The following are biosketches for speakers participating in the KHI workshop titled "Standardized Pharmacokinetics Assessment in Patients Receiving Continuous Renal Replacement Therapy (CRRT)" on Tuesday, November 11.

Patrick Archdeacon, MD

Patrick Archdeacon is a medical officer in the Office of Medical Policy with the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). His work at the Office of Medical Policy includes involvement in the Clinical Trials Transformation Initiative (a public-private partnership that identifies practices to increase the quality and efficiency of clinical trials) and the Sentinel Initiative (a system that will draw on existing automated healthcare data from multiple sources to actively monitor the safety of medical products continuously and in real time). Dr. Archdeacon originally joined FDA in 2008 as a medical officer in the Division of Special Pathogens and Transplant Products in the Office of New Drugs. He attended medical school at Columbia University's School of Physicians and Surgeons. Prior to joining FDA, he completed his training in internal medicine at the New York Presbyterian Hospital and in nephrology and transplant nephrology at the University of North Carolina.

Dr. Archdeacon is the FDA Co-Chair on the KHI Board of Directors.

George R. Aronoff, MD, MS, FACP

Doctor Aronoff graduated from Indiana University with a Bachelor of Arts degree in Chemistry with honors and received his Doctor of Medicine from Indiana University School of Medicine, where he also completed a Master of Science degree in Pharmacology . He is a member of the medical honor society, Alpha Omega Alpha.

He completed training in Internal Medicine at the Indiana University Medical Center and served as Chief Resident at Marion County General Hospital (Wishard Memorial) in Indianapolis. He completed a Fellowship in Nephrology at the Indiana University Medical Center and a Fellowship in Clinical Pharmacology at Eli Lilly and Company.

Doctor Aronoff served on the Faculty at Indiana University School of Medicine for 8 years, before becoming Chief of the Nephrology Division at the University of Louisville, a position he held for 23 years. He is currently Professor of Medicine and Pharmacology at the University of Louisville.

Doctor Aronoff's research has focused on individualization of drug therapy in patients with impaired kidney function. His research has been funded by the National Institutes of Health, the Department of Veterans Affairs and the pharmaceutical industry. He is the editor of Drug Prescribing in Renal Failure: Dosing Guidelines for Adults and Children. While at the University of Louisville, Doctor Aronoff maintained an active clinical practice in chronic kidney disease, dialysis and transplantation. He maintains Special Certification in Hypertension from the American Society of Hypertension.

Doctor Aronoff has been active in the Renal Physicians Association, having served on its Board of Directors and has chaired several committees for the American Society of Nephrology. He served as a member of the Board of Directors of the Kidney Health Initiative, a public-private partnership of the American Society of Nephrology and the Food and Drug Administration of the United States. He co-chaired the Drug Dosing and Continuous Renal Replacement Therapy Work Group. He is also President

of the Board of Trustees of Network Strategies and Innovation, a contractor to the Centers for Medicare and Medicaid Services, which oversees the quality of dialysis care in Illinois, Indiana, Ohio, and Kentucky (The Renal Network, Inc.) and Iowa, Kansas, Missouri, and Nebraska (The Heartland Kidney Network).

Doctor Aronoff joined Renal Ventures Management, LLC in December, 2013, where he serves as the Assistant Chief Medical Officer.

Barry I. Eisenstein, MD, FACP, FIDSA, FAAM

Barry Eisenstein received his MD from Columbia University followed by training in Internal Medicine and Infectious Diseases at the University of North Carolina. He has spent his career in academy and industry, serving as chief of the ID division at the University of Texas Health Sciences Center, San Antonio then as Professor and Chair of the Department of Microbiology and Immunology at the University of Michigan. Following four years as VP, Lilly Research Labs, in charge of ID discovery and clinical development, he moved to Boston as VP of Science and Technology, Beth Israel Deaconess Medical Center and Professor of Medicine, Harvard Medical School. Since 2003 he has worked at Cubist Pharmaceuticals, where he helped lead the approval process for Cubicin at the FDA and is now Senior Vice President, Scientific Affairs. He is the author of more than 100 original papers, book chapters, and editorials, has edited several books on infectious diseases and microbiology. A past editor of Infection and Immunity, he currently serves (since 2004) as an editor of Antimicrobial Agents and Chemotherapy. In 2008 he provided testimony before the US Senate on, "Emergence of the Superbug: Antimicrobial Resistance in the U.S.", and in both 2010 and 2012 before the US Congress hearings on antibiotic resistance that led to the passage of the GAIN Act. He co-chaired a 2010 FDA Workshop panel on endpoints and non-inferiority margins for antibiotic development, and was a panelist at a 2011 joint Pew/IDSA/PhRMA workshop on antibiotic resistance. He was recently a member of the Research Committee and of the Research on Resistance Working Group of the IDSA and chaired the PhRMA taskforce on "emerging pathogens", a group that met twice in 2012 with FDA leadership to discuss ways to reduce ATB registration hurdles. He is presently a member of the FNIH Biomarkers Consortium on endpoints in bacterial infections, of the CTTI group working on expediting clinical trials for bacterial infection, and of the Brookings Institution Council on Antibacterial Drug Development.

