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

Sponsored by the FDA Oncology Center of Excellence
Supported by: LUNGevity, Ovarian Cancer Research Alliance &
Pancreatic Cancer Action Network

October 8, 2019

Speakers and *Panelists*
(order of appearance)

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

Paul G. Kluetz, MD, Deputy Director, 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.

Kristen Santiago, Senior Director of Public Policy Initiatives, LUNGevity Foundation

Kristen Santiago has substantial experience working in the healthcare industry in roles in the public, private, and not-for-profit sectors. As Senior Director of Public Policy Initiatives for the LUNGevity Foundation, Kristen is focused on breaking down barriers to patient access to high-quality care and treatment innovation. In her role, Kristen participates on a variety of committees and advisory boards to represent the interests and perspectives of lung cancer patients, presents at Capitol Hill briefings, submits letters to legislators, regulators, and independent organizations seeking patient input, and convenes multi-stakeholder meetings to resolve complex issues that hinder patient access to diagnostics and the most advanced therapeutics.

Speakers and *Panelists*
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In Kristen's previous positions include: Senior Director, Policy & Advocacy for the Cancer Support Community; Director, Strategic Initiatives & Outreach for C-Change; as well as positions with TAP and Takeda Pharmaceuticals, The Commonwealth of Pennsylvania, and the American Speech-Language-Hearing Association. Kristen earned a Master of Science in Health Promotion Management at American University and a Bachelor of Arts in Speech Language Pathology from The George Washington University and is driven by a strong personal desire to impact the health status and quality of life of individuals through strategic alliance development and advocacy.

Vanessa Cramer, Director of Policy, Ovarian Cancer Research Alliance

Vanessa Cramer is Policy Director for Ovarian Cancer Research Alliance (OCRA). In this role, she works closely with OCRA's Vice President of Policy, grasstop leaders, and partner organizations around the country to develop and implement OCRA's policy and advocacy agenda at both federal and state levels.

Prior to joining OCRA, Ms. Cramer worked on Capitol Hill for Congressman Gary Ackerman and more recently, as staff for the House Energy & Commerce Committee's Select Investigative Panel. She also worked in the Government Relations Department at Planned Parenthood Federation of America, and in the private sector lobbying and consulting for a range of health care clients. Having worked in the government as well as private and non-profit sectors, Ms. Cramer has experience in multiple aspects of policymaking.

Ms. Cramer graduated from the University of Washington Honors College with a bachelor's degree in Sociology. She completed her undergraduate honors thesis on the impact of state laws criminalizing HIV/AIDS exposure.

Victoria Manax, MD, Chief Medical Officer, Pancreatic Cancer Action Network

Dr. Victoria Manax is the Chief Medical Officer of the Pancreatic Cancer Action Network. She provides strategic direction and operational oversight to the organization's high-priority clinical initiatives, with emphasis on the Precision Promise initiative and its Clinical Trial Consortium. She works closely with clinical cancer research institutions and biopharmaceutical companies to build a productive and collaborative team that will accelerate progress toward the goal to double pancreatic cancer survival by 2020.

Dr. Manax received her medical degree from University College Dublin and completed her medical training at St. Vincent's University Hospital in Dublin and University Hospital Galway. Dr. Manax joined the Pancreatic Cancer Action Network in 2016 after holding many leadership positions in the pharmaceutical industry including Abraxis Bioscience and Celgene Corporation. Manax was involved in

Speakers and *Panelists*
(order of appearance)

the development and approval of the drug Abraxane for multiple indications including pancreatic cancer. Her areas of interest include drug development, precision medicine strategy, and innovative clinical trial design.

Preeti Narayan, MD, Medical Officer, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), FDA

Dr. Preeti Narayan is a medical officer on the breast cancer team in the Division of Oncology Products 1 (DOP1). She received her medical degree from St. George's University in the West Indies and completed her internal medicine residency at SUNY Downstate Medical Center in Brooklyn, NY. She completed her fellowship in Hematology and Oncology at the University of Florida. Her professional interests include precision medicine use in diagnosis and treatment of solid tumors and treatment of high-risk breast cancer.

Vishal Bhatnagar, MD, Associate Director for Patient Outcomes, Oncology Center of Excellence, 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.

