2024 FDA Oncology Center of Excellence Pediatric Advocacy Forum
October 15, 2024

In-Person	**Virtual**
FDA White Oak Campus, Building 31, Great Room	Via Zoom Webinar

BIOGRAPHIES

Pamela Balcazar, MS
Senior Health Scientist, Oncology Center of Excellence

Pamela Balcazar is a Senior Health Scientist at the Oncology Center of Excellence (OCE) at the U.S. Food and Drug Administration (FDA). She joined the FDA in 2015 as a Regulatory Health Project Manager in Division of Oncology 1 (DO1) and in 2017 joined the OCE as a Health Scientist supporting the various regulatory programs. She was one of the founding members of the Oncology Subcommittee of Pediatric Review Committee (PeRC). Pamela received her MS in Regulatory Affairs for Drugs, Biologics and Medical Devices from Northeastern University in 2016.

Najat Bouchkouj, MD
Associate Director for Pediatrics, Office of Therapeutic Products, CBER

Dr. Najat Bouchkouj is a pediatric hematologist oncologist and the Associate Director for Pediatrics in the Office of Therapeutic Products (OTP) at the Center for Biologics Evaluation and Research (CBER). In this role, she acts as a senior advisor, providing support and guidance to the clinical staff in developing regulatory, scientific, and policy initiatives that advance the development of cellular, tissue and gene therapy products for pediatric patients. Dr. Bouchkouj has been with the FDA since 2016, initially joining as a clinical reviewer at the Malignant Hematology Branch of the Division of Clinical Evaluation Hematology at OTP. She earned her M.D. from the University of Damascus, Faculty of Medicine in Syria, and completed her pediatric residency at the State University of New York, Downstate Medical Center, followed by a fellowship in Pediatric Hematology and Oncology at Children's National Medical Center.

Rosane Charlab Orbach, PhD
Team Lead, Pediatrics Group, Office of Clinical Pharmacology

Rosane Charlab Orbach is a Team Lead in the Pediatrics Group, Office of Clinical Pharmacology (OCP), Center of Drug Evaluation and Research, FDA. Her primary work areas include molecular oncology and pharmacogenomics, with a focus in pediatrics. She was previously a Genomics Team Lead in OCP. Prior to joining FDA, she was a member of the team of scientists that annotated the first draft of the Human Genome at Celera Genomics. She holds a Ph.D. degree in Biochemistry from the Federal University of Rio de Janeiro, Brazil.

Martha Donoghue, MD
Associate Director for Pediatric Oncology and Rare Cancers, Oncology Center of Excellence

Martha Donoghue, MD is a board-certified pediatric oncologist and serves as the Associate Director for Pediatric Oncology and Rare Cancers in the FDA's Oncology Center of Excellence, Office of the Commissioner and the Acting Associate Director for Pediatric Oncology in the Office of Oncologic

Diseases, Center of Drug Evaluation and Research (CDER). In these roles, she oversees the implementation of pediatric regulations designed to facilitate the timely investigation of drugs and biological products for pediatric patients with cancer, supports and promotes consistency of regulatory work relating to pediatric oncology and rare cancer drug development across CDER and the Center for Biologics Evaluation and Research (CBER), and works with members of the oncology community to address challenges and foster development of drugs to treat pediatric and other rare cancers. Areas of special interest include the use of innovative clinical trial designs and use of real-world data to optimize drug development for rare cancers. Prior to joining FDA in 2009, Dr. Donoghue completed a fellowship in Pediatric Hematology and Oncology at the Children's National Medical Center after working for several years as a general pediatrician in private practice. She received her medical degree from Emory University and completed a residency in general pediatrics at the Georgetown University Medical Center.

Nicole Drezner, MD
Deputy Director, Division of Oncology 2

Dr. Nicole Drezner is a pediatric oncologist and the Deputy Director of the Division of Oncology 2 (DO2) at the U.S. Food and Drug Administration (FDA). She joined the thoracic and head and neck oncology team in DO2 as a clinical reviewer in 2016, became team lead of the thoracic and head and neck team in 2020, and began her role as Deputy Division Director in 2022. Dr. Drezner completed her residency in pediatrics at Cohen Children's Medical Center of NY. She was selected to serve as chief resident for one year after her pediatric residency and then moved to Washington, DC for her pediatric hematology/oncology fellowship at Children's National Hospital. She remained at Children's National Hospital for an additional year as a pediatric neuro-oncology fellow prior to joining the FDA.

