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

Organized by FDA

Supported by: Cancer Support Community; Leukemia and Lymphoma Society; and Susan G. Komen Foundation

November 27, 2018

Speakers and *Panelists*

By order of appearance

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.

Elizabeth Franklin, MSW, Cancer Support Community

Elizabeth Franklin, LGSW, ACSW, is Executive Director of the Cancer Policy Institute (CPI) at the Cancer Support Community (CSC). CSC is the largest provider of social and emotional support services for cancer patients and their loved ones in the United States. The CPI brings together patient advocates and policy experts to ensure that the voices of cancer patients and their loved ones play a central role in federal and state legislative, regulatory, and executive policy making. The CPI works in partnership with patient advocates, the CSC affiliate network, and numerous allied health care and oncology organizations to work towards a future where 15.5 million cancer survivors have access to comprehensive, high-quality, timely, and affordable medical, social, and emotional care. Elizabeth is responsible for all aspects of the CPI including legislative, regulatory, policy, and research priorities as well as operations, fundraising, and management. Elizabeth was previously Senior Director of Policy and Advocacy at CSC.

Elizabeth was formerly Director of Policy and Engagement at the George Washington University Cancer Institute where she worked at both the macro level, developing and implementing the Institute's policy agenda, and at the micro level, working with the patient-centered care team to ensure that all patients had access to high-quality, timely cancer care. Previously, Elizabeth was Senior Director of Policy and Advocacy with the Prevent Cancer Foundation as well as Special Assistant to the Chief Executive Officer at the headquarters of the National Association of Social Workers.

Elizabeth is a recognized author and speaker. Her articles have appeared in publications such as the Journal of Cancer Education, Health and Social Work, and Conquer Cancer Magazine. She has co-

authored two books on non-profit leadership and co-edited two social work texts. In addition, she is a member of various organizations and coalitions, including the National Association of Social Workers (where she serves as President of the DC Chapter), Association of Oncology Social Work (where she serves on the advocacy committee), Academy of Oncology Nurse and Patient Navigators (where she serves on the leadership council and as Chair of the Policy and Advocacy Committee), Alliance for Quality Psychosocial Cancer Care, and Society for Social Work and Research.

Currently a doctoral candidate at the University of Maryland School of Social Work, Elizabeth is focusing her dissertation on the ways in which patients define value in the cancer care system and how those definitions can be incorporated into public policy and clinical practice. Elizabeth obtained her Master's Degree in Social Work from the University of Illinois at Chicago and her Bachelor's Degree in Social Work from the University of Kentucky. She is a Licensed Graduate Social Worker in the District of Columbia and a member of the Academy of Certified Social Workers.

Liza Holder, JD, Director, Policy, The Leukemia & Lymphoma Society (LLS)
Liza Holder manages regulatory policy initiatives on behalf of LLS, working with the FDA and NIH to advance the organization's mission. Her portfolio of work includes policies related to drug competition, innovations in clinical trial design, patient-focused drug development, and real-world evidence. Liza has over a decade of experience in healthcare policy and consulting, including serving as Manager at the Advisory Board Company, where she oversaw research programs dedicated to improving hospital operations and efficiency. Liza has a B.A. in government from Lehigh University and a J.D. from The University of Maryland.

Patty Spears, Susan G. Komen, Research Advocate
Patty Spears is a 19-year breast cancer survivor and cancer research advocate. Ms. Spears has extensive clinical trial advocacy experience serving as an advocate on the Translational Breast Cancer Research Consortium (TBCRC) and NCI Breast Cancer Steering Committee (BCSC) Breast Immuno-Oncology (BIO) Task Force. She is also Chair of the Patient Advocate Committee of the Alliance for Clinical Trials in Oncology. She is a Komen Scholar, serves as Co-Chair on the Komen Advocates in Science Steering Committee and is an FDA Patient Representative. She has an interest in Patient Reported Outcome Measurements (PROMs) in drug development. Ms. Spears is currently working as a scientific research manager and patient advocate at UNC Lineberger Comprehensive Cancer Center.

