SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

Day 1 Presenters

Marc Theoret
Deputy Director
Oncology Center of Excellence (OCE)
US FDA

Dr. Marc Theoret is a medical oncologist and serves as Deputy Director in the Oncology Center of Excellence (OCE), FDA, and Acting Supervisory Associate Director of Oncology Sciences in the Office of Oncologic Diseases (OOD), Center for Drug Evaluation and Research, FDA. Dr. Theoret earned his medical degree from the Penn State College of Medicine. He completed internship and residency training in Internal Medicine at the Beth Israel Deaconess Medical Center in Boston, and fellowship training in Hematology and Oncology at the National Cancer Institute (NCI) in Bethesda. While a medical student as a Howard Hughes Medical Institute-National Institutes of Health (NIH) Medical Student Research Fellow and subsequently during fellowship training, he performed basic and translational clinical research in the Surgery Branch, NCI, to investigate novel immunotherapeutic strategies to treat patients with melanoma and other advanced solid tumors.

In 2009, Dr. Theoret came to FDA and served as medical officer in the Division of Biologic Oncology Products and then in the Division of Oncology Products (DOP) 2. He served as the Clinical Team Leader of the Melanoma-Sarcoma team, DOP2, from 2013 to 2017. Subsequently, he served as Associate Director of Immunotherapeutics in the Office of Hematology and Oncology Products (OHOP) as well as an Acting Associate Director of Immuno-oncology Therapeutics in the Oncology Center of Excellence. Prior to his current position as Deputy Director in the OCE, he served as the Acting Deputy Office Director in OOD. In these roles in OHOP / OOD and OCE, Dr. Theoret has led the reviews of numerous breakthrough therapies, new molecular entities, and novel biologics. Dr. Theoret has contributed extensively to initiatives—regulatory, scientific, and policy efforts—in cancer therapeutic development, in particular immuno-oncology therapeutics, and consistently has provided FDA leadership in this field to wide-ranging external stakeholders.

Jeffrey Summers, MD
Associate Director
Translational Sciences Office of Oncologic Diseases (OOD)
US FDA

Jeff Summers, MD is a pediatric oncologist and serves as an Associate Office Director in the Office of Oncology Drug Products at the U.S. Food and Drug Administration. Dr. Summers earned his medical degree from the University of Washington School of Medicine. He was a postdoctoral fellow at Fred Hutchinson Cancer Research Center from 1990 to 1995. He completed fellowship training in Pediatric Hematology and Oncology in 2002 at the National Cancer Institute (NCI) in Bethesda, MD.

Keith Marmer, DPT, MBA
Chief Innovation & Economic Engagement Officer
University of Utah

Keith Marmer, DPT, MBA, serves as Chief Innovation & Economic Engagement Officer at the University of Utah. In this role, Keith has transformed the culture of commercialization at University of Utah, launching three accelerators, a business incubator and a venture fund to support startup companies, facilitating the creation of 52 companies, and generating more than $60 million in university revenue from licensing and industry collaborations. His strong leadership skills come from 30 years of experience as an inventor, entrepreneur and investor. He has three patents, launched three companies, and helped entrepreneurs raise more than $1 billion in investment capital. Previously, Keith was co-founder and managing director of SG3 Ventures, a venture capital fund focused on early-stage life science companies. Prior to SG3 Ventures, Keith was chief business officer at Penn Center for Innovation, University of Pennsylvania. Before his university-based commercialization roles, he was an entrepreneur, founding and scaling two companies and co-founding a consulting firm that advised early-stage growth companies. Across his career, Keith has launched, help to launch or overseen teams responsible for starting more than 140 companies. Keith serves, and has served on numerous corporate and non-profit boards and is a past entrepreneur-in-residence at Princeton University. He received an MBA, Doctor of Physical Therapy, Master of Physical Therapy and Bachelor of Science in Health Sciences from University of the Sciences.

