Potential Medication Error Risks with Investigational Drug Container Labels
Public Meeting
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Speaker Bios

Sapna R. Amin, PharmD
Manager, Investigational Pharmacy Services, MD Anderson Cancer Center

Sapna Amin, PharmD, has more than 19 years of experience in oncology pharmacy. She currently leads one of the largest investigational pharmacy service programs in the nation at MD Anderson Cancer Center in Houston, Texas. Amin also serves as the Committee Co-Chair for the NCCN Investigational Pharmacy Sub-Group and leads the Investigational Drugs Committee Subgroup for the Alliance of Dedicated Cancer Centers. Sapna earned her BS Pharm and her PharmD from the Philadelphia College of Pharmacy and Science. She completed her oncology residency at the MD Anderson Cancer Center. She is a Board-Certified Oncology Pharmacist.

Jamie N. Brown, PharmD, FCCP, BCPS, BCACP
Investigational Drug Service Program Manager, Durham VA Health Care System

Jamie N. Brown, PharmD, FCCP, BCPS, BCACP, is the Investigational Drug Service Program Manager at the Durham VA Health Care System and a Clinical Professor of Pharmacy Practice with Campbell University College of Pharmacy and Health Sciences. He received his PharmD degree from Campbell University and then completed an ASHP-accredited specialty residency in drug information. After completing his residency, Dr. Brown began working with the Durham VA Health Care System where he also serves as the Residency Program Director for the Post-Graduate Year Two Medication-Use Safety and Policy residency program. He has spoken nationally and published multiple peer-reviewed papers on the topic of medication safety in the setting of the investigational drug service, is board certified in pharmacotherapy and ambulatory care pharmacy, and is a Fellow of the American College of Clinical Pharmacy.

Nichelle Cobb, PhD
Senior Advisor for Strategic Initiative, Association for the Accreditation for Human Research Protection Programs

Nichelle Cobb, PhD, is Senior Advisor for Strategic Initiatives for the Association for the Accreditation for Human Research Protection Programs (AAHRPP). She is also the Senior Advisor for the SMART IRB initiative. Her SMART IRB work involves developing resources and providing educational materials to help institutions transition to single IRB review. In addition, Dr. Cobb serves as a member of the SMART IRB Harmonization Steering Committee and participates in working groups that develop harmonized approaches for key human subjects' issues. Prior to joining AAHRPP, she was the Human Subjects Protection Officer for the Institute for Clinical & Translational Research and served as the Director of the Health Sciences IRBs for 16 years. She has worked with IRBs since 1999.

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President, Institute for Safe Medication Practices

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP, is President of The Institute for Safe Medication Practices (ISMP), a non-profit healthcare organization that specializes in understanding the causes of medication errors, providing error-reduction strategies to the healthcare community, policy makers, and the public. He serves as co-editor of the *ISMP Medication Safety Alert!* publications that reach over one million health professionals in the US as well as regulatory authorities and others in over 30 foreign countries. Cohen is also co-editor of the ISMP consumer website, www.consumermedsafety.org. He is the Chairperson of the International Medication Safety Network (www.intmedsafe.net). He has served terms on the US FDA Drug Safety and Risk Management Advisory Committee (DSaRM), the Nonprescription Drugs Advisory Committee (NDAC), the USP Expert Committee on Labeling and Nomenclature, and is a consultant to FDA.

Gerald J. Dal Pan, MD, MHS
Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, FDA

Gerald J. Dal Pan, MD, MHS, 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. Dr. Dal Pan 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.

He 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.

Janet Donnelly, RAC
Policy Analyst, Office of Good Clinical Policy and Programs, FDA

Janet Donnelly, RAC, is a Policy Analyst in FDA's Office of Good Clinical Practice (OGCP). OGCP is the focal point within FDA for Good Clinical Practice (GCP) and Human Subject Protection (HSP) issues arising in human studies regulated by FDA. She brings over twenty years of experience to FDA in regulatory affairs and regulatory compliance in the sponsor, CRO and independent IRB settings. Prior to joining FDA in 2008, Donnelly served as Director of Compliance for an independent IRB providing regulatory consultation to the IRB and external clients.