William H. Fissell, MD

Dr. Fissell has undergraduate training in physics and electrical engineering, and received his MD from Case Western Reserve University. Early in his fellowship and junior faculty positions, Dr. Fissell worked with David Humes on the bioartificial kidney in treatment of sepsis, and then shifted to the Cleveland Clinic, where his clinical effort focused entirely on renal support of the critically ill patient. Dr. Fissell now serves as an Associate Professor at Vanderbilt University's Division of Nephrology and Hypertension.

Michael F. Flessner, PhD, MD

Dr. Flessner is the Director, Inflammatory Renal Disease Program at the Division of Kidney, Urologic, and Hematologic Diseases. He oversees clinical research programs in Polycystic Kidney Disease, Transplantation, Diabetic Nephropathy, Glomerular Diseases, and Chronic Kidney Disease. This includes early development and Phase III trials of drugs within these disease entities. Besides his professional training in nephrology and clinical trials, he has a doctorate in Chemical Engineering and has specific interest in application of quantitative techniques to biological phenomena.

Dr. Flessner was previously Director of Nephrology at the University of Mississippi Medical Center and a researcher at the Jackson Heart Study. During his 25 years in Academia, he has lectured on the use of drugs in patients with altered physiologic or metabolic states. His basic research was funded by AHA and NIH and included trans-peritoneal transport of water and solutes in support of dialysis and intraperitoneal drug therapy. In addition, he has examined foreign body reactions to polymers in the peritoneal cavity and demonstrated how "sterile inflammation" affects peritoneal anatomy and transport characteristics. He has an extensive background in mathematical modeling of transport within tissue and is author of over 140 publications and has given more than150 invited talks around the world.

Stuart L. Goldstein, MD

Stuart L Goldstein, MD, is Professor of Pediatrics and Director, Center for Acute Care Nephrology at Cincinnati Children's Hospital Medical Center. He received his medical degree from Columbia University and completed both clinical and research fellowships in pediatric nephrology at the Children's Hospital in Boston, Massachusetts. Dr. Goldstein is a member of the American Academy of Pediatrics, the American Society of Nephrology, the International Pediatric Nephrology Association, the American Society of Pediatric Nephrology, the International Society of Nephrology, and the Society for Pediatric Research. In addition, he served as the first Chairman of the Medical Advisory Committee to the FORUM of ESRD Networks and as a member of the Medical Review Board for the ESRD Networks 9, 10, and 14. He is the Pediatric Nephrologist Representative for the International Society of Nephrology Commission of Acute Renal Failure, and has been elected to the Council of the American Society of Pediatric Nephrology. Dr. Goldstein has developed and validated the pediatric modified RIFLE (pRIFLE) AKI criteria, is Founder and Principal Investigator for the Prospective Pediatric Continuous Renal Replacement Therapy (ppCRRT) Registry Group, and has evaluated novel urinary AKI biomarkers in the pediatric critical care setting. He was one of two pediatric work group members for the KDIGI International AKI Guideline Work Group and has served on the KDOQI Hemodialysis Adequacy, Vascular Access and Pediatric Nutrition Guideline Work Groups. He has written over 110 journal articles and contributed book chapters to numerous texts including, Critical Care Nephrology, Evidence-Based Nephrology, Handbook of Dialysis Therapy, Management of Acute Kidney Problems, Pediatric Critical Care, Pediatric Nephrology, and Pediatric Nephrology in the ICU.

