CDER Prescription Drug Labeling Conference 2019

Speaker Biographies

Jibril Abdus-Samad, PharmD

Policy Lead
Compendial Operations and Standards Staff
Office of Policy for Pharmaceutical Quality, CDER, FDA

Lieutenant Commander (LCDR) Jibril Abdus-Samad is a pharmacist in the U.S. Public Health Service. Currently, he works at FDA in the Center for Drug Evaluation and Research (CDER), Office of Policy for Pharmaceutical Quality in the Compendial Operations and Standards Staff. He serves as a Government Liaison to the United States Pharmacopeia Nomenclature and Labeling Expert Committee. Previously, he was the Labeling Reviewer for the Office of Biotechnology Products (OBP) in CDER in which he evaluated labeling for biological products for compliance with labeling regulations. Prior to OBP, LCDR Abdus-Samad served as a Safety Evaluator within the Division of Medication Error Prevention and Analysis at FDA for 6+ years. He practiced in various pharmacy settings within Veterans Affairs and the private sector. LCDR Abdus-Samad received his PharmD from the University of the Sciences in 2000 and a Graduate Certificate in Patient and Product Safety from the University of Southern California in 2010.

Kristie Baisden DO, FACOG

Medical Officer
Maternal Health Team
Division of Pediatric and Maternal Health (DPMH)
Office of New Drugs (OND), CDER, FDA

Kristie Baisden, DO, FACOG is a board certified OBGYN. She joined the FDA in 2017 as a medical officer on the Maternal Health Team within the Division of Pediatric and Maternal Health (DPMH). The Maternal Health Team is responsible for evaluating the safe use of drug and biologic products in pregnant and lactating women; including review of labeling and study protocols, as well as policy development. Prior to joining FDA, Dr. Baisden spent six years in OBGYN clinical practice at Georgetown University Hospital and served as Assistant Professor at the Georgetown School of Medicine.

Debra Beitzell, BSN

Clinical Advisor for Labeling
Labeling Policy Team (LPT)
Office of New Drugs (OND), CDER, FDA

As a clinical advisor for labeling, Ms. Beitzell participates in the implementation of prescribing information regulations, guidances, and policies, assists in the development and review of the prescribing information, participates in guidance development, provides labeling review training, and provides oversight of labeling quality and consistency. Previously, Ms. Beitzell served as a Senior Regulatory Project Manager in CBER. Prior to joining the FDA, Ms. Beitzell practiced as a Registered Nurse in cardiac inpatient and outpatient facilities. She received a Bachelor of Science in Nursing from the University of Maryland School of Nursing.

Eric Brodsky, MD

Associate Director
Labeling Policy Team (LPT)
Office of New Drugs (OND), CDER, FDA

As the Associate Director of the LPT, Dr. Brodsky oversees OND's implementation of prescribing information regulations, guidances, and policies to help promote consistency in labeling practices across CDER; provides labeling review training; develops labeling resources for CDER staff and industry; provides oversight of labeling quality; and assists review teams in review and development of the prescribing information. Previous OND roles included the labeling team leader of the LPT; and medical officer in three review divisions (i.e., the Division of Pulmonary, Allergy, and Rheumatology Products; the Division of Anesthesia, Analgesia, and Addiction Products; and the Division of Gastroenterology and Inborn Errors Products). Prior to joining the FDA, Dr. Brodsky practiced as an internist with a focus in primary care and hospital medicine in the Washington D.C. area. He received his medical degree from Tufts University School of Medicine, completed an internal medicine residency program at the University of Massachusetts Medical Center, and is board certified in Internal Medicine.

Miriam Dinatale, DO

Maternal Health Team Leader
Division of Pediatric and Maternal Health (DPMH)
Office of New Drugs (OND), CDER, FDA

As a Maternal Health team leader, Dr. Dinatale oversees quality initiatives that improve pregnancy and lactation-related information in product labeling. Prior to her role as team leader, Dr. Dinatale served as a medical officer in DMPH. Dr. Dinatale received her medical degree from the New York College of Osteopathic Medicine. She completed her residency training in Family Medicine at Malcolm Grow Medical Center, Joint Base Andrews, and is board certified in Family Medicine. Prior to joining the FDA, Dr. Dinatale practiced Family Medicine at Joint Base Andrews and served as an officer in the United States Air Force. Dr. Dinatale is a commissioned officer in the United States Public Health Service and has been at the FDA for six years.

John Gallagher

Science Policy Analyst
Labeling Policy Team (LPT)
Office of New Drugs (OND), CDER, FDA

As a Science Policy Analyst on the Labeling Policy Team, Mr. Gallagher participates in the implementation of prescribing information regulations, guidances, and polices, assists in the development and review of the prescribing information, provides labeling review training, and provides oversight of labeling quality and consistency. Prior to joining the FDA, Mr. Gallagher developed HIV therapeutics at the National Institutes of Health in the National Institute of Allergy and Infectious Disease. He has a Bachelor of Science degree in Microbiology from the University of Maryland.

Jessica Greenbaum J.D.

Regulatory Counsel
Office of Therapeutic Biologics and Biosimilars
CDER, FDA

Jessica Greenbaum is a Regulatory Counsel in CDER's Office of Therapeutic Biologics and Biosimilars, which oversees the development and implementation of regulatory policy related to biosimilar, interchangeable, or other therapeutic biologic products. Previously, Ms. Greenbaum was an Associate Chief Counsel in FDA's Office of the Chief Counsel, where her portfolio included issues related to drugs and tobacco products. Prior to joining FDA, Ms. Greenbaum was a litigator at Gibson, Dunn & Crutcher LLP handling patent litigation disputes relating to pharmaceutical and biotechnology products. She earned her J.D. from New York University School of Law and her B.S. in cognitive neuroscience from Brown University.

LaShawn Griffiths MSHS-PH, BSN, RN

Associate Director for Patient Labeling
Division of Medical Policy Programs (DMPP)
Office of Medical Policy Initiatives (OMPI)
Office of Medical Policy (OMP), CDER, FDA

LaShawn Griffiths is the Associate Director for Patient Labeling in the Division of Medical Policy Programs in the Office of Medical Policy Initiatives, Center for Drug Evaluation and Research (CDER). Mrs. Griffiths holds a Masters in Health Science with a concentration in Public Health, Bachelor of Science in Nursing, and a graduate certificate in Health Education. Prior to joining the FDA, Ms. Griffiths spent many 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.

Joseph A. Grillo, PharmD

Associate Director of Labeling and Health Communication
Office of Clinical Pharmacology
Office of Translational Sciences (OTS), CDER, FDA

Dr. Grillo is the Associate Director for Labeling and Health Communication for the Office of Clinical Pharmacology in the Center for Drug Evaluation and Research of the United States Food and Drug Administration. The Labeling and Health Communications group ensures labeling consistency, coordinates prescription drug labeling enhancement initiatives, and fosters outreach and stakeholder engagement for the Office of Clinical Pharmacology. Prior to this, Dr. Grillo was a senior clinical pharmacologist in the Office of Clinical Pharmacology for seven years. Preceding his FDA career, Dr. Grillo was on faculty in the Departments of Pharmacy Practice at St. John's University and Shenandoah University and is currently an Affiliate Associate Professor of Pharmaceutics at Virginia Commonwealth University.

Jeanne Herndon, MD

Clinical Advisor for Labeling
Labeling Policy Team (LPT)
Office of New Drugs (OND), CDER, FDA

As a clinical advisor for labeling, Dr. Herndon participates in OND's implementation of prescribing information regulations, guidances, and policies to promote consistency in labeling practices across CDER, assists in the review and development of prescribing information, provides oversight of labeling quality, and provides labeling review training. She received her medical degree from New York University School of Medicine, completed internship in Internal Medicine at Georgetown University Medical Center, residency in Anatomic and Clinical Pathology at New York Presbyterian Hospital- Weill Cornell Medical Center, and clinical fellowship in Transfusion Medicine at the National Institutes of Health Clinical Center. She is board certified in Anatomic and Clinical Pathology. Prior to joining the Labeling Policy Team, Dr. Herndon was a clinical reviewer in the Office of Hematology and Oncology Products, Division of Hematology Products.

Iris Masucci, PharmD

Special Assistant for Labeling
Office of Medical Policy, CDER, FDA

Dr. Masucci joined FDA in 1998 and has been focusing on professional labeling and related policy since 2002. In CDER's Office of Medical Policy, she serves as the Office lead on professional labeling policies. She leads Office efforts on the development and implementation of labeling regulations and guidances, working closely with staff from the Office of New Drugs, the Office of Regulatory Policy, and other Offices and Centers as needed.

Byron Pearsall

Director
Division of Medical Policy Programs
Office of Medical Policy (OMP), CDER, FDA

Bryon M. Pearsall, J.D., R.Ph., serves as the Director of the Division of Medical Policy Programs within the Office of Medical Policy Initiatives (OMPI) in the Office of Medical Policy (OMP). He is responsible for working with OMPI and OMP management and staff to develop and establish policy and procedures, prepare topic papers, and proactively research topics to aid in the development and maintenance of a variety of FDA programs. Bryon has over 20 years of professional work experience in the pharmaceutical and legal fields including experience in policy development, pharmacovigilance, retail pharmacy, and medical malpractice law. He received a JD and a certificate in health law from Widener University School of Law in Delaware and a Bachelor of Pharmacy from the University of the Sciences in Philadelphia, formerly Philadelphia College of Pharmacy and Science. Bryon is registered to practice pharmacy in PA and DE and licensed to practice law in PA, NJ, and before the Patent and Trademark Office.

Farrokh Sohrabi, MD

Clinical Advisor for Labeling
Labeling Policy Team (LPT)
Office of New Drugs (OND), CDER, FDA

As a clinical advisor for labeling, Dr. Sohrabi participates in OND's implementation of prescribing information regulations, guidances, and policies to help promote consistency in labeling practices across CDER, assists in the development and review of the prescribing information, provides oversight of labeling quality, and provides labeling review training. Prior to joining the Labeling Policy Team, Dr. Sohrabi was a clinical reviewer in the OND Division of Gastroenterology and Inborn Errors Products. Prior to joining FDA, Dr. Sohrabi practiced as an internist with a focus on hospital medicine. He holds a Doctorate in Medicine from the University of Maryland School of Medicine, completed residency training in Internal Medicine at the University of Virginia Health System, and is board certified in Internal Medicine.

Mongthuong Tran Pharm.D., BCPS

Labeling Lead
Labeling and Health Communication (LHC)
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS), CDER, FDA

Mongthuong Tran is Labeling Lead in the Labeling and Health Communication (LHC) group within the Office of Clinical Pharmacology (OCP) in FDA's Office of Translational Sciences (OTS). She joined FDA as an LHC Specialist in 2016. Her primary responsibilities are to lead and coordinate OCP labeling initiatives, as well as improve and promote comprehension, consistency, and clarity of clinical pharmacology information in drug labeling. Dr. Tran also plays an active role in developing labeling-related training, and stakeholder outreach and education. She is a member of the Drug Interaction Labeling Guidance Working Group and provides input on several labeling policy initiatives. Dr. Tran received her Pharm.D. from University of North Carolina at Chapel Hill. She completed a pharmacy practice residency in community pharmacy at Virginia Commonwealth University, and a specialized pharmacy residency in endocrinology and metabolic bone disease at McGuire VA Medical Center in Richmond, VA. Prior to joining OCP, Dr. Tran supported providers and patients as a Clinical Pharmacy Specialist (CPS) in Endocrinology, Supervisor in Specialty Services, and CPS in Utilization Management during her time at Kaiser Permanente Colorado.

Ann Marie Trentacosti, MD

Medical Lead/Labeling Reviewer
Labeling Policy Team (LPT)
OND, CDER, FDA

As the LPT medical lead and a labeling reviewer, Dr. Trentacosti participates in CDER labeling policy initiatives and assists in the development and review of the prescribing information, provides oversight of labeling quality, and provides labeling review training. Dr. Trentacosti's previous OND responsibilities included endpoint reviewer for the Study Endpoint and Labeling Development team and clinical reviewer in the Division of Gastroenterology and Inborn Errors Products. Prior to joining FDA, Dr. Trentacosti practiced internal medicine. She received her M.D. degree from New Jersey Medical School, completed residency in Internal Medicine at the Emory Health Care System, and is board certified in Internal Medicine.

Chi-Ming (Alice) Tu, PharmD, FISMP, BCPS

Team Leader
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE), CDER, FDA

LCDR Chi-Ming Tu goes by the name Alice. She graduated from the University of North Carolina-Chapel Hill Eshelman School of Pharmacy in 2008, completed the managed care pharmacy residency at Medco Health Solutions, Inc. in 2009 and the joint safe medication management fellowship at ISMP/FDA in 2010. LCDR Tu has worked at the Food and Drug Administration for over 9 years now. She started as a reviewer in FDA's Division of Medication Error Prevention and Analysis in 2010 and has served in her current role as the team leader since 2013.

LCDR Morgan Walker, PharmD, MBA, CPH

Senior Patient Labeling Reviewer
Division of Medical Policy Programs
Office of Medical Policy, CDER, FDA

LCDR Morgan Walker is a pharmacist who serves as a Regulatory Review Officer for the Division of Medical Policy Programs in the Office of Medical Policy. LCDR Walker joined the FDA as a civilian in 2011, starting as a Safety Evaluator in the Division of Medication Error Prevention and Analysis in the Office of Surveillance and Epidemiology. She joined PHS in 2013 and subsequently joined the Division of Medical Policy Programs as a Regulatory Review Officer in 2014. Prior to joining the FDA, LCDR Walker served as an Operations Manager in an oncology pharmacy at the Johns Hopkins Hospital in Baltimore, Maryland.

Ruby Wu, PharmD, MPH

Captain, U.S. Public Health Service
Labeling Reviewer
Office of Therapeutic Biologics and Biosimilars (OTBB)
OND, CDER, FDA

Chi-Ann Ruby Wu has worked in FDA/CDER for over 20 years and is currently a labeling reviewer in the Office of Therapeutic Biologics and Biosimilars (OTBB). OTBB works collaboratively with CDER Offices and Review divisions responsible for providing scientific and regulatory advice to sponsors seeking to develop biosimilar and interchangeable products. OTBB also contributes to the development of policies, procedures and guidance necessary to further implement the Biologics Price Innovation and Competition Act.