U.S. FOOD & DRUG ADMINISTRATION

Oncology Center of Excellence - Public Workshop
Project Facilitate and EA Navigator – FDA's OCE and Reagan-Udall Foundation for the FDA, Working Together to Enable Patient Access to Investigational Oncology Drugs

May 16, 2019

Speakers & Panelists

Workshop Moderator

Rea Blakey

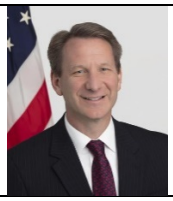
Associate Director for External Outreach and Engagement, Oncology Center of Excellence
FDA

Ms. Blakey joined the immediate office of the FDA Oncology Center of Excellence in July 2018. Since the start of her 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.

Prior to coming to the FDA Oncology Center of Excellence Ms. Blakey served in the FDA Center for Drug Evaluation and Research (CDER) Center Director's office in Professional Affairs and Stakeholder Engagement. During her 4-year tenure there she served as Engagement Team Lead facilitating and participating in meetings with key national and international stakeholders both within and outside the federal government.

Her private sector career focused on communications and TV news. Before her government service work Rea was Director of Communications at The George Washington Medical Faculty Associates in Washington, DC, a physicians' group representing the work of hundreds of doctors. Rea is also a former CNN medical correspondent who was responsible for covering international and domestic health & medical news on all CNN platforms. For several years she worked as a Discovery Channel CME program moderator appearing on-air hosting nearly 60 programs. Rea is an Emmy-winning news anchor and health reporter who initially came to the Nation's Capital to work at Washington's ABC-affiliate, WJLA-TV where she her reporting was featured weekdays during the 5pm newscast for 13 years.

Workshop Speakers



Norman E. "Ned" Sharpless, M.D.

Acting Commissioner of Food and Drug Administration

Norman E. "Ned" Sharpless, M.D., became Acting Commissioner of Food and Drugs on the afternoon of April 5, 2019. Previously, he was confirmed as the 15th director of the National Cancer Institute (NCI) on October 17, 2017. Prior to his NCI appointment, Dr. Sharpless served as the director of the University of North Carolina (UNC) Lineberger Comprehensive Cancer Center, a position he held since January 2014.

Dr. Sharpless was a Morehead Scholar at UNC–Chapel Hill and received his undergraduate degree in mathematics. He went on to pursue his medical degree from the UNC School of Medicine, graduating with honors and distinction in 1993. He then completed his internal medicine residency at the Massachusetts

General Hospital and a hematology/oncology fellowship at Dana-Farber/Partners Cancer Care, both of Harvard Medical School in Boston.

After 2 years on the faculty at Harvard Medical School, he joined the faculty of the UNC School of Medicine in the Departments of Medicine and Genetics in 2002. He became the Wellcome Professor of Cancer Research at UNC in 2012.

Richard Pazdur, M.D.

Director, Oncology Center of Excellence
FDA

Dr. Pazdur is director of the U.S. Food and Drug Administration's (FDA) Oncology Center of Excellence (OCE), which leverages the combined skills of the FDA's regulatory scientists and reviewers with expertise in drugs, biologics and devices to expedite the development of novel cancer products. He 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. He previously served as director of the Office of Hematology and Oncology Products 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, he 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. He was director of the FDA's Division of Oncology Drug Products from 1999 to 2005. Prior to joining the FDA, he was a professor of medicine at the University of Texas M.D. Anderson Cancer Center in Houston, where he also served as assistant vice president for academic affairs, associate director of clinical trials administration and director of educational programs in the Division of Medicine. He served on the faculty of Wayne State University from 1982–1988. He received his bachelor's degree from Northwestern University, his M.D. from Loyola Stritch School of Medicine, and completed clinical training at Rush-Presbyterian St. Luke's Medical Center and the University of Chicago Hospitals and Clinics. He has published more than 600 articles, book chapters and abstracts. In 2015, Fortune magazine named him one of the 50 World's Greatest Leaders. In 2016, Dr. Pazdur was named to Massachusetts General Hospital Cancer Center's "The One Hundred" list. In 2017, Bloomberg honored him as one of The Bloomberg 50. He is the recipient of many other professional awards, including: the American Society of Clinical Oncology Service Recognition Award and Public Service Award; the American Association for Cancer Research Distinguished Public Service Award; the National Coalition for Cancer Survivorship Public Service Leadership Award; the LUNGevity Foundation Face of Hope Award; the Gary Neil Prize for Innovation in Drug Development from the American Society for Clinical Pharmacology and Therapeutics; and the National Organization for Rare Disorders Rare Impact Award.

