



Bridging Drug Efficacy and Safety to the Obese: Considerations and Scientific Approaches

University of Maryland Center of Excellence in Regulatory Science and Innovation
Food and Drug Administration
Public Webinar
November 9, 2022 | 8:15 am – 4:15 pm Eastern Time

Biographies

Robert M. Califf, M.D.

Commissioner of Food and Drugs
Office of the Commissioner, FDA



