison. She received her M.D. and completed residency training at the University of Rochester School of Medicine, and did a fellowship in neuro-oncology at Memorial Sloan-Kettering Cancer Center. While at the FDA, she has worked closely with advocacy groups and stakeholders interested in the development of neuro-oncology products. She also continues to see patients at the National Institutes of Health, Center for Cancer Research.

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Janet Woodcock, MD, Director, Center for Drug Evaluation and Research (CDER), FDA

In 2015, Dr. Woodcock also assumed the role of Acting Director of CDER's newly formed Office of Pharmaceutical Quality, (OPQ). Dr. Woodcock first joined CDER in 1994. For three years, from 2005 until 2008, she served FDA's Commissioner, holding several positions, including as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer. Her responsibilities involved oversight of various aspects of scientific and medical regulatory operations. Before joining CDER, Dr. Woodcock served as Director, Office of Therapeutics Research and Review, and Acting Deputy Director in FDA's Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School and completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

Kevin Wright, PharmD., Regulatory Review Officer, Office of Prescription Drug Promotion (OPDP), CDER, FDA.

OPDP is charged with protecting the public health by assuring prescription drug promotion is truthful, balanced, and accurately communicated. In this position, Dr. Wright reviews promotional materials for products used in the treatment of breast cancer, ovarian cancer, and prostate cancer. These materials include promotion intended for healthcare professionals and consumers such as journal ads, sales aids, and TV advertisements. Kevin earned his Bachelor in Science (Chemistry) from the University of Pittsburgh and Doctor of Pharmacy from Howard University. After earning his PharmD, Kevin completed a pharmacy practice residency at the Veterans Affairs Medical Center in Washington, DC.