Ellen V. Sigal, Ph.D.

Board Chair
Regan-Udall Foundation for the FDA

Ellen V. Sigal, PhD, is Chair of the Board of Directors of the Reagan-Udall Foundation, a partnership designed to modernize medical product development, accelerate innovation and enhance product safety in collaboration with the U.S. Food and Drug Administration. She is the Chairperson and Founder of Friends of Cancer Research (Friends). Friends is an advocacy organization based in Washington, DC that

drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients. During the past 20 years, Friends has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible.

Dr. Sigal also serves on the Board of the Foundation for the National Institutes of Health, where she chairs its Public Private Partnerships Committee.

In 2010, Dr. Sigal was appointed to the inaugural Board of Governors of the Patient Centered Outcomes Research Institute (PCORI) as a representative of patients and health consumers and was recently reappointed to another six-year term.

Additionally, in 2016 Dr. Sigal was named to Vice President Biden's Cancer Moonshot Blue Ribbon Panel, to the Parker Institute for Immunotherapy Advisory Group and joined the inaugural board of advisors for the George Washington University's Milken Institute of Public Health.

She also holds leadership positions with a broad range of cancer advocacy, public policy organizations and academic health centers including: MD Anderson Cancer Center External Advisory Board, the Duke University Cancer Center Board of Overseers, and The Sidney Kimmel Comprehensive Cancer Center Advisory Council.

Amar Bhat, Ph.D.

Interim Executive Director
Regan-Udall Foundation for the FDA

Dr. Amar Bhat is the Interim Executive Director of the Reagan-Udall Foundation for the FDA, a non-profit organization created by Congress to advance the mission of the U.S. Food and Drug Administration. In this role, he provides strategic direction, leadership and oversight for the Foundation's programs and initiatives intended to foster advances in regulatory science and help FDA modernize product development and accelerate innovation. Dr. Bhat joined the Foundation in 2018 as the Director of Business Planning and Programs, with a portfolio that focused on new initiatives, program development and strategic planning.

Prior to joining the Foundation, Dr. Bhat held a variety of executive positions in health and science policy, including Vice President of Open Health Systems Laboratory, President and Co-Founder of TwoFour Insight Group, and Assistant Vice President of the Pharmaceutical Research and Manufacturers of America (PhRMA). He has a deep understanding of the Washington political and business environment and has built a substantial network of stakeholders in the global healthcare industry, U.S. Government agencies, universities, NGOs, foundations, and multilateral agencies. In addition, Dr. Bhat is a recognized speaker on global health and pharmaceutical policy.

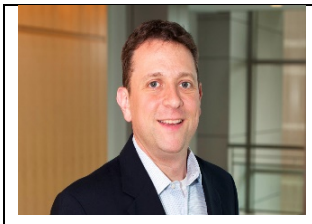
Dr. Bhat started his career as a Presidential Management Intern at the U.S. National Institutes of Health (NIH) in 1990, eventually rising to become Acting Director for the Division of International Relations within NIH's Fogarty International Center from 1999 to 2001. Afterwards, he was recruited to be the first Director of the Office of Asia and the Pacific within the Office of Global Affairs in the Office of the Secretary of the U.S. Department of Health and Human Services (HHS), managing for over six years a cadre of senior health professionals based in Washington, D.C., and in U.S. Embassies across Asia. While at NIH and HHS, Dr. Bhat negotiated dozens of bilateral agreements and developed an in-depth knowledge of the health systems around the world. He worked closely with FDA, CDC, and other U.S. Government agencies on a number of high-profile activities such as the Global Fund and PEPFAR, as well as the U.S. Government's response to various epidemics and natural disasters. Through these various roles, Dr. Bhat also developed a keen understanding of the role of regulatory science and the development of experimental therapies into commercial products.