Susan Chittooran, MSW, Patient Engagement Project Manager, Office of Clinical Policy and Programs, Office of the Commissioner, FDA

Susan Chittooran is a Patient Engagement Project Manager on the Patient Affairs Staff (PAS) within the Office of the Commissioner at the FDA. Susan serves as the central point of contact in Patient Affairs for patients, caregivers, and patient advocates who wish to engage with the Agency, resolves patient-related concerns and inquiries, and serves as the liaison between patients and subject matter experts within FDA's medical product centers. In her role, Susan also assists offices in FDA's three medical product centers in identifying and coordinating patient stakeholder participation in FDA meetings and workshops. Susan also manages the communications and social media for Patient Affairs. Prior to joining Patient Affairs, Susan spent three years at FDA's Office of Health & Constituent Affairs where she was responsible for engaging with stakeholders including healthcare professionals, patients and patient advocacy groups, and consumers to incorporate their perspectives in regulatory processes and policies, coordinated FDA's stakeholder communication calls, and managed portfolios on biosimilars and opioids.

Speakers and *Panelists*
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She was also responsible for managing and planning the Center for Devices & Radiological Health (CDRH)'s inaugural Patient Engagement Advisory Committee (PEAC) meeting - the only FDA advisory committee that is comprised solely of patients and caregivers. Prior to joining FDA, Susan worked in the New York office of the Women's Bureau, U.S. Department of Labor for six years where she planned meetings, listening sessions, and events related to agency priority areas with diverse stakeholder groups including other federal agencies, non-profit organizations, foundations, and businesses. She also served as a Special Assistant to former Women's Bureau (WB) Director in Washington, DC, where she was responsible for supporting the Director and WB leadership in the planning and implementation of the White House Summit on Working Families. A social worker by background, Susan has experience with case management and direct service to clients in various clinical settings in non-profit organizations in New York City. Susan has a Master of Science in Social Work Policy from Columbia University, and a Bachelor of Arts in Psychology from Auburn University.

Amy Williams, Director, Office of Advocacy Relations, National Cancer Institute (NCI), National Institutes of Health

Amy Williams is Director of NCI's Office of Advocacy Relations where she and her team facilitate advocate engagement across the NCI. The team works with national level advocacy organizations to advance understanding of policy, partnerships, and strategic investments in cancer research, and serves the individual research advocacy community by engaging advocates in NCI's scientific initiatives. Before joining NCI, Ms. Williams worked in public relations as a communications consultant for both government and pharmaceutical clients. She hails from North Carolina and looks forward to March Madness every year.

Susan Leighton, Patient Advocate and Director, National Program, Survivors Teaching Students®, Ovarian Cancer Research Alliance

An ovarian and breast cancer survivor, Susan Leighton is the National Program Director of Ovarian Cancer Research Alliance's (OCRA) "Survivors Teaching Students®" program. She serves as a reviewer on the Programmatic Panel of the Department of Defense Ovarian Cancer Research Program (OCRP) and for NIH, is a member of the National Cancer Institute's Ovarian Cancer Task Force and is an OCRA Advocate Leader. Susan spearheaded the formation of the Alabama Study Commission for Gynecologic Cancers, is a cofounder of the Lilies of the Valley Gynecologic Cancer Awareness and Support Group in Huntsville, Alabama, has served as an FDA Patient Representative, and is an Advocate Leader for OCRA. Susan is a veteran of the United States Army and lives in Huntsville with her husband of 43 years. Her life goal is to learn the definition of the word retire, something she supposedly did 15 years ago.

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Janice Kim, PharmD, MS, Senior Regulatory Health Project Manager, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), FDA

Janice Kim is a practicing pharmacist. She graduated from the University of Virginia with a bachelor's degree in biomedical engineering. In addition, she received her master's degree in biochemistry at Georgetown University before completing her pharmacy degree at the Medical College of Virginia. She completed her ambulatory care residency at a free clinic. She contributes to the policy development for the patient-focused drug development program in the Oncology Center of Excellence at the FDA. She enjoys working with patients and continues to work in the free clinic setting.

'Lola Fashoyin-Aje, MD, MPH, Medical Officer, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), FDA

Dr. Fashoyin-Aje is a medical oncologist in the Office of Oncology and Hematology Products (OHOP) at the Food and Drug Administration. Her work focuses on the evaluation of investigational new drug applications and marketing applications for products developed for the treatment of solid tumor malignancies. She is the Oncology Center of Excellence Scientific Liaison for Cancer Disparities and in this role, she leads the Office's efforts to improve inclusion of diverse demographic subgroups in clinical trials and participates in several internal and external scientific and policy working groups.