John Leighton, PhD
Director
Division of Hematology, Oncology, Toxicology (DHOT)
OOD | CDER | US FDA

John K. Leighton, PhD is the Director of the Division of Hematology Oncology Toxicology (DHOT) in the Office of Oncologic Diseases in CDER, where his primary responsibility is providing policy direction and review oversight of nonclinical studies submitted to support IND, NDA and BLA applications for oncology. Dr. Leighton received his PhD in 1984 from the Department of Physiology and Biophysics at the University of Illinois, Urbana-Champaign, working on cloning and characterization of phenobarbital-induced rabbit liver cytochrome P450s. Dr. Leighton first came to FDA in 1993 as a reviewer in the Center for Veterinary Medicine and moved in 1998 to the Division of Oncology Drug Products (DODP) in CDER as a reviewing pharmacologist/toxicologist. He served as FDA's Topic Lead and Rapporteur for ICH S9 (2009) and Rapporteur for the ICH S9 Q&A (2018) guidances for anticancer pharmaceuticals and is Deputy Topic Lead for FDA for ICH Q3D and its addendum for Elemental Impurities. Dr. Leighton is co-chair of the Pharmacology/Toxicology Coordinating Committee Subcommittee for Computational Toxicology.

Deepa Narayanan
Program Director & Team Lead
NCI Small Business Innovation Research Development Center
National Cancer Institute, NIH

Deepa Narayanan is a Lead Program Director in the Small Business Innovation Research (SBIR) Development Center at the National Cancer Institute (NCI), where she assists small businesses in securing funding for innovative cancer startups. In addition to funding, Deepa focuses on developing several non-funding resources to accelerate commercialization for federally funded businesses including investor initiatives, regulatory assistance, mentoring programs and webinars and workshops for entrepreneurial training.

Deepa has extensive experience with the research, development and commercialization of medical devices and molecular imaging technologies. Previously she was the Director of Clinical Data Management at Naviscan, Inc. where she managed all aspects of clinical trials including FDA-regulated multi-center clinical trials for 510(K) clearance as well as phase IV post marketing studies. Prior to Naviscan, Deepa was a Scientific Associate with the Molecular Imaging laboratory at Fox Chase Cancer Center. Deepa is a certified Clinical Data Manager and has a Master's degree in Biomedical Engineering from the University of Virginia and a Bachelor's degree in Biomedical Engineering from University of Mumbai.

Colleen Cuffaro, PhD
Partner
Canaan Partners

Dr. Colleen Cuffaro is a Partner on Canaan Partner's healthcare investment team. She currently serves on the boards of Arrakis Therapeutics, Comet Therapeutics and the NEVCA (New England Venture Capital Association). She also serves as a board observer at RallyBio and Antiva Biosciences. Previously she was a board observer at Spyryx Biosciences, NextCure (NXTC), Arvinas (ARVN), and Novira Therapeutics which was acquired by Johnson & Johnson. Prior to joining Canaan in 2014, Colleen was an analytical chemist at Pharmaceutical Manufacturing and Research Services (PMRS, Inc), where she worked with small and large pharmaceutical companies on drug product development, ranging from preclinical feasibility studies to commercial supply. She also served as a bioscience analyst for Entrepreneurship Lab NYC, an accelerator program for healthcare startups. Colleen holds a PhD in Cellular and Molecular Physiology from Yale University and a BA in Chemistry from the University of Pennsylvania.

Christy Shaffer, PhD
Partner
Hatteras Venture Partners

Seasoned entrepreneur and biotech executive, Christy Shaffer, Ph.D. has 30 years of experience in the life science industry. Following her career as a clinical scientist, international project leader and Associate Director of Pulmonary and Critical Care Medicine at Burroughs Wellcome Co., she joined Inspire Pharmaceuticals in 1995 as the first, full-time employee. She was responsible for raising over $300m for the company, including taking the company public in 2000. As President and CEO, Christy grew the company from 20 scientists to nearly 250 employees with revenues of over $100 million. Under her leadership, Inspire was named as "Best Place to Work for Scientists" by the Scientist magazine, and "Best Place to Work in North Carolina." Christy retired from Inspire in 2010 and the company was acquired by Merck in 2011. She joined Hatteras in 2011 as the Managing Director of Hatteras Discovery and became a general partner in 2016.

Christy currently serves as a board member of five Hatteras portfolio companies: Artizan Biosciences (Chair), Clearside Biomedical, GrayBug Vision (Chair), Trefoil Therapeutics, and Perfuse Therapeutics. Christy is a receptor pharmacologist by training, earning her Ph.D. in Pharmacology from the University of Tennessee Health Science Center, Memphis TN in 1985. She received her post-doctoral training at The Chicago Medical School and the University of North Carolina at Chapel Hill.