James Duhig, PhD
Director, Patient Integration, International Pharmacovigilance Network, AbbVie

James Duhig, PhD, is Director of Patient Integration for AbbVie Pharmacovigilance and Patient Safety. He is an expert in the application of human factors and health literacy in the investigation of medication errors and in the development of drug and device instructional materials for patients and healthcare professionals.
In his role with AbbVie's International Pharmacovigilance Network, Dr. Duhig works with physicians, nurses, pharmacists, safety data scientists, engineers, and others in the synthesis and evaluation of multiple sources of post-marketing safety data. Applying cognitive behavioral science techniques to the assessment of information from adverse event databases, patient support programs, spontaneous reports and known sources of use error from existing research to the analysis of post-marketing safety data, his teams work to investigate medication errors, identify root cause and when needed, develop systematic mitigations that will improve patient outcomes and reduce medication errors.

Han Feng, PharmD
Supervisory Pharmacist for Medication Safety, National Institute of Health

Han Feng, PharmD, serves as the Supervisory Pharmacist for Medication Safety at the National Institute of Health in Bethesda, MD. He received his Doctor of Pharmacy degree from Shenandoah University in Winchester, VA. Following graduation, Dr. Feng completed a PGY-1 Pharmacy Practice residency at Memorial Hospital in Colorado Springs, Colorado, and a PGY-2 Medication-Use Safety residency at the Johns Hopkins Hospital in Baltimore, Maryland. He served as a

Medication Safety Pharmacist at The Ohio State University Wexner Medical Center prior to serving as a Quality/Safety pharmacist at Children's National in Washington, DC. His passion is to understand how the human factors of modern healthcare practice impacts patient safety.

Bruce Gordon, MD
Assistant Vice Chancellor for Regulatory Affairs and Executive Chair of Institutional Review Boards, University of Nebraska Medical Center

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Bruce Gordon, MD, is Vice-Chancellor for Regulatory Affairs, and Professor of Pediatrics at the University of Nebraska Medical Center (UNMC). He has been a member of the UNMC Institutional Review Board since 1992, served as chair since 1996, and as executive chair since 2011. Dr. Gordon has served on a variety of national committees and task forces, including the Secretary's Advisory Committee on Human Research Protections Subpart A Subcommittee, the American Society of Clinical Oncology Task Force on Oversight of Clinical Research, the AAMC Informed Consent Working Group, and the National Institute of Environmental Health Sciences Best Practices Working Group for IRB Review of Disaster Research. He was the first chair of the National Cancer Institute Pediatric Central IRB. Dr. Gordon currently serves on the Board of Directors for PRIMR (Public Responsibility in Medicine and Research).

Paul Gouge, JD
Regulatory Counsel, Division of Clinical Trial Quality, Center for Drug Evaluation and Research, FDA

Paul Gouge, JD, is a regulatory counsel in the Division of Clinical Trial Quality at FDA. In this capacity he works to communicate and develop policy related to FDA's IND safety reporting requirements.

Tony Heeley, PharmD
Associate Director of Production Services, Parexel International

Tony Heeley, PharmD, has over 30 years experience working in global pharmaceutical companies and contract manufacturing organizations. He is currently Associate Director of Production Services, supporting label manufacture and production planning and documentation at Parexel International. Prior to joining Parexel, Heeley worked in the clinical supply chain in Shire and Wyeth. Previously, he held positions in Almedica Technology Group focused on the development of Labelling and Supply Chain Systems, identifying client requirements and Almedica Europe with responsibility for Label Management, Production Services and Clinical Shipments and clinical

supply chain roles with Ciba-Geigy and Beecham Animal Health. He is a registered pharmacist in the United Kingdom.

Susan Johnston, PharmD
Health Pharmacy Director, University of Wisconsin, Madison

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Susan Johnston, PharmD, is the UW Health Pharmacy Director with oversight of the Oncology, Research and Nuclear Medicine Pharmacy Service lines. Prior to that, she was the Pharmacy Manager for the Pharmaceutical Research Center which is the comprehensive investigational drug service for UW Health. Johnston has provided investigational drug management services since 1995 and has been a member of the University of Wisconsin Health Sciences Institutional Review Board for over 20 years. She has a B.S. in Pharmacy from the University of Wisconsin, and a Doctor of Pharmacy from the University of North Carolina. Susan's areas of interest include pharmacy residency education, clinical trial design, protection of human research subjects and the unique handling and compounding of gene therapy agents within clinical trials.