Elizabeth Duke, MD
Clinical Reviewer, Division of Oncology 2

Elizabeth Duke is a Pediatric Neuro-Oncologist serving as a Clinical Reviewer in the Division of Oncology 2 (DO2), in the Office of Oncologic Diseases (OOD), at the U.S. Food and Drug Administration (FDA). She received her M.D. from University of Maryland School of Medicine in 2014. She completed Pediatrics and Child Neurology residencies at Boston Children's Hospital/Harvard Medical School, followed by a Pediatric Neuro-Oncology fellowship at Children's National Hospital in Washington, D.C. Since joining FDA in 2020, Dr. Duke's work has centered on the evaluation of investigational new drugs and marketing applications for drugs and biologics for the treatment of neuro-oncologic and pediatric solid tumors.

Lori Ehrlich, MD, PhD
Clinical Team Leader, Division of Hematologic Malignancies 1

Dr. Lori Ehrlich is a pediatric hematologist/oncologist serving as a clinical team leader in the FDA's Division of Hematologic Malignancies I in the Office of Oncologic Diseases. She joined the FDA in 2014 and reviews drugs for malignant hematology indications with a focus on acute leukemias and pediatric drug development. Dr. Ehrlich completed her residency and fellowship training as a pediatric hematologist-oncologist at the Children's Hospital of Philadelphia. She received her medical degree and doctorate from the University of Pittsburgh School of Medicine.

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Brenda Gehrke, PhD
Supervisory Pharmacologist, Division of Hematology Oncology Toxicology

Dr. Brenda Gehrke is a Supervisory Pharmacologist in the Division of Hematology Oncology Toxicology with the Office of Oncologic Diseases at the US Food and Drug Administration (FDA). Her Pharmacology/Toxicology team reviews the nonclinical pharmacology and toxicology data supporting Investigational New Drug (IND) and marketing applications for drug products for the treatment of hematologic malignancies. Dr. Gehrke received her Ph.D. in Experimental Psychology from the University of Kentucky in 2004 and was a post-doctoral fellow at the National Institute on Drug Abuse from 2004 to 2008. She began working at the FDA as a Pharmacologist in 2008.

Ruby Leong, PharmD
Team Lead, Division of Cancer Pharmacology I

Lieutenant Commander (LCDR) Ruby Leong is a team lead in the Division of Cancer Pharmacology I in the Office of Translational Sciences, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). As a clinical pharmacology team lead, she is part of the multidisciplinary team responsible for the approval of safe and effective drugs for cancer. She joined FDA in 2011. Her previous roles included clinical pharmacology reviewer in the Division of Clinical Pharmacology V, and post-doctoral fellow in the Office of Clinical Pharmacology Immediate Office working on pediatrics physiologically-based pharmacokinetic modeling. LCDR Ruby Leong received a Doctorate of Pharmacy from the University of Michigan and completed a post-doctoral industry fellowship in oncology drug development at Rutgers University/Hoffmann-La Roche. She has board certification in oncology pharmacy and practices as a volunteer oncology pharmacist at the Walter Reed National Military Medical Center Hematology/Oncology Pharmacy.

Pallavi Mishra-Kalyani, PhD
Deputy Director, Division of Biometrics V

Pallavi Mishra-Kalyani, Ph.D. is the Deputy Division Director of the Division of Biometrics V, Office of Biostatistics which supports Office of Oncology Drugs at the Center for Drug Evaluation and Research (CDER). Since joining the Food and Drug Administration (FDA) in 2015, Dr. Mishra-Kalyani has contributed to the efforts to understand and address the statistical issues related to the potential use of Real-World Data and Real-World Evidence for regulatory purposes. Her research interests include statistical methods for observational data, causal inference, and non-randomized trial design. She has participated at several statistics and oncology workshops, conferences, and working groups on these topics. Dr. Mishra-Kalyani received her Ph.D. in Biostatistics from Emory University and her Master's degree in Epidemiology from the T.H. Chan School of Public Health at Harvard University.

Lauren Price, PharmD
Team Lead, Division of Cancer Pharmacology II

Lauren Price, PharmD, is a Clinical Pharmacology Team Lead in the Division of Cancer Pharmacology II, Office of Clinical Pharmacology, US Food & Drug Administration. Dr. Price received a PharmD from the

University of Washington School of Pharmacy and subsequently completed an academic oncology fellowship at the University of North Carolina Eshelman School of Pharmacy. She joined FDA in 2018 as a Clinical Pharmacology Reviewer supporting review of oncology products and has special interest in pediatric drug development.