Community and Board Engagements:
Christy was a member of the initial Innovation Circle for Entrepreneurship at UNC-Chapel Hill from 2010 – 2013. She has served on numerous non-profit boards including the NC Biotechnology Center, the Biotechnology Institute, BIO, PhRMA the Cystic Fibrosis Foundation and the CFF Therapeutics's Inc., the NC School of Science and Math Foundation Board and the Morehead Planetarium and Science Center. She received the Lifetime Women in Business Award by the Triangle Business Journal in 2016 and was named one of the top BizWomen to Watch in December 2016. Christy currently serves on multiple non-profit boards including the Chordoma Foundation, the Council for Entrepreneurial Development, the Burroughs Wellcome Regulatory Initiative Advisory board and RTI International.

Julie M. Bullock, PharmD
VP, Global Head of Clinical Pharmacology and Translational Medicine
Certara, Integrated Drug Development

Dr. Julie Bullock is currently the Vice President and Head of Clinical Pharmacology & Translational Medicine at Certara. She has over 16 years of drug development experience and is a recognized drug development scientist with clinical pharmacology and regulatory experience focused in the therapeutic areas of hematology/oncology and coagulation. Julie has extensive experience in all development phases including regulatory interactions with major global health authorities (FDA, EMA, PMDA), due diligence, design of clinical development approaches, pediatrics, dose-finding strategy and streamlining development for breakthrough therapies and accelerated approval.
In her current role, Dr. Bullock supports a global team of clinical pharmacologists, regulatory strategy and drug development scientists who create value for clients across the drug development ecosystem and ultimately accelerate patients' access to medicines.
Prior to her role at Certara Dr. Bullock was the Clinical Pharmacology Team Leader for the Hematology/Oncology review team in the Office of Clinical Pharmacology at the Center for Drug Evaluation and Research at the FDA. Julie's FDA career spanned 10 years where she contributed to over 14 new molecular entity NDA/BLA filing applications, multiple supplemental NDA/BLA applications, countless IND related submissions submitted to the hematology/oncology division.
Dr. Bullock received her Doctor of Pharmacy from Drake University and completed a clinical pharmacology drug development fellowship with the State University of New York at Buffalo and Novartis Pharmaceuticals.

Christopher Scull, PhD, PMP, RAC
Senior Consultant
Biologics Consulting

Christopher Scull, PhD, is a senior consultant on the nonclinical team at Biologics Consulting. Dr. Scull's expertise includes product development strategy, design and management of pharmacology and toxicology studies, writing and reviewing FDA submissions, and achieving GLP compliance.
Prior to joining Biologics Consulting, Chris served as Global Director, Discovery Sciences, at Innovimmune Biotherapeutics, where he managed development of a portfolio of pre-IND drug candidates. In addition to being the site-head for the Brooklyn-based research team, Chris was responsible for preclinical development planning and management of nonclinical studies.
Dr. Scull also served in multiple roles at Memorial Sloan Kettering Cancer Center (MSKCC). As a member of the Investigational Products team, he co-authored and reviewed IND applications and assisted investigators with FDA compliance during the design and conduct of pharmacology and toxicology studies. In a subsequent role at MSKCC, Chris led the establishment of a new testing facility for GLP-compliant nonclinical studies which included the design of laboratory and animal facilities, installation and validation of new equipment, authoring of SOPs, and training of personnel for GLP compliance.
Chris received his BS in Chemistry and PhD in Cellular and Molecular Pathology from UNC Chapel Hill. He completed postdoctoral training at Columbia University, is a member of the American College of Toxicology, and also holds the Regulatory Affairs Certification (RAC) from the Regulatory Affairs Professionals Society. Chris has also served on the Grants Working Group of the California Institute of Regenerative Medicine (CIRM) since 2017.

Kimberly Schultz PhD
Gene Therapy Reviewer
Division of Cellular & Gene Therapies Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Dr. Kimberly Schultz is a Gene Therapy Product Reviewer in the Division of Cellular and Gene Therapies (DCGT) at FDA's Center for Biologics Evaluation (CBER). She is responsible for review of pre-IND, IND, and BLA submissions for gene therapy products, specializing in ex vivo modified cells and adeno-associated virus (AAV) vectors. Kim actively participates in inter- and intra-agency working groups, meetings, and conferences focused on advancing cell and gene therapy products and has contributed to regulatory guidance documents for gene therapy products. She was a member of the BLA review team for the first approved CAR T cell therapy product (KYMRIAH).
Kim joined the FDA in 2015 as a Commissioner's Fellow to conduct a cross-study analysis of CAR T cell CMC data. Prior to joining the FDA, she received her PhD from the University of Wisconsin and conducted postdoctoral studies at Johns Hopkins Bloomberg School of Public Health specializing in virology and immunology.