Virginia Kwitkowski, MS, Associate Director for Labeling, Division of Hematology Products, Office of Hematology and Oncology Products, CDER, FDA.
Ms. Kwitkowski, MS, ACNP-BC, joined the FDA in 2006 as a clinical reviewer in oncology. She is now the Associate Director for Labeling in the Division of Hematology Products and in this role is responsible for coordinating, planning, evaluating, overseeing and managing all labeling activities within the Division. She is also a Patient Reported Outcomes Lead for the division. She is also a Patient Reported Outcomes Lead in DHP. Prior to joining the FDA, Ms. Kwitkowski was a Nurse Practitioner in the Medicine Branch of the National Cancer Institute in Bethesda, MD.

Rosanna Setse, MD, PhD, Medical Officer, Office of Hematology and Oncology Products, CDER, FDA
Dr. Setse is an internal medicine specialist. She earned her Medical Degree from the University of Ghana Medical school and her PhD from the Johns Hopkins University School of Public Health. She completed her residency in internal medicine at the Howard University Hospital. She joined the FDA as a clinical reviewer in the Division of Hematology Products in 2016. Prior to joining the FDA, Dr. Setse practiced as a hospitalist at the Medstar Montgomery Medical Center in Olney, MD. Her research and professional interests include hemoglobinopathies, hematological malignancies and patient reported outcomes. She serves as one of the leads for Patient Reported Outcomes within the Division of Hematology Products.

Rea Blakey, Associate Director for External Outreach and Engagement, Oncology Center of Excellence, FDA
Ms. Blakey joined the immediate office of the newly formed Oncology Center of Excellence in July 2018. Since the start of her nearly 5-year tenure at FDA, she's worked in patient and stakeholder engagement roles serving as a liaison leader for patients, advocacy groups, health care providers and medical associations interested in influencing medical product regulatory decision-making.

Ms. Blakey joined the FDA Oncology Center of Excellence after serving for 4 years in the FDA's Center for Drug Evaluation and Research (CDER) Center Director's office in Professional Affairs and Stakeholder Engagement. Prior to her career in the federal government Rea was Director of Communications at The George Washington Medical Faculty Associates, a CNN medical correspondent covering international and domestic health & medical news, a Discovery Channel CME program on-air host for nearly 60 programs, and an Emmy-winning news anchor and health reporter at Washington's ABC-affiliate, WJLA-TV.

Andrea Furia-Helms, MPH, Director, Patient Affairs Staff, Office of Medical Products and Tobacco, Office of the Commissioner, FDA
Andrea Furia-Helms works with the FDA medical product centers and other offices to support the FDA's ongoing patient engagement efforts and is coordinating cross-cutting patient engagement activities to ensure patients, caregivers, and advocates have opportunities to share their perspectives in the FDA regulatory meetings. Ms. Furia-Helms spent the over ten years in the FDA's Office of Health and Constituent Affairs where she directed the FDA Patient Representative Program and coordinated patient engagement activities.

Prior to FDA, Ms. Furia-Helms was Director of the Back to Sleep (now Safe to Sleep) campaign, a public-private partnership to educate communities on Sudden Infant Death Syndrome (SIDS), at the National Institutes of Health. She developed SIDS targeted outreach initiatives for African American, American Indian and Latino communities.

Ms. Furia-Helms has a B.A. in psychology from Framingham State University, a B.S. degree in community health education from University of Maryland, and a Master of Public Health degree from The George Washington University.