Alicja Kasina, MSc, BPharm
Senior Regulator Advisor for Clinical Trials Compliance Program, Health Canada

Alicja Kasina, MSc, BPharm, is a Senior Regulatory Advisor for Clinical Trials Compliance Program, Health Canada. She joined the Public Service in 1996 where she has been active in several roles including Drug Inspector and Medical Devices Specialist for Health Canada. Kasina has performed many clinical trial inspections in Canada and some in Europe under the umbrella of the Pharmaceutical Inspection Co-operation Scheme Joint Visits Programme. She also participated as a mentor at APEC Advanced GCP Inspection Workshop in Asia. She received a MSc in Molecular Biology from Jagiellonian University, Cracow, Poland and BPharm, Dalhousie University, Halifax Nova Scotia. Kasina has worked over 15 years in medical research in the areas of endocrinology, immunology and microbiology and is a licensed pharmacist. She is a co-author of several research papers and has given several presentations on subjects related to regulatory matters concerning health products both domestically and internationally.

Neil McCullough, PhD
Senior Vice President, Enterprise Quality Assurance, Iqvia

Neil McCullough, PhD, is Senior Vice President of Enterprise Quality Assurance with Iqvia. He has vast experience leading global quality and compliance teams within the industry. Dr. McCullough is a seasoned, innovative executive with expertise in quality assurance, regulatory affairs, risk-based auditing, continuous improvement, and project management. A past chairman of the ACRO Ethics and Regulatory Compliance Committee, he's received training in Risk Management and Leadership at Harvard University School of Business and Kennedy School of Government. He earned a Masters in

Pharmaceutical Medicine from Hibernia College in Dublin and a PhD in Chemistry from the University of Kent at Canterbury.

Lubna Merchant, PharmD, MS
Deputy Director, Office of Medication Error Prevention and Risk Management, Center for Drug Evaluation and Research, FDA

Lubna Merchant, PharmD, MS, is 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). Dr. Merchant serves as expert/scientific advisor on medication errors associated with drug and biological products within the Center and outside agencies. She provides oversight, coordination, and technical expertise for the pre- and post-marketing activities involving medication error prevention and analysis of regulated drug and drug/device products, including the review of proposed proprietary names for CDER. Dr. Merchant graduated from Massachusetts College of Pharmacy and Health Sciences with a Master of Science in Industrial Pharmacy, a Doctorate of Pharmacy and completed a PGY1 Pharmacy Practice Residency.

Alexander Mills
Director, Combination Product Commercialization, Manufacturing Division, Merck & Co.

Alexander Mills leads a team focused on medical device and combination product development and has also supported medication error risk management across all product types. His team conducts development activities in support of clinical and commercial manufacturing, working closely with clinical research and safety to ensure that potential medication errors are understood and mitigated.

Raymond J. Muller, MS, RPh, FASHP
Director of Pharmacy Quality, Safety and Training Programs, Memorial Sloan-Kettering Cancer Center

Raymond J. Muller, MS, RPh, FASHP, is Director of Pharmacy Quality, Safety and Training Programs at Memorial Sloan-Kettering Cancer Center in New York City. His primary responsibilities at Memorial Sloan-Kettering include directing the drug policy management programs of a 630-member pharmacy division and overseeing the quality, training, and safety division. Muller directs the PGY-2 medication safety and policy pharmacy residency program. He serves as the core head of the research

pharmacy which has been funded by the NCI since 1986. He has served as co-investigator of over 20 research drug studies, including antineoplastic, antiemetic, and analgesic drugs. He received his BS and master's in hospital pharmacy administration at St. John's University College of Pharmacy and Allied Health Professions in Jamaica, New York. He also completed a residency in hospital pharmacy at Temple University Hospital in Philadelphia.

Richard Needleman, RPh
Investigational Drug Services Specialist, Fox Chase Cancer Center

Richard Needleman, RPh, is the Investigational Drug Services Specialist at Fox Chase Cancer Center in Philadelphia. He's been in this role since 2002. Prior to this, Mr. Needleman was an oncology pharmacist at Fox Chase and Temple University Hospital. In addition to his IDS responsibilities, he has been a member of the Fox Chase IRB for over 20 years. In 2015, he was the initial recipient of the Fox Chase Cancer Center Award for Excellence in Research Ethics.

