Biographies: CDER Prescription Drug Labeling Conference 2017

Melissa Beaman

Director Global Regulatory Affairs, GlaxoSmithKline
Director of US Artwork, Coordination, and Delivery, Global Regulatory Affairs, GlaxoSmithKline

Melissa has extensive experience in the pharmaceutical industry, first with Burroughs Wellcome, then Glaxo Wellcome, and currently with GlaxoSmithKline. Her experience includes 5 years in Pharmacology; 9 years in Clinical Research, where she was integral in the centralization of Case Report Form Development; and 26 years in Labeling. She has experience with labeling for multiple therapeutic areas including Anti-infectives, Cardiovascular, Neurology, Oncology, Metabolic and Endocrine, Respiratory, and Psychiatry. In her current position, Melissa oversees the development of US packaging copy, labeling artwork, and labeling submissions, and assists in the development and review of prescribing information. She analyzes changes to FDA policies regarding drug labeling and recommends/develops new procedures and coordinates the implementation of modifications to procedures to promote compliance/consistency in GSK labeling practices. She serves as an authoritative source on GSK standards and US laws and regulations pertaining to the labeling development of GSK products.

Roya Behbahani, PharmD, MBA

Director and Labeling Cluster Head in Global Labeling Management, Pfizer

Dr. Behbahani is responsible for Oncology, Cardiovascular, Metabolic and Endocrine Therapeutic areas. She is also responsible for oversight of Labeling Executive Committee which is the highest labeling governance at Pfizer. She has over 20 years of experience in Pharmaceutical industry with 12+ years of experience in labeling strategy. She has also worked in Medical Affairs (Medical Information) for 8 years prior to her work in labeling. She has been involved with various labeling initiatives and influences externally via Industry forums, giving lectures and teaching pharmacy students. Roya is a licensed pharmacist and earned her Doctor of Pharmacy degree from the Philadelphia College of Pharmacy & Sciences at the University of the Sciences in Philadelphia and MBA from Regis University in Denver. She has also completed a Post-PharmD Fellowship in Pharmacokinetics and 5 years of Clinical Pharmacy at Cooper Hospital in NJ responsible for PK monitoring and anti-infectives before joining Industry.

Eric Brodsky, MD

Associate Director, Labeling Development Team (LDT), Office of New Drugs (OND), CDER, FDA

As the Associate Director of the LDT, 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 LDT; 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.

Ingrid Bryzinski, MS, RPh

Senior Director, Strategic Global Labeling, Regulatory Affairs, AbbVie

Ingrid Bryzinski received her BS in Pharmacy from the Philadelphia College of Pharmacy and Science and her Masters in Clinical Pharmacy from St John's University.Ingrid spent 20 years in hospital pharmacy in a clinical pharmacist role prior to joining the pharmaceutical industry. Ingrid joined Abbott Laboratories in March 1997 working on Company Core Data Sheets in International Medical Compliance. The group moved to Regulatory Affairs and evolved to include the management of US Package Inserts and initial SmPCs for Europe as well as creating draft labeling for early phase pipeline products. Ingrid is the Senior Director of the Labeling Group in Regulatory Affairs at AbbVie. One of her personal interests is ensuring product information is clear for patients.

Miriam Dinatale, DO

Maternal Health Team Leader, Division of Pediatric and Maternal Health (DPMH), 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 commissioned officer in the United States Public Health Service and has been at the FDA for four years.

Joseph A. Grillo, PharmD

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

Medical Officer/Labeling Reviewer, Labeling Development Team (LDT), Office of New Drugs (OND), CDER, FDA

As a medical officer/labeling reviewer on OND's Labeling Development Team, Dr. Herndon assists in the review and development of the 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 Warren G. Magnusen Clinical Center. She is board certified in Anatomic and Clinical Pathology. Prior to joining the Labeling Development Team, Dr. Herndon was a clinical reviewer in OND's Office of Hematology and Oncology Products, Division of Hematology Products.

Tamara Johnson, MD, MS

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

Dr. Johnson earned her Doctorate in Medicine from the Rutgers Robert Wood Johnson Medical School. She completed residency training at the University of Maryland Medical Center and is board certified in General Preventive Medicine/Public Health. She has been with FDA for over seven years, first as a Medical Officer in the OND Division of Gastroenterology and Inborn Errors Products and currently as the team leader for the DPMH Maternal Health Team. The Maternal Health Team is responsible for evaluating the safe use of drug and biologics products in pregnant and lactating women; including the review of labeling and study protocols, as well as policy development.

Traci Lee, PharmD

Director, Labeling Development, GSK

Traci has led the development of prescriber and patient labeling for US and global markets across multiple therapeutic areas including vaccines, anti-infectives, immuno-inflammation, oncology, and respiratory for over 10 years at GSK. For the past few years she has led the Pregnancy and Lactation Labeling Rule (PLLR) initiative within the GSK Labeling group. She held previous positions within Clinical Research and Medical Information, also at GSK. Traci obtained her B.S. in Chemistry and her PharmD at the University of Michigan, Ann Arbor, MI, and completed a pharmacy practice residency at Wake Forest Baptist Medical Center, Winston-Salem, NC.

Jane Liedtka, MD

Medical Officer (MO), Maternal Health Team, DPMH, OND, CDER, FDA

Dr. Liedtka earned her Doctorate in Medicine from Tufts University School of Medicine. She completed residency training at Brown University and is board certified in Dermatology. Prior to coming to the FDA, she was on faculty in the Department of Dermatology at George Washington University, served as volunteer Dermatology Clinical Center Staff at the National Institute of Health and was in private practice in Dermatology at University Dermatology Associates. She has been at the FDA for 10 years, first as a MO in the OND Division of Dermatology and Dental Products and now as an MO in DPMH.

Edward D. Millikan, PharmD

Dr. Millikan is the Director of Product Development and Maintenance and a Clinical Informaticist within eHealth Solutions at ASHP. He received his Doctor of Pharmacy from the School of Pharmacy at Campbell University and completed a Specialty Residency in Pharmaceutical Informatics and Drug Information from First DataBank (FDB) and the University of California, San Francisco. He is interested in and has over 12 years of experience utilizing and extracting FDA Structured Product Labeling (SPL), RxNorm, and other standard health care identifiers, nomenclature, and data mappings. He also developed the original proposed SPL schema for REMS data standardization and codification for NCPDP in 2010 based upon the FDA draft "Guidance for Industry Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications".

Gina Monteiro, BA

Global Regulatory Affairs Manager – Global Labeling Department, Eli Lilly and Company

Laurie Myers, MBA

Laurie Myers has the honor of serving as the Global Health Literacy Director for Merck & Co., Inc. For the past six years, she has led the company's health literacy efforts in support of improved patient communications, including medication labeling, packaging, clinical trial materials, lay summaries, and patient education. She is a member of the NAS Health Literacy Roundtable and the EMA lay summaries task force. She received the IHA health literacy research award in 2016, recognizing efforts to include people with low health literacy in market research. She has co-authored several publications. She graduated from Yale University and received an MBA in Health Care Management from the Wharton School. She joined Merck in 1999. Before Merck, she worked for many years serving people with developmental disabilities.

Corey Schmidt, MBA

Global Labeling Systems and Compliance Team Lead, Regulatory Affairs, Novartis Pharmaceuticals

Corey Schmidt is the Global Labeling Systems and Compliance Team Lead at Novartis Pharmaceuticals. This position providing expert support for Global Labeling technology-related initiatives including implementation, maintenance, enhancement, and optimization of systems, tools, and processes while ensuring Global Labeling technology is continuously improving in quality and efficiency. Since 2008 Corey has managed all SPL activities for Novartis Pharmaceuticals including the SPL/XML conversion process, product drug listing, and FDA establishment registration. Corey is a member of the industry SPL Tech Team and was part of the recent FDA REMS SPL pilot. Corey joined Novartis in 2006 as part of the Technical Regulatory Operations (TRO) group and prior to Novartis Corey achieved 8 years of Regulatory Operations and Systems experience within global pharmaceutical companies. Corey received his MBA in Information Systems from Quinnipiac University and his Bachelor of Science from Pennsylvania State University.

Lonnie Smith

Office of Health Informatics, Office of the Chief Scientist, FDA

Farrokh Sohrabi, MD

Medical Officer/Labeling Reviewer, Labeling Development Team (LDT), Office of New Drugs (OND), CDER, FDA

As a labeling reviewer, Dr. Sohrabi 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 Development Team, he was a Clinical Reviewer in the OND Division of Gastroenterology and Inborn Errors Products. Prior to joining FDA, Farrokh 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.

Ann Marie Trentacosti, MD

Medical Lead/Labeling Reviewer, Labeling Development Team (LDT), OND, CDER, FDA. As the LDT 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 also participates in clinical outcome assessment initiatives lead by OND's Clinical Outcome Assessment Staff. 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.

Ebony Whaley PharmD, BCPPS

Safety Evaluator, Division of Medication Error Prevention and Analysis, Office of Surveillance and Epidemiology, CDER, FDA

As a safety evaluator in DMEPA, Dr. Whaley conducts premarket reviews of proposed proprietary medication names, labels and labeling, packaging, and human factor studies to reduce the potential for medication errors for CDER-regulated products and also analyzes post-marketing medication errors submitted to CDER. Dr. Whaley received her Doctor of Pharmacy degree from Hampton University School of Pharmacy. She completed a pharmacy practice residency at Mayo Clinic's Mayo Eugenio Litta Children's Hospital and is a board certified pediatric pharmacy specialist. Prior to joining FDA, Dr. Whaley served as a clinical pharmacist at Johns Hopkins Children's Center.