Salina Miller, MBA, Manager, FDA Patient Representative Program℠ , Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Office of the Commissioner, FDA
Salina Miller, MS, MBS, joined FDA's Advisory Committee Oversight and Management Staff (ACOMS), located within the agency's Office of the Commissioner (OC), as a Health Programs Coordinator in April 2018. Prior to that, she was within OC's Office of Health and Constituent Affairs, where she served on the Patient Liaison Team as the primary patient advocacy lead for neurology, psychiatry, and anti-malarial-related issues. It was during this time that Ms. Miller began work on the FDA's Patient Representative Program, a critical agency patient engagement initiative that ensures patient perspectives are included in the medical product review process. Patients and caregivers are actively recruited and managed in preparation for various agency meetings and other activities. Now, within ACOMS, Ms. Miller serves as the Manager for the Program and responds to the needs and requirements for Patient Representatives for all the agency's medical product Centers. Prior to FDA, Ms. Prasad was with FDA's sister agency, the Agency for Healthcare Research and Quality, for nearly 18 years where she worked on patient safety and medical errors issues. Ms. Prasad received a B.S. in chemistry and biology from Columbia Union College and a Master of Science and a Master of Business Administration in Biotechnology from Johns Hopkins University.

Nicholas Richardson, DO, Medical Officer, Office of Hematology and Oncology Products, CDER, FDA
Nickolas Richardson, DO, MPH, is a pediatric hematologist-oncologist. Prior to joining the FDA, he earned his medical degree from the Philadelphia College of Osteopathic Medicine. He completed his residency and chief residency at A.I. duPont Hospital for Children/Thomas Jefferson University, and his fellowship in pediatric hematology and oncology at Vanderbilt University Medical Center. Dr. Richardson's clinical and regulatory interest include Hodgkin and non-Hodgkin lymphoma, pediatric drug development in hematology and oncology, and patient advocate engagement.

Aviva Krauss, MD, Medical Officer, Office of Hematology and Oncology Products, CDER, FDA
Dr. Krauss is a pediatric hematologist/oncologist in the Division of Hematology Products (DHP) and a clinical associated in the Blood and Marrow Transplant Division of the Center for Cancer and Blood Disorders at Children's National Medical Center. Prior to joining FDA, Dr. Krauss served as an attending physician in the Bone Marrow Transplantation unit at Schneider Children's Medical Center of Israel. 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, bone marrow transplantation, patient advocacy engagement and toxicity assessment. She serves as the scientific liaison for pediatric hematopoietic stem cell transplantation.

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Jennifer Gao, MD, Medical Officer, Office of Hematology and Oncology Products, CDER, FDA
Dr. Gao is a physician in Division of Oncology and Oncology Products 1 on the breast cancer team and an Adjunct Assistant Professor in the Department of Medicine at Georgetown University Medical Center. She graduated from Harvard College and spent a year in Bonn, Germany as a Fulbright Fellow before completing medical degree at Brown University. She completed her internal medicine residency at Massachusetts General Hospital and her medical oncology fellowship at the National Cancer Institute. She is the Oncology Biosimilars Scientific Liaison and has an interest in medical education, treatment related side effects, and patient reported outcomes. She also continues to see breast cancer patients at Georgetown Lombardi Comprehensive Cancer Center.

Mary Lou Smith, JD, Research Advocacy Network
Mary Lou Smith is a Co-founder of the Research Advocacy Network. She is a two-time breast cancer survivor and an ovarian and colon cancer survivor and serves as Chair of the ECOG-ACRIN Cancer Research Advocates Committee. She also serves on the National Comprehensive Cancer Network (NCCN) Breast Cancer Screening and Treatment Guidelines Committees. She is a member of the Mayo Breast SPORE and the NCI Breast Steering Committee's BOLD Task Force. Mary Lou serves on the boards of the National Accreditation Program for Breast Centers and Gateway for Cancer Research. She was a community member of the Rush University Medical Center Institutional Review Board for 10 years. Mary Lou is past president of Y-ME National Breast Cancer Organization and has served on the Cancer Leadership Council and the National Breast Cancer Coalition's Board of Directors.