Prior to joining the FDA, Dr. Fashoyin-Aje completed her residency in internal medicine and fellowship in medical oncology at Johns Hopkins. She completed her undergraduate and graduate training at Columbia University and Yale University, respectively, and earned her medical degree from the University of Rochester.

Natasha Kormanik, Senior Regulatory Health Project Manager, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), FDA

LCDR Natasha Kormanik is a Senior Regulatory Health Project Manager in the U.S. Food and Drug Administration's (FDA) Office of Hematology and Oncology Products and led the first phase of Project Facilitate in the FDA's Oncology Center of Excellence. LCDR Kormanik' s career started as an Oncology Intern at the National Institutes of Health, working on a Hematology/ Blood and Marrow Transplant Unit.

At this time, she was commissioned as an officer in the U.S. Public Health Service (PHS). After the two-year internship, she transitioned on to be a Research Nurse Specialist, working as an Association Investigator in Hairy Cell Leukemia, Chronic Lymphocytic Leukemia, and Adult T-Cell Leukemia clinical trials with the National Cancer Institute. Since 2013, LCDR Kormanik has been serving as a Senior

Speakers and *Panelists*
(order of appearance)

Regulatory Health Project Manager, managing Hematology/Oncology drug approvals at the FDA. As a PHS officer, she serves as a deputy team lead nurse for a rapid deployment team that is equipped to serve in public health crises- including natural disasters, disease outbreaks, humanitarian missions, and terrorist attacks. She earned her Bachelor of Science in Psychology from Virginia Commonwealth University, and Bachelor of Science in Nursing and Master of Science in Nursing from The Johns Hopkins University.

Bindu Kanapuru, MD, Medical Officer, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), FDA

Dr. Kanapuru professional interests include: the treatment of hematological malignancies, geriatric oncology and patient-reported outcomes (PRO). She serves as the scientific liaison for geriatric hematology and the division PRO lead at OHOP. Prior to joining the FDA, Dr. Kanapuru was in private hematology/oncology practice and has experience in adult and geriatric hematology and oncology.

Dr. Kanapuru received her medical degree from Chennai Medical College in India. She completed her fellowship in hematology and oncology at the University of Maryland Medical Center in Baltimore, and her residency in internal medicine at Harbor Hospital in Baltimore. During her fellowship she did her research training on mechanisms of unexplained anemia and cancer incidence in older adults at the National Institute of Aging, and co-authored multiple publications and book chapters. She is board-certified in hematology, medical oncology and internal medicine.

Michael Menefee, MD, Medical Officer, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), FDA

Dr. Menefee is a medical oncologist on the thoracic and head and neck malignancies team in the Office of Hematology and Oncology Products. He earned his medical degree from Meharry Medical College and completed a residency in internal medicine at the Mayo Clinic. He went on to complete his fellowship training in oncology and hematology at the National Cancer Institute.

Prior to joining the FDA in 2018, Dr. Menefee served as an assistant professor of oncology at Mayo Clinic for 11 years. His clinical focus was on thoracic and endocrine malignancies and served as a clinical investigator on numerous clinical trials. During his tenure at Mayo Clinic, Dr. Menefee also served as a permanent member of the FDA Oncologic Drug Advisory Committee.

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Poornima Sharma, MD, Medical Officer, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research (CBER), FDA

Dr. Poornima Sharma is a hematologist oncologist at the FDA' s Clinical Hematology Branch, Division of Clinical Evaluation and Pharmacology/Toxicology. Dr. Sharma received her MBBS at Lady Hardinge Medical College, University of Delhi, India. She completed her residency in Internal Medicine at NYU Downtown hospital, New York. Subsequently, Dr. Sharma completed her fellowship in Hematology and Oncology at University of Cincinnati, Ohio. Prior to Joining the FDA, Dr. Sharma worked as consultant physician at Tate Cancer Center, UM Baltimore-Washington Medical Center and Clinical assistant professor, University of Maryland . She continues to hold her clinical and academic appointments.

Tara Ryan, MD, MS, MBA, Medical Officer, Division of Cardiovascular Devices, Center for Devices and Radiological Health (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.