Mayurika Ghosh, MD

Dr. Ghosh is currently a Medical Officer and clinical reviewer with the Division of Anti-Infective Products, Office of Antimicrobial Products, FDA. She also serves as Clinical Assistant Professor of Medicine at the University of Maryland School of Medicine with the Division of General Internal Medicine. Prior to coming to the FDA she served as Assistant Professor of Medicine at the University of Maryland School of Medicine with the Division of Infectious Diseases/Institute of Human Virology. She received her training in Infectious Diseases from Tufts- New England Medical Center and she is a Fellow of the American College of Physicians.

Shiew-Mei Huang, PhD

Dr. Huang is currently Deputy Director, Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), FDA. She received her B.S. in Pharmacy from National Taiwan University, School of Pharmacy in 1975 and her Ph.D. from University of Illinois, Medical Center in Pharmacokinetics and Biopharmaceutics in 1981. She has 15+ year drug development experience (Ortho pharmaceutical Corp. and Dupont-Merck Pharmaceutical Company) before joining the FDA in 1996. She chairs CDER working groups that published draft guidance on drug interactions in 2012 and a draft guidance on pharmacokinetics in renal impairment in 2010. She is a member of the FDA Pharmacogenomics Working Group and CDER Hepatic impairment working group.

She has published over 160 peer-reviewed articles and book chapters focusing on topics in clinical pharmacology, drug metabolism/transport interactions, physiologically based pharmacokinetic modeling and pharmacogenomics areas, and has been invited to present more than 60 presentations in the past 5 years at national and international meetings and workshops. Dr. Huang is an associate editor for a Nature journal "Clinical Pharmacology and Therapeutics" and on the editorial boards of several other journals including Expert Review in Clinical Pharmacology, Biomarkers in Medicine, Expert Opinion-Pharmacotherapy; Pharmacogenomics. She has received many awards, including an FDA Outstanding Achievement Award, FDA Clear Communication Award, and FDA Distinguished Service Award. Dr. Huang is an AAPS Fellow (American Association of Pharmaceutical Scientists), a JSSX Fellow (Japanese Society of the Study of Xenobiotics) and a diplomate of the American Board of Clinical Pharmacology. She is an Adjunct Professor at the School of Pharmacy, University of Maryland and has been a faculty member of an elective course on pharmacogenomics since 2008. She was the President (2009-2010) of the American Society for Clinical Pharmacology and Therapeutics (ASCPT). She has received a prestigious ASCPT Award "Gary Neil Prize for Innovation in Drug Development" in March 2014.

Joanna Q Hudson, PharmD, BCPS, FASN, FCCP, FNKF

Dr. Hudson is Associate Professor in the Departments of Clinical Pharmacy and Medicine (Division of Nephrology) at the University of Tennessee, Memphis.

Dr. Hudson received a B.A. in chemistry from the University of Virginia in 1992, a Doctor of Pharmacy from Virginia Commonwealth University-Medical College of Virginia (VCU/MCV) in 1996, and completed a 2-year Nephrology fellowship at VCU-MCV. She joined the faculty at the University of Tennessee in 1998 where her teaching activities for students, residents and fellows focus in nephrology. Dr. Hudson's research interests include drug disposition in the chronic kidney disease (CKD) population and during renal replacement therapy. She currently has an active grant to evaluate antibiotic removal by sustained low efficiency dialysis.

She also maintains her practice as a Clinical Pharmacist specializing in Nephrology at Methodist University Hospital in Memphis and is a consultant for outpatient dialysis units.

Dr. Hudson is the past President of the National Kidney Foundation of West TN and an active member of pharmacy and nephrology related organizations. She has been recognized as a Fellow of the American Society of Nephrology, the American College of Clinical Pharmacy and the National Kidney Foundation. She also serves as a reviewer for the professional journals including the *American Journal of Kidney Disease, Kidney International,* and *Pharmacotherapy*.