Mary Lou has worked in health care for over 20 years in both hospital administration and consulting. She was involved in the development of numerous managed care products for the Blue Cross and Blue Shield Association, including a Pediatric Cancer Network. Mary Lou has a Juris Doctorate with a Health Law Certification and a master's degree in Business Administration.

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's 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.

LaShawn Griffiths, MSHS-PH, Associate Director for Patient Labeling, Division of Medical Policy Programs in the Office of Medical Policy Initiatives, CDER.
LaShawn Griffiths, MSHS-PH, BSN, RN, is the Associate Director for Patient Labeling Division of Medical Policy Programs in the Office of Medical Policy Initiatives, Center for Drug Evaluation and Research (CDER). Prior to joining the FDA, Ms. Griffiths spent 8 years working with the Department of Defense in clinical practice with experience in the areas of Labor and Delivery, Pediatrics, Adolescent psychology, and as an Operating Room First Assistant. Mrs. Griffiths came to the FDA in the Fall of 2008 from Walter Reed Army Medical Center, where she worked as the Regional Clinical Nurse Consultant for the North Atlantic region Exceptional Family Member Program.
She leads the Patient Labeling Team, a group of nurses and pharmacist with more than 30 years of experience collectively. The Patient Labeling Team promotes the safe and effective use of prescription medications by providing accurate and easily understood patient medication information. The Patient Labeling Team collaborates with and responds to consult requests from CDER review divisions on patient labeling and is responsible for the review of Medication Guides, Patient Package Inserts, and Instructions for Use.

Kristen Booze, MPH, Health Communications Specialist, Office of Communications, CDER, FDA
Kristen Booze joined CDER's Office of Communications in March 2018. Her role includes planning strategic communications for many of the offices within the Office of New Drugs, to include the Office of Hematology and Oncology Products. Prior to the FDA, Kristen was a Public Affairs Specialist in the Office of Public Affairs and Consumer Education at the USDA Food Safety and Inspection Service, where she led internal communications and was also involved in external communications, to include food recall communications, media pitching and partnerships. Kristen earned her B.S. in Biology at SUNY Geneseo and her M.P.H. at The George Washington University.

Rachel Ershler, MD, Medical Officer, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), FDA
Rachel Ershler is a Pediatric Hematologist/Oncologist and Medical Officer in the Division of Hematology Products (DHP), Office of Hematology and Oncology Products (OHOP) at the FDA.
Dr. Ershler received her Master's in Health Science (MHS) in Biochemistry and Molecular Biology from Johns Hopkins University, and her MD from George Washington University School of Medicine. She completed her residency in pediatrics at the University of Wisconsin and fellowship in pediatric hematology and oncology in the combined fellowship program at Johns Hopkins University/National Cancer Institute (NCI). During the research years of her fellowship, she joined the Pediatric Oncology Branch (POB) at the NCI where her research focused on drug development for pediatric cancers and neurofibromatosis type 1 (NF1).

Dr. Ershler joined the FDA as a Medical Officer in September 2015 and is currently on the Multiple Myeloma review team within DHP. Her FDA role has included the review and regulatory oversight of more than 100 Investigational New Drug Applications (INDs), as well as multiple NDAs and BLAs. Dr. Ershler is involved in the Pediatric Oncology Working Group and has a special interest in pediatric oncology drug development.

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Najat Bouchkouj, MD, Medical Officer, Clinical Hematology Branch, Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER), FDA
Dr. Bouchkouj is a pediatric hematologist oncologist. Her professional interests include hematologic malignancies, gene therapies and patient advocacy engagement. She serves as the scientific liaison for cell and gene therapy and as the Patient Engagement representative for OTAT. 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, and her fellowship in Pediatric Hematology and Oncology at Children's National Medical Center. Dr. Bouchkouj is an assistant professor of pediatrics at Georgetown University Medical School and a consulting oncologist at Children's National Health System.

Tara Ryan, MD, Medical Officer, Division of Cardiovascular Devices, CDRH, FDA.
Tara Ryan, MD, MS, MBA, 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.