Nicholas Richardson, DO, MPH
Deputy Director, Division of Hematologic Malignancies 2

Nicholas C. Richardson DO, MPH, is the Deputy Division Director for the Division of Hematologic Malignancies 2 at the U.S. Food and Drug Administration, which oversees the development of products for patients with lymphoma, chronic lymphocytic leukemia, and multiple myeloma. Dr. Richardson joined FDA in 2016 and in his role, he actively engages with the lymphoma and CLL communities regarding development and utilization of MRD or ctDNA and innovative clinical trial designs. He also has an active role in several pediatric oncology initiatives in the Oncology Center of Excellence. Dr. Richardson completed his pediatric fellowship in pediatric hematology-oncology at Vanderbilt University Medical Center.

Haleh Saber, PhD
Acting Director, Division of Hematology Oncology Toxicology

Dr. Saber is the Acting Director in the Division of Hematology Oncology Toxicology (DHOT), in the Office of Oncologic Diseases (OOD), in CDER. In this role she provides leadership for day-to-day activities, participates in inter-Agency initiatives, leads and coordinates scientific research, and participates in guidance development. Dr. Saber is a member of the OCE Pediatric Review Committee (PeRC) and engages in discussions on nonclinical proof-of-concept studies for molecularly targeted products. Dr. Saber has over 20 years of experience in drug development in pharmaceutical industry and at the FDA. She was the lead author of several guidance documents, including *Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations*, and *Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations*. She is recognized for her efforts in establishing acceptable approaches in first-in-human dose selection for new classes of products. Dr. Saber received her PhD in Biochemistry from Lehigh University, PA, and conducted her post-doctoral studies at Fox Chase Cancer Center, PA.

Stacy Shord, PharmD
Deputy Division Director, Division of Cancer Pharmacology II

Stacy S. Shord, PharmD, BCOP, FCCP, is a Deputy Director in the Division of Cancer Pharmacology II in the Office of Clinical Pharmacology within U.S. Food and Drug Administration. Dr. Shord received her Doctor of Pharmacy from University of Maryland School of Pharmacy. She then completed a Pharmacy Practice residency at the University of Pittsburgh Medical Center, an Oncology Pharmacy Practice residency at UNC Hospitals, and a fellowship in Oncology Pharmacotherapy at the UNC Eshelman School of Pharmacy. Dr. Shord joined the faculty at the University of Illinois at Chicago College of Pharmacy in 2001 as an assistant professor where her research focused on drug metabolism in patients with cancer and hematological diseases. She joined the Food and Drug Administration in 2009 and served as a

primary reviewer and Lead Pharmacologist in the Office of Clinical Pharmacology and an Associate Director of Labeling in the Office of Oncologic Diseases. Special interests include dosage optimization, labeling and pediatric drug development. Dr. Shord earned her Board Certification in Oncology Pharmacy in 2000. She has authored 55 peer-reviewed papers and 10 book chapters. Dr. Shord is a member of ASCPT, ASCO, ACCP and HOPA.

Sonia Singh, MD
Clinical Reviewer, Division of Oncology 2

Sonia Singh, MD, is a pediatric oncologist and clinical reviewer at the U.S. Food and Drug Administration (FDA). She completed a residency in Pediatrics at New York Presbyterian/Weill Cornell Medical Center, followed by a fellowship in Pediatric Hematology/Oncology at Memorial Sloan Kettering Cancer Center. Since joining the FDA in 2018, she has served as a clinical expert to guide drug development programs investigating therapies for pediatric cancers, neuro-oncologic diseases, and rare tumors.

Kristin Wessel, MD
Clinical Reviewer, Division of Oncology 2

Dr. Kristin Wessel is a pediatric hematologist/oncologist serving as a medical officer for the Division of Oncology 2 in the Office of Oncologic Diseases on the team dedicated to neurologic, pediatric, and rare cancers. Prior to joining the FDA, Dr. Wessel completed her pediatric residency at the University of Chicago and went on to complete her pediatric hematology/oncology training at Johns Hopkins Children's Center and the National Cancer Institute in Maryland. Dr. Wessel spent an additional year as an Advanced Clinical Fellow in the Pediatric Oncology Branch of the National Cancer Institute, where she focused on translational research in pediatric sarcomas as well as early-phase clinical trials in pediatric patients with solid tumors.