Bo Liang, PhD
Gene Therapy Reviewer
Division of Cellular & Gene Therapies (DCGT)
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Dr. Bo Liang is a gene therapy CMC reviewer in the Division of Cellular and Gene Therapies (DCGT), Office of Tissues and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research (CBER). He joined CBER OTAT in 2019. Dr. Liang is primarily responsible for reviewing oncolytic viruses, viral vector-based cancer vaccines, and adeno-associated virus (AAV) vectors. He has worked on numerous pre-INDs, INDs, and BLAs, and also participated in pre-approval inspection of manufacturing facility.

Dr. Liang earned his Ph.D. degree in 2011 from the University of Missouri-Columbia, where he was trained as a virologist. His major focus of study was the mechanisms that regulate the replication/reactivation of human polyomavirus BK. He completed his postdoctoral training in preclinical development of live-attenuated paramyxovirus-based vaccines at the National Institute of Allergy and Infectious Diseases (NIAID), NIH. After his postdoctoral training, he continued to work at NIAID as a Research Fellow on the development of pediatric vaccines against human respiratory syncytial virus (RSV) and parainfluenza viruses (PIVs).

Ying Huang, PhD
Pharmacology/Toxicology Reviewer
Division of Clinical Evaluation and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Dr. Ying Huang joined FDA/CBER/OTAT/DCEPT in 2004 and is a Pharm/Tox master reviewer responsible for the review of regulatory submissions for cell and gene therapies, including genome editing and edited products on oncology and non-oncology diseases. She is the FDA Topic Leader in the ICH S12 Expert Working Group on Non-clinical Biodistribution Studies for Gene Therapy Products. Prior to the FDA, Dr. Huang received her Ph.D. degree in Pharmacology and Toxicology at the University of Toronto, Canada, and subsequently an NIH IRTA fellowship before became a senior scientist at former Genetic Therapy Inc., a Novartis Company.

Peter Bross, MD
Chief (Acting) Oncology Branch
Division of Clinical Evaluation and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Peter Bross, MD is acting Chief of Oncology Branch and clinical team leader in the FDA Center for Biological Evaluation and Research (CBER), Office of Tissue and Advanced Therapies (OTAT) and previously worked as a clinical reviewer in the Division of Oncology Drug Products in the Center for Drug Evaluation and Research (CDER). Over 20 years at FDA, Dr. Bross has gained expertise in the design and analysis of clinical oncology trials of cellular, tissue and gene therapies, especially cancer vaccines, combination therapies, and companion diagnostics. As a regulatory reviewer, he has reviewed new molecular entities for marketing approvals in solid tumors and hematological malignancies, including oncolytic viruses, cellular immunotherapies, targeted kinase inhibitors, proteasome inhibitors and an antibody-drug conjugate. He has presented FDA perspectives at professional meetings and review findings at FDA advisory committee meetings and has authored several manuscripts. Dr. Bross is a graduate of University of Virginia Medical School and trained in Hematology and Oncology at The George Washington University and has been at FDA since 1999.

Day 2 Presenters

Jeffrey Summers, MD – *(see biography on Day 1)*
Associate Director
Translational Sciences Office of Oncologic Diseases (OOD)
US FDA

Paresma Patel, PhD
Acting Branch Chief, Division of New Drug API
Office of Pharmaceutical Quality (OPQ)
Office of New Drug Policy (ONDP)
CDER | US FDA

Dr. Paresma Patel is a Quality Assessment Lead in the Office of New Drug Products, Division of New Drug API. She started at the FDA in 2015 as a review chemist supporting the oncology divisions. She has worked across multiple clinical divisions as a drug substance and drug product CMC reviewer and served as a quality lead for the last two years. Prior to FDA, she worked as a medicinal chemist at the National Institutes of Health with a focus on target validation and lead optimization of small molecule kinase inhibitors. Dr. Patel completed her Ph.D. in organic chemistry at The Scripps Research Institute in 2005 working on the development and application of novel cycloaddition synthetic methods, and then went on to complete a postdoctoral fellowship at the California Institute of Technology working on the development of novel ruthenium-based catalysts and synthesis of bioactive polymers.

