Pharmacovigilance and Risk Management Conference

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Speakers Biographies

Doris Auth is the Associate Director of the Division of Risk Management (DRM), Office of Medication Error and Risk Management (OMEPRM) Office of Surveillance and Epidemiology, CDER, FDA. Doris joined the agency in January 2011 as a Risk Management Analyst in DRM, and was the team leader of the REMS Assessment team from 2012-2016. Prior to joining the FDA, Doris worked as a clinical pharmacist in California, Hawaii, Washington D.C. and Virginia in both hospitals and long-term care. Doris has a Bachelor of Science in Pharmacy from the University of Pittsburgh and a Doctor of Pharmacy from the University of Maryland and completed a pharmacy residency at the National Institutes of Health Clinical Center.

Sonja Brajovic, Medical Officer, OSE, CDER

Sonja Brajovic is a Medical officer in the Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). She is responsible for coordination of projects related to the Medical Dictionary for Regulatory Activities (MedDRA), including monitoring MedDRA coding quality of reports in the FDA Adverse Event Reporting System (FAERS). Sonja represents FDA on the International Conference on Harmonisation (ICH) MedDRA Points to Consider workgroup. Sonja obtained her medical degree in the former Yugoslavia.

CAPT **Melissa Burns**, MS, is a Senior Program Manager in FDA's Office of Combination Products and is responsible for coordinating activities related to combination product review and regulation including development and review of guidance documents, regulations, and procedures and policies. She has significant experience in current good manufacturing practices and postmarketing safety reporting for combination products and has been heavily involved in FDA's ongoing efforts to improve the intercenter consult process. She has 14 years of FDA experience in compliance, premarket review, and policy development, including previous work at the Center for Devices and Radiological Health. Before joining FDA, CAPT Burns worked for several years in the private sector including positions with a medical device manufacturer, a large acute-care hospital, a healthcare architecture firm, and a consulting firm. CAPT Burns received a Bachelor of Science degree in Mechanical Engineering from Virginia Tech and a Master of Science degree in Biomedical Engineering from The University of Connecticut.

Meredith Chuk, M.D., is acting associate director for safety in the Office of Hematology and Oncology Products in the Center for Drug Evaluation and Research at the U.S. Food and Drug Association (FDA). She completed her pediatric hematology/oncology fellowship at the Johns Hopkins/National Cancer Institute (NCI) fellowship program and was an instructor in the Pediatric Oncology Branch of the NCI while completing a master's degree in clinical research through Duke University. She was an assistant professor of pediatrics at the Children's Hospital of Pittsburgh in the Department of Hematology/Oncology before joining the FDA in 2013 as a medical officer.

Gerald J. Dal Pan became the Director of the Office of Surveillance and Epidemiology (known then as the Office of Drug Safety) in November 2005. Before that, he was the Director of the Division of Surveillance, Research, and Communication Support in CDER's Office of Drug Safety, a position he held since December 2003.

He received his medical degree from Columbia University, and his Master's degree in clinical epidemiology from Johns Hopkins University. He trained in internal medicine at the Hospital of the University of Pennsylvania, and in neurology at Johns Hopkins Hospital.

Dr. Dal Pan is board certified in internal medicine and neurology. He was an instructor in the Neurology Department at Johns Hopkins. He next worked for Guilford Pharmaceuticals in Baltimore, and then for HHI Clinical Research and Statistical Services in Hunt Valley, MD. He joined FDA in July 2000 as a medical officer in the Division of Anesthetic, Critical Care, and Addiction Drug Products.

Suranjan De has over seventeen years of demonstrated achievements, across Food and Drug Administration (FDA), National Institute of Health (NIH) & Pharma, impacting superior program performance through alignment of policies and regulation and innovative healthcare informatics solutions with strategic business objectives. His experience includes providing strategic direction to the life sciences industry for the use of innovative tools and products. He has also served as a SME/liaison between the IT management and the business owner in integrating methods and process with technology. Suranjan received a Masters in Computer Science from the Institute for Technology and Management, India and a Masters in Business Administration from Johns Hopkins University. Currently, Mr. De is the Deputy Director at FDA's CDER, Office of Surveillance and Epidemiology, in the Regulatory Science Staff. He provides expert advice and technical direction on regulatory science for developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products. This includes interpretation of regulations, guidance documents and/or other policies relevant to activities in the Office of Surveillance and Epidemiology (OSE) in order to implement best practices and provide the right tools and technology. His current work includes, but is not limited to compounding reporting guidance, data management of FDA Adverse Events Reporting System (FAERS) and automating triaging of voluntary reporting and Safety Reporting Portal for mandatory post-marketing electronic submissions.

Danielle Harris serves as Deputy Director in the Division of Medication Error Prevention and Analysis (DMEPA) within the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). Danielle has 12+ years of medication safety experience and provides oversight of the pre- and post-marketing safety activities related to drug nomenclature, labels, labeling and product design for drug and therapeutic biologic products to mitigate the risk of medication errors. She has also participated in Agency guidance development in the area of medication error prevention. Danielle earned her Doctor of Pharmacy degree from Northeastern University and completed a Pharmacy Practice Residency at Beth Israel Deaconess Medical Center in Boston, Massachusetts.

Dr. Shelly Harris has over 20 years of experience in program evaluation, health policy, qualitative research, health communication, health outcomes, and health disparities. She has expertise in the evaluation of methodologies and assessments of risk management plans, survey design, project management, qualitative data collection and analysis, patient and site recruitment, research design and implementation, and manuscript and report writing. She has worked in various topic areas, including risk management, risk evaluation and mitigation strategies (REMS), opioid analgesic misuse and abuse, patient-reported outcomes, tuberculosis, HIV/AIDS/STDs, health disparities, cancer, diabetes, community-based participatory research, maternal and child health, oral health, dermatology, and gastrointestinal diseases. She has a BA in Psychology and a MPH in Health Behavior and Health Education from the University of North Carolina at Chapel Hill, and a ScD in Global Health Management and Policy from the Tulane University School of Public Health and Tropical Medicine. She joined the FDA in 2013 as a reviewer and is currently the team leader for the REMS Assessment team in the Division of Risk Management.

Cynthia LaCivita, Director, Division of Risk Management, OSE, CDER

Cynthia LaCivita earned her undergraduate degree in microbiology and Doctor of Pharmacy from the University of Maryland (U of MD) and completed an oncology residency at the University of Maryland Cancer Center (UMCC). She was an assistant professor in the Department of Pharmacy Practice and Science at the U of MD School of Pharmacy and assistant professor of Oncology at UMCC, Director of Clinical Standards and Quality for the American Society of Health-System Pharmacists (ASHP) and Director of Education and Special Programs for the ASHP Research and Education Foundation. In April 2010 she joined the Food and Drug Administration, she has served as the director of Division of Risk Management (DRISK) since 2015.

Dr. **Manish Kalaria** is a Medical officer in the Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER) at the FDA. He is responsible for monitoring Medical Dictionary for Regulatory Activities (MedDRA) and coding quality of reports in the FDA Adverse Event Reporting System (FAERS).

Manish received his Doctor of Medicine from Rosalind Franklin University of Medicine and Science in Illinois, after which he completed an accredited Ophthalmology residency at Eastern Virginia Medical School and fellowship in Neuro-Ophthalmology at the Bascom Palmer Institute in Miami Florida.

Elaine Lippmann, J.D., is a Senior Regulatory Counsel in the Office of Regulatory Policy in FDA's Center for Drug Evaluation and Research. Ms. Lippmann provides oversight and leadership in the development of policies, regulations, procedures and guidances, specializing in post-market drug safety. Prior to joining the FDA in 2011, Ms. Lippmann was an attorney at the law firm of Spiegel & McDiarmid, where she represented municipalities and public unions in administrative law and regulatory matters.

Ashleigh Lowery is currently an acting team leader in the FDA's Division of Medication Error Prevention and Analysis (DMEPA). She has also worked on postmarket and policy projects on DMEPA's Rapid Response Team. She is a graduate of the University of Maryland School of Pharmacy and completed her PGY-1 Pharmacy Practice and PGY-2 Critical Care residencies at the University of Maryland Medical Center (UMMC) and the R Adams Cowley Shock Trauma Center. Prior to coming to FDA, she worked as a clinical pharmacy specialist and clinical assistant professor in the Cardiac Surgery ICU at UMMC.

Lubna Merchant, Deputy Office Director, OMEPRM, OSE, CDER
Dr. Merchant currently serves as the acting Director of the Division of Medication Error Prevention and Analysis. She is also the Deputy Director of the Office of Medication Error Prevention and Risk Management in FDA's Center for Drug Evaluation and Research's (CDER) where she is responsible for the Center's programs in risk management and medication error prevention. She provides expertise on development and implementation of programs and initiatives to support the Center's policies related to Risk Evaluation and Mitigation Strategies (REMS). She serves as expert/scientific advisor on medication errors associated with drug and biological products within the Center and outside agencies.

CDR **Monica Muñoz** is the Deputy Director of the Division of Pharmacovigilance I (DPV-I) in the Office of Surveillance and Epidemiology within the FDA's Center for Drug Evaluation and Research. In this role she provides scientific oversight for DPV pharmacovigilance activities and initiatives. Prior to her current position, she served as safety evaluator team leader for cardiology and renal products and safety evaluator for neurology products in DPV-I. CDR Muñoz also serves as a pharmacy officer in the U.S. Public Health Service and has been deployed for several public health missions including to West Africa as part of the Ebola response mission and most recently for COVID19. Her current research interests include safety signal identification methodologies and optimizing signal management. CDR Muñoz received her PharmD from Texas Tech University and PhD in Pharmacoepidemiology from the University of Florida.

Dr. **Jacqueline Sheppard** serves as an acting Team Leader in the Division of Risk Management (DRM) in the Office of Surveillance and Epidemiology within the FDA's Center for Drug Evaluation and Research. In this role, she oversees a team of Risk Management Analysts and a Health Communication Analyst to provide risk management expertise on the review of the need for risk evaluation and mitigation strategies (REMS) as well as development of REMS programs. Jacqueline has held previous positions as a Risk Management Analyst and Safety Evaluator within the FDA and as a Clinical Pharmacist at the Children's National Medical Center in Washington, DC. Dr. Sheppard received her Pharm.D. from University of Maryland at Baltimore School of Pharmacy and B.S. in Marine Biology from the University of Maryland-College Park.

LCDR **Danijela Stojanovic** is an epidemiologist on the Sentinel Core Team in the Office of Surveillance and Epidemiology within the FDA's Center for Drug Evaluation and Research. She manages the daily operations of the Sentinel System and provides clinical and epidemiological expertise to teams assessing the safety of drug products. Prior to this role, she served as a safety evaluator in the Division of Pharmacovigilance and an epidemiologist in the Division of Epidemiology for neurology products. LCDR Stojanovic is a pharmacy officer in the U.S. Public Health Service. Her interests include epidemiologic methods, drug safety in pregnancy, and signal detection. She received her PharmD from the University of Texas at Austin and a PhD in pharmacoepidemiology from the University of Florida.

Gita Toyserkani, Associate Director for Research & Strategic Initiatives, CDER
Gita Toyserkani, PharmD, MBA, is the Associate Director for Research and Strategic Initiatives in the Division of Risk Management in FDA's Office of Surveillance and Epidemiology. She has over 15 years of experience in risk management and advises on pre and post-marketing activities and policies involving REMS for products regulated by CDER. Dr. Toyserkani has led several REMS standardization efforts and initiatives to advance the science of risk management. Her career at FDA started in 2005 as a Safety Evaluator in the Division of Pharmacovigilance where she was primarily responsible for assessing safety-related issues for opioid products. Prior to FDA, she was a clinical pharmacist at Walter Reed National Military Medical Center.

Dr. **Lolita White** is a Team Leader for the Division of Medication Error Prevention and Analysis at the US Food and Drug Administration since 2014. In her current role at the FDA, her focus is on Human Factors data evaluation and the review of combination products in both the pre market and post market setting. She has presented locally and nationally on medication error prevention and analysis. Dr. White obtained her PharmD from Howard University in 1999 and completed a residency at Children's National Medication Center in Washington, DC. She most recently completed the ASHP Medicating Safety Certificate program in 2018. Currently she is working to address over 200 comments from industry and FDA Staff received in July 2019 regarding the draft Guidance titled "Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications". In her spare time she enjoys baking and she has a daughter who is a senior at the University of Southern California studying Journalism and Cinematic Arts.

Eileen Wu received her Doctor of Pharmacy degree from the University of Maryland School of Pharmacy. She has been with the FDA since 2010, with experience as Safety Evaluator, Team Leader, and Associate Director in the Division of Pharmacovigilance I (DPV-I), Office of Surveillance and Epidemiology (OSE) in the Center for Drug Evaluation and Research.
As an Associate Director in DPV, Dr. Wu has spearheaded several critical Agency initiatives. She has led and co-led cross-disciplinary teams to identify solutions to challenges in postmarket safety surveillance, with a focus on methods and tools. She has also led efforts to ensure consistency in the development and application of policies and procedures across DPV teams. Since joining the FDA, Dr. Wu has worked to disseminate information and findings on drug safety through several publications in peer-reviewed scientific journals and poster presentations at professional conferences. She continues to provide expertise and leadership in the development of standards and methods used to evaluate drug and therapeutic biologic safety issues.

Judith (Judy) Zander M.D. is the Director of the Office of Pharmacovigilance and Epidemiology (OPE), in the Office of Surveillance and Epidemiology (OSE), in the Center for Drug Evaluation (CDER) at the U.S. Food and Drug Administration (FDA).She oversees the Divisions of Pharmacovigilance 1 and 2 and the Divisions of Epidemiology 1 and 2. Judy joined FDA in January 2017. She has more than 20 years of pharmaceutical industry in leadership roles in drug safety and risk management.

Dr. **Laura Zendel** is a Team Leader in the Division of Risk Management (DRM) in the Office of Surveillance and Epidemiology within the FDA's Center for Drug Evaluation and Research. In this role, she oversees a team of risk management analysts and a health communication analyst to provide risk management expertise on the review of the need for risk evaluation and mitigation strategies (REMS) as well as development of REMS programs. She has experience in the development of branded and shared system REMS, including waived and separate (parallel-system) REMS. Prior to her current position, she served as a risk management analyst within DRM and currently practices as a clinical pharmacist at Medstar Washington Hospital Center. Dr. Zendel received her Pharm.D. from University of Maryland Baltimore School of Pharmacy and B.S. in Anthropology from the University of Wisconsin, Madison.