Dr. Bhat has a Ph.D. in Public Policy from The George Washington University where his doctoral research focused on developing methods for measuring the economic impacts of biomedical research. Dr. Bhat also received a Master's in Public Policy and a Bachelor's in Chemistry from Duke University.

Jessica Boehmer, M.B.A.

Regulatory Scientist, Office of Hematology and Oncology Products
FDA

Jessica Boehmer is a Regulatory Scientist in the Office of Hematology and Oncology Products (OHOP) at FDA and works with the Associate Director of Regulatory Affairs to provide regulatory advice to project managers in OHOP. She previously served as a Senior Regulatory Project Manager in the Division of Hematology Products. Prior to joining FDA in May 2012, she acquired more than 10 years of experience in the biotechnology industry with a diverse background including: research and development to optimize real-time PCR-based viral diagnostic assays; performing molecular and tissue culture-based assays for patient sample testing and product release of gene therapy products; and sales, marketing, and business development for biologics contract manufacturing organizations. She earned her MBA from Robert H. Smith School of Business, University of Maryland.

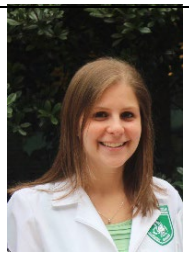


Gideon M. Blumenthal, M.D.

Deputy Director, Oncology Center of Excellence
Associate Director, Precision Oncology
FDA

Gideon M. Blumenthal, M.D. is Deputy Office Director of the Oncology Center of Excellence, and Associate Director for Precision Oncology, FDA. He earned a medical degree and completed internal medicine residency training from the University of Maryland School of Medicine and completed hematology/oncology fellowship at the National Cancer Institute (NCI). At the NCI, his research focused on translational research of oncogene targeted therapy in lung cancer. Since joining the FDA in 2009, Dr. Blumenthal worked as a Medical Oncology reviewer in breast cancer, followed by an appointment as Clinical Team Leader in thoracic oncology and head and neck cancer. He was also an associate investigator on early phase clinical trials in the thoracic malignancy branch of the NCI, treating patients with lung cancer and other thoracic malignancies. Since 2017, he has been involved in the conception and implementation of the Oncology Center of Excellence and in advancing Precision Oncology initiatives for the Agency.

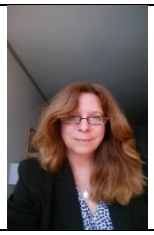
Workshop Panelists



Monica Epstein, B.S.N., R.N., O.C.N.®

Senior Research Nurse Specialist
National Cancer Institute, Surgery Branch-Immunotherapy
National Institutes of Health

Monica is a graduate of the University of Maryland School of Nursing. She has worked in the NIH Clinical Center for 10 years. Monica started at NIH in the Oncology Nurse Residency program on a medical/surgical oncology unit. For the past 5 years she has worked for the Office of Research Nursing, under the Surgery Branch Immunotherapy Section of the National Cancer Institute. She ensures that the integrity of protocols is maintained while also paying close attention to patient safety and needs. She manages and maintains data and toxicity collections as well as regulatory aspects of multiple clinical trials.



Elena Gerasimov, M.P.H., M.A.

Director of Programs
Kids v Cancer

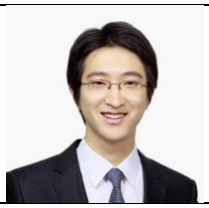
Elena is Director of Programs at Kids v Cancer, a nonprofit pediatric cancer advocacy organization. Kids v Cancer promotes pediatric cancer research by identifying structural impediments at key junctures in the research process and developing strategies to address them. Elena built and for the past three years has directed the Compassionate Use Navigator program, providing guidance and personal assistance to physicians and families in applying for experimental drugs. Previously Elena worked as a science and business journalist, as an epidemiological researcher, and as a program manager at Johns Hopkins University. Elena holds a Master of Public Health degree in maternal and child health and an M.A. degree in journalism.