Olen Stephens, PhD
Chemistry, Manufacturing, and Controls Small Molecule Reviewer
Office of Pharmaceutical Quality (OPQ) Office of New Drug Policy (ONDP)
CDER | US FDA

Dr. Olen Stephens is a chemistry reviewer for the CMC branch that supports the Oncology Center for Excellence. Over the past 12 years, he has served as a reviewer, CMC lead, and acting branch chief to support over half the clinical division in the Office of New Drugs at CDER. His formal training began as a bioorganic chemist at the University of Utah for his Ph.D., where he studied double stranded RNA ● protein interactions and continued as a post-doc at Yale in biophysical chemistry, designing de novo secondary structures using □-peptides. Olen currently serves as the CDER Nanotechnology Working Group Coordinator and on the FDA Nanotechnology Taskforce

Kristen Nickens, PhD
Product Quality Team Lead
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ)
CDER | US FDA

Dr. Kristen Nickens is a Product Quality Team Lead in the Office of Biotechnology Products (OBP), Office of Pharmaceutical Quality, Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). Her regulatory career began at the FDA in 2013 as a National Institutes of Health-FDA Interagency Oncology Task Force Fellow in the Center for Biologics Evaluation and Research (CBER), after which, she joined CDER/OBP as a product quality assessor in 2014. Throughout her tenure in the FDA, Dr. Nickens has acquired extensive regulatory expertise in the lifecycle management of biotechnology products from early-phase development through post-licensure for products under both 351(k) and 351(a) regulatory pathways. Dr. Nickens received her Ph.D. in Molecular Medicine with a concentration in Oncology from The George Washington University's Institute for Biomedical Sciences in Washington, DC and completed a post-doctoral fellowship at the Henry M. Jackson Foundation's Center for Prostate Disease Research in Rockville, MD.

Wendy Weinberg, PhD
Chief, Laboratory of Molecular Oncology
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ
CDER | US FDA

Dr. Weinberg is Senior Investigator and Chief of the Laboratory of Molecular Oncology (LMO) in the Office of Biotechnology Products (OBP), CDER, FDA. As Laboratory Chief, she supervises the regulatory work of a team of researcher-reviewers in OBP where she participates in policy development and is responsible for product quality review of Investigational New Drug applications and Biologic License Applications, primarily antibody-based therapies targeting signaling pathways for oncology indications. To support the regulatory review, Dr. Weinberg also oversees a research program focused on in vivo, in vitro and in silico modeling of molecular events contributing to multistep squamous cancer pathogenesis and therapeutic efficacy.

Whitney Helms, PhD
Supervisor
Pharmacology/Toxicology
Division of Hematology, Oncology, Toxicology (OOD)
CDER | US FDA

Whitney Helms, PhD is a pharmacology supervisor in the Division of Hematology Oncology Toxicology for the team supporting the Division of Oncology 2 in CDER's Office of Oncologic Diseases at the FDA, serving in this role since 2012. She started at the Agency as a pharmacologist in the Division of Drug Oncology Products following a postdoctoral fellowship at UAB where she worked on Th17 cell commitment in the laboratory of Dr. Casey Weaver. Before moving to UAB, she completed her Ph.D. in immunology at UNC-Chapel Hill working on G alpha 13 pathway signaling in T cell development and activation.

Martha Donoghue, MD
Acting Deputy Director
Division of Oncology 2
Office of Oncologic Diseases (OOD)
Office of New Drugs (OND)
CDER | U.S. FDA

Martha Donoghue, MD is the Acting Deputy Director of the Division of Oncology 2 in the Office of Oncologic Diseases at the U.S. Food and Drug Administration (FDA). Dr. Donoghue provides regulatory oversight, engages in clinical review activities, and advises stakeholders regarding strategies for clinical development of drugs and therapeutic biologics for the diagnosis, prevention, and treatment of cancer. Areas of special interest include development of treatments for rare cancers and the use of innovative designs in clinical trials to optimize drug development. 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.

Donna M. Roscoe, Ph.D.
Deputy Director, Molecular Genetics and Pathology Division
Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health | US FDA

Dr. Donna Roscoe is the Deputy Director for the Molecular Genetics Branch in the Division of Molecular Genetics and Pathology in FDA's Office of In Vitro Diagnostic Device Evaluation and Radiological Safety having previously served as Chief of the Molecular Genetics Branch in the Division which is responsible for reviewing IVDs principally in the area of oncology, companion diagnostics and hereditary genetics. Prior to coming to the FDA, Dr. Roscoe worked for various

CROs and the National Center for Biotechnology Information (NCBI) after completing a post-doctoral fellow in the clinical cancer research Laboratory of Molecular Biology at the National Cancer Institute (NCI) at NIH.

Anthony Fotenos, MD
Lead Medical Officer
Division of Imaging and Radiation Medicine
US FDA

Anthony Fotenos, MD works as a lead medical officer in FDA's Division of Imaging and Radiation Medicine. He has served on multiple review teams responsible for approving new diagnostic radiopharmaceuticals, as well as new indications for iodinated and gadolinium-based contrast agents. His team of physicist, radiation oncologist physician, and nuclear medicine physician reviewers provides subject matter expertise to therapeutic review divisions throughout FDA on questions related to radiation dosimetry; theranostic use of imaging and imaging agents; and a new regulatory pathway at the intersection of drug and device law specific to imaging agents. He is board-certified in nuclear medicine and has worked clinically in Baltimore at the MedStar Franklin Square and Johns Hopkins hospitals, where he trained in radiology and nuclear medicine. He is a graduate of the Medical Scientist Training Program at Washington University in St. Louis. His contributions to the peer-reviewed literature have focused on structural neuroimaging of the aging and Alzheimer's brain and on improving diagnostic study endpoints in research and time-to-diagnosis in practice. In his free time, he enjoys spending time with family (especially in the mountains of West Virginia and Lake Tahoe), streaming media, and hacking away at software/hardware hobby projects.

Donika Plyku, PhD
Senior Staff Fellow
Division of Imaging and Radiation Medicine
Office of Specialty Medicine
Office of New Drugs (OND)
CDER | US FDA

Donika Plyku, PhD works as a senior staff fellow at the FDA's Division of Imaging and Radiation Medicine. She leads a research team that focuses on regulatory challenges regarding radiation dosimetry of diagnostic and therapeutic radiopharmaceuticals. She provides subject matter expertise to review decisions throughout FDA on questions related to radiation dosimetry. She is a nuclear medicine physicist and has worked at the Johns Hopkins Hospital PET center and Division of Nuclear Medicine and at MedStar Washington Hospital Center after completing a post-doctoral fellowship at the Radionuclide Therapy and Dosimetry Laboratory, Johns Hopkins University, Radiological Physics Division. She has clinical experience on quality assurance, instrumentation and radiation dosimetry in nuclear medicine. She received her PhD from Old Dominion University, Norfolk, VA after completing her research in the nuclear/high-energy physics at the Relativistic Heavy Ion Collider, Brookhaven National Laboratory, Long Island, NY. Throughout her career, Dr. Plyku has received several teaching and research awards and has published in peer-reviewed journals in both nuclear and medical physics fields. Her contributions in nuclear medicine have focused on patient-specific radiobiological dosimetry for radiopharmaceutical therapy and on dose reduction in pediatric molecular imaging. She is an active member of the Society of Nuclear Medicine and Molecular Imaging Women in Nuclear Medicine and the American Association of Physicists in Medicine. In her free time, she enjoys spending time in nature, learning foreign languages and reading about history of science and religion. She greatly enjoys participating in community service and inter-faith dialogue events.

Brian Booth, PhD
Director
Division of Cancer Pharmacology 1
Office of Clinical Pharmacology (OCP)
Office of Translational Science (OTS)
CDER | US FDA

Brian Booth, Ph.D. is the Director of the Division of Cancer Pharmacology I, in the Office of Clinical Pharmacology at the U.S. Food and Drug Administration. Dr. Booth obtained a Bachelor of Science in Physiology at McGill University in 1988, and subsequently pursued a Doctorate in Pharmacology and Toxicology at Queen's University (1993) in Canada. Following a Post-Doctoral Fellowship in the Department of Pharmaceutics at the State University of New York at Buffalo, where he studied the interaction between nitric oxide donors and the neuropeptide calcitonin gene-related peptide, Dr. Booth joined the Office of Clinical Pharmacology and Biopharmaceutics, FDA, in 1998. In 2004, he became the Acting Team Leader in the Division of Oncology Drug Products, after serving as a reviewer/pharmacometrician in this division. In November 2006, Dr. Booth was appointed as Deputy Director of the Division of Clinical Pharmacology V. At the FDA, Dr. Booth has been involved with the clinical pharmacology development of several hundred new oncology drugs, ranging from phase 1 to phase 4. In addition to IND and NDA reviews, Dr. Booth has been involved with teaching and development of new clinical pharmacology reviewers and medical officers, development of the bioanalytical method validation, food effect studies, PPI DDI studies, clinical pharmacology of ADCs, liposome drug product and studies in hepatic impairment Guidances for Industry, and clinical pharmacology modeling and simulation projects. He has authored 70 peer reviewed articles and book chapters. Dr. Booth is a member of AAPS.