Richard L. Lalonde, PharmD, FAAPS, FCP, FCCP

Richard is currently Vice President, Global Head of Clinical Pharmacology and Head of Clinical Pharmacology, Global Innovative Pharmaceuticals Business at Pfizer. Prior to joining Pfizer via the legacy Warner Lambert organization in 1998, he was Scientific Director and Head of Clinical Pharmacology and Pharmacokinetics at Phoenix International in Montreal from 1991 to 1998. From 1984 to 1991 he was Assistant Professor and then a tenured Associate Professor and Vice Chair for Research in the Department of Clinical Pharmacy, College of Pharmacy, University of Tennessee, and Memphis. He also worked from 1980 to 1984 at the University of Ottawa Health Sciences Centre. Richard is a Fellow of the American College of Clinical Pharmacology, the American Association of Pharmaceutical Scientists and the American College of Clinical Pharmacy. He was President of the American Society for Clinical Pharmacology and Therapeutics (2011 – 2012) and a member of its Board of Directors (2010-2013). He also served from 2004 – 2009 on the Board of Regents of the American College of Clinical Pharmacology. He has been a member of the editorial board of Clinical Pharmacology and Therapeutics since 2005 (Associate Editor 2007-2010) and was a member of the editorial board of Pharmaceutical Research from 1998 – 2001. He currently serves on the National Advisory General Medical Sciences Council at the National Institutes of Health, Bethesda, MD. Over the past 33 years, Richard has been an invited speaker at various national and international meetings of professional societies, universities, FDA and served on advisory committees at FDA and NIH. His work has been focused on the quantitative application of pharmacokinetic and pharmacodynamic principles to the optimal development and utilization of new drugs in patients. Richard has authored over 130 manuscripts, abstracts and book chapters in this discipline. He is a graduate of the University of Minnesota (PharmD) and the University of Toronto (B.Sc. Pharmacy).

Rajanijanth (Raj) Madabushi, PhD

Rajanikanth (Raj) Madabushi, Ph.D., is a Team Leader for Cardio-Renal products in the Division of Clinical Pharmacology I of Office of Clinical Pharmacology, Center for Drug Evaluation and Research, FDA, Silver Springs, MD. Dr. Madabushi received his Ph.D. degree in Pharmaceutical Sciences from Birla Institute of Technology and Sciences (BITS), Pilani, India. Following his Ph.D., he did a post-doctoral fellowship with Prof. Hartmut Derendorf at university of Florida, Gainesville. He joined the Pharmacometrics Group at FDA in 2005. As a pharmacometrics reviewer, he was predominantly involved in the application of quantitative clinical pharmacology approaches for regulatory decision making and addressing various drug development issues in the areas of Cardio-Renal, Hematology and Endocrinology drug products. In 2009, he became the Team Leader in the Division of Clinical Pharmacology I. Since then, he has been involved in the drug development, regulation, research and policy for cardiovascular and renal products from a clinical pharmacology perspective.

Bruce A. Mueller, PharmD, FASN

Dr. Bruce A. Mueller is a Professor of Pharmacy and Associate Dean of Academic Affairs, College of Pharmacy at the University of Michigan. He is director of the College's Critical Care Nephrology Fellowship program. He received his baccalaureate degree from the University of Wisconsin in 1984 and completed Doctor of Pharmacy and postdoctoral residency from University of Texas in 1988. He joined the University of Michigan in 2000 after serving on the faculty at the Purdue University School of Pharmacy and Pharmacal Sciences since 1988. Mueller's clinical and laboratory-based research has focused on issues faced by patients with kidney disease for over 25 years. He has published over 110 peer-reviewed papers in the areas of dialysis, pharmacokinetics, continuous renal replacement

therapies, and pharmacotherapeutics of kidney disease. He has trained many current leaders in this area of pharmacy through his work in graduate, residency, and post-doctoral fellowship training programs. He has been named a Fellow of the American College of Clinical Pharmacy, the American Society of Nephrology and the National Kidney Foundation. He has received numerous teaching awards.

Thomas D. Nolin, PharmD, PhD, FASN

Tom Nolin, PharmD, PhD is an Assistant Professor in the Department of Pharmacy & Therapeutics, and in the Department of Medicine Renal-Electrolyte Division at the University of Pittsburgh. Dr. Nolin is an NIH funded investigator whose primary research focuses on developing an understanding of the impact of kidney disease on nonrenal drug metabolism and transport pathways and corresponding effects on drug exposure and response, and evaluating the effect of renal replacement therapy on drug disposition. He maintains an active laboratory focusing on development and validation of quantitative analytical methods, with expertise in HPLC and mass spectrometry. Dr. Nolin is a Fellow of the American College of Clinical Pharmacy, the American College of Clinical Pharmacology, and of the American Society of Nephrology. He serves on the editorial board of the American Journal of Kidney Disease, and is the chair of the KHI Pharmacokinetics Workgroup.

Amin Rostami-Hodjegan, PhD, FCP, FAAPS, FJSSX

Amin is a Professor of Systems Pharmacology at the Centre for Applied Pharmacokinetic Research (CAPKR) in the Pharmacy School at the University of Manchester. He has an active program of training PhD students in CAPKR in Systems Pharmacology and Pharmacokinetics and numerous students have graduated under his supervision from the University of Sheffield, where he was a Professor of Systems Pharmacology before joining the University of Manchester in 2009. As the Vice President of Research & Development at Simcyp Limited (a Certara Company), Amin leads a team of over 30 scientists working on extrapolation of *in vitro* data on drug metabolism to predict *in vivo* pharmacokinetics and pharmacodynamics in virtual patient populations. Professor Rostami has authored/co-authored over 150 peer-reviewed full articles and serves on the Editorial Boards of several journals. He has been an invited speaker at over 140 national and international meetings and has led a number of hands on workshops in the area of *in vitro-in vivo* extrapolation as applied to ADME in Drug Development.

Alan Murray Shapiro, MD, PhD, FAAP

Alan Shapiro is a Pediatrician Infectious Diseases Specialist working in the Division of Antiviral Products at Center for Drug Evaluation and Research (CDER) at FDA.

Alan Shapiro received his BS in Life Sciences (1985) from the Massachusetts Institute of Technology (1985). He was a member of the Medical Scientist Training Program (MSTP) and received his Ph.D. in Biochemistry (1993) and his M.D. (1994) from the University of California San Francisco. He completed his residency in Pediatrics at University of California Los Angeles (UCLA) Medical Center and continued his fellowship training there initially in Pediatric Nephrology and then transitioned to Pediatric Infectious Diseases. Dr. Shapiro is certified by the American Board of Pediatrics in General Pediatrics and Pediatric Infectious Diseases. He is also a member of the U.S. Department of Health and Human Services Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission.

Dr. Shapiro has been a medical officer at the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration since 2003. He originally joined the Division of Pediatric Drug Development and later transferred to the Division of Antiviral Products.

Vikram Sinha, PhD

Dr. Sinha is the Director, Division of Pharmacometric at the USFDA. In his current role, Vikram leads the Pharmacometrics Division. The Division plays a critical role in understanding the impact of variability in response to drugs and relates it to assessing benefit and risk. He leads a multidisciplinary team of quantitative clinical pharmacologists, statisticians, engineers, and data management experts. Within CDER, pharmacometric work is conducted with the intent to aid the decision to approve and label the drug product. There is particular attention on providing a consulting function on drug dosing for patients and advice on trial design decisions by sponsors. Previously, Vikram was at Eli Lilly, where he was scientific lead for global pharmacokinetics/pharmacodynamics and pharmacometrics. At Lilly, he was accountable for developing quantitative translational strategies, clinical plans, and regulatory strategies in the area of clinical pharmacology. He has 16 years of experience in the pharmaceutical industry. He has made notable contributions to the general scientific community through teaching, publications, and engagement with industry/government consortia dedicated to advancing innovation in the area of drug discovery and development. Vikram earned a bachelor's degree in pharmacy and a doctorate degree in pharmaceutical sciences from the University of Arizona. He completed post-doctoral training at the University of Nebraska Medical Center.

Issam Zineh, PharmD, MPH, FCP, FCCP

Dr. Zineh is Director, Office of Clinical Pharmacology (OCP), and Co-Director of the Biomarker Qualification Program, Office of Translational Sciences, CDER, U.S. FDA. From 2008-2012, Dr. Zineh was the Associate Director for Genomics in OCP. He is an experienced clinical pharmacist who was formerly on the faculty of the University of Florida (UF) Colleges of Pharmacy and Medicine and Associate Director of the UF Center for Pharmacogenomics. Dr. Zineh received his PharmD from Northeastern University and completed his residency at Duke University Medical Center. He did a fellowship in cardiovascular pharmacogenomics at UF where he also obtained his MPH in Health Policy and Management. He is a recognized expert in the field of clinical pharmacology, pharmacotherapy, and pharmacogenomics. Dr. Zineh is chair of the Coriell Personalized Medicine Collaborative Pharmacogenomics Advisory Group, and sits on the Centers for Disease Control and Prevention's EGAPP steering committee. As Director of OCP, Dr. Zineh is a member of the CDER Senior Management Team and leads a staff of 200 regulatory scientists, project managers, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through applied clinical pharmacology.