Monica Hughes

Chief, Project Management Staff
Division of Oncology Products 2
FDA

Ms. Hughes earned her B.S, and M.S., degrees in Combined Science (Biology and Chemistry) and Molecular Biology respectively. She then went on to work as a Pharmaceutical Sales Representative for Eli Lilly; instructed various General Biology Laboratory sections and Science Writing courses at the University of Pittsburgh; and, in 2002, joined the U.S. Food and Drug Administration (FDA) as an Investigator in the Detroit District Office. In 2003, Ms. Hughes transitioned in her career to Regulatory Affairs/Project Management in the Center for Biologics Evaluation and Research (CBER) and subsequently to the Center for Drug Evaluation and Research (CDER) as part of the Office of Hematology Oncology Products, Division of Oncology Products 2 (DOP2). In her Regulatory Affairs career with the Agency, focused mainly in Oncology, Ms. Hughes served in CDER as a Regulatory Health Project Manager from 2003-2007, as a Team Leader from 2007-2012 where she worked both in CDER, and for a period of time (2010-2011), in FDA's newly formed Center for Tobacco Products (CTP) to help lead the science-based implementation of certain provisions of the new Family Smoking Prevention and Tobacco Control Act (FSPTCA); and, then in 2012 to the position she currently holds in CDER as a Chief Project Manager.

In her current position as a Chief Project Manager in DOP2, Ms. Hughes provides support to expanded access requestors through the submission process. Ms. Hughes also wants to increase awareness about expanded access by representing the perspective of a caretaker of a patient with cancer in a smaller rural town.



Chul Kim, M.D., M.P.H

Assistant Professor
Medstar Health
Georgetown University Hospital

Dr. Chul Kim is an Assistant Professor at Georgetown University focusing on thoracic oncology. He strives to bring novel cancer immunotherapies and targeted therapies to the clinic and devise innovative clinical trials to develop personalized cancer treatments. He also aims to reduce health disparities and increase the generalizability of study findings by engaging underrepresented populations in clinical trials. Dr. Kim graduated Summa Cum Laude from Sungkyunkwan University School of Medicine in Seoul, South Korea and obtained his Master's degree in Public Health from Harvard School of Public Health. He received training in internal medicine at the University of Minnesota. He was a clinical fellow in hematology and oncology at the National Cancer Institute of the National Institutes of Health. He received a Norman Rales Young Investigator Award from the Conquer Cancer Foundation of the American Society of Clinical Oncology (ASCO) in 2018.

Michael Menefee, M.D.

Medical Officer
Thoracic and Head and Neck Malignancies Team,
Division of Oncology Products 2
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. He was the inaugural director of phase I clinical trials at Mayo Clinic Florida with a clinical focus on thoracic and endocrine malignancies. During his tenure at Mayo Clinic, Dr. Menefee also served as a permanent member of the FDA Oncologic Drug Advisory Committee.

Judith Carrithers, J.D., M.P.A

Director, Regulatory Affairs
Advarra

Judith Carrithers is an attorney with more than twenty years of professional experience working in the area of human subject protections and ethical oversight. She is currently the Director of Regulatory Affairs at Advarra, which provides IRB, IBC and research quality and compliance consulting services. Prior to joining Advarra in October 2016, she was the Assistant Dean for Human Research Protection at Johns Hopkins University School of Medicine. She serves as co-lead on the Regulatory/Ethics Core Working Group for the NIH Health Care Systems Research Collaboratory, has served as a peer reviewer for the Department of Defense Congressionally Directed Medical Research Programs, presented at local and national conferences, and served as a consultant on research regulatory issues. She holds a JD from Stanford Law School and an MA in Public Administration from Seattle University.