Ryan Raffaelli, MD
Medical Officer/Team Leader, Good Clinical Practice Compliance Oversight, Division of Clinical Compliance Evaluation, Office of Scientific Investigations, FDA

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Ryan Raffaelli, MD, is a Medical Officer and Acting Team Leader in the Good Clinical Practice Compliance Oversight Branch of the Division of Clinical Compliance Evaluation in the Office of Scientific Investigations (OSI) at U.S. FDA. OSI is within the Office of Compliance in the Center for Drug Evaluation and Research. His team evaluates referrals regarding clinical investigators, sponsors, monitors and contract research organizations and directs inspections, in collaboration with the Office of Regulatory Affairs to determine compliance with federal regulations. The team reviews post-inspection reports and provides findings to divisions in the Office of New Drugs regarding the adequacy of the protection of rights and welfare of human subjects, and the quality, integrity, and acceptability of study data, and develops appropriate regulatory correspondence to inspected parties. Dr. Raffaelli received a degree as a Doctor of Medicine from Jefferson Medical College at Thomas Jefferson University and is board certified in both general pediatrics and pediatric nephrology.

Janine Stewart, BS, PharmD
Safety Evaluator, Division of Medication Error Prevention and Analysis, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, FDA

Janine Stewart, BS, PharmD, joined FDA in 2013 as a Safety Evaluator in the Division of Medication Error Prevention and Analysis within the Office of Surveillance and Epidemiology of the Center for Drug Evaluation and Research. There, she has gained extensive knowledge and experience in mediation safety through the review of product labels and labeling, proprietary name review, product design and human factors and post market surveillance. Prior to joining the FDA, Dr. Stewart gained a wealth of pharmacy practice experience from Johns Hopkins Hospital where she was a clinical pharmacist in adult oncology. While there, she gained experience working in various capacities within oncology pharmacy practice including clinical research with the Investigational Drug Service, point of care services, outpatient infusion, and ambulatory care. She obtained her pharmacy doctorate degree from the University of Maryland School of Pharmacy.

Jason Wakelin-Smith
Lead Inspector, Good Clinical Practice, Medicines and Healthcare Products Regulatory Agency (UK)

Jason Wakelin-Smith joined the Medicines and Healthcare Products Regulatory Agency (MHRA) in November 2006 as a Good Clinical Practice (GCP) Inspector, became a Senior Inspector in 2015 and a Lead Senior Inspector in August 2017. He has a split role between the GCP and laboratories inspection teams within the MHRA conducting a variety of inspections including GCP inspections of sponsors, CROs and analytical laboratories, bioequivalence trials and GLP inspections. Mr. Wakelin-Smith has a BSc (hons) in Biomedical Science and a Postgraduate Diploma in Pharmaceutical Technology & Quality Assurance (PTQA). Previously, he spent seven years in the UK National Health Service working in hospital pharmacy (including clinical trials and manufacturing).

Jo Wyeth, PharmD
Associate Director for Post-Market Assessments; Acting Director, Division of Mitigation Assessment and Medication Error Surveillance, FDA

Jo Wyeth, PharmD, is currently the Associate Director of Post-Market Assessment in the Office of Medication Error Prevention and Risk Mitigation (OMEPRM) and Acting Director for the Division of Mitigation Assessment and Medication Error Surveillance (DMAMES) within FDA's Center for Drug Evaluation and Research (CDER), Office of Surveillance and Epidemiology (OSE). She is responsible for guiding a wide range of activities related to risk assessment and mitigation, quality assurance, research, training, and policy. Dr. Wyeth is widely recognized for her expertise in surveillance and risk mitigation and has worked on a number of high-profile safety issues for FDA. Before joining OMEPRM, she was the post-market safety program lead for the Division of Medication Error Prevention and Analysis (DMEPA), a regulatory health information manager for the Regulatory Science Staff (RSS), and a team lead and safety reviewer for the Division of Pharmacovigilance (DPV). She earned a doctorate in pharmacy from North Dakota State University and completed her residency training at Mayo Clinic.

Susan C. Winckler, RPh, Esq.
CEO, Reagan-Udall Foundation for the FDA

Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, she served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Winckler directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters.

As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), she managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.

The FDA and the FDA Foundation wish to thank the following individuals for their contributions to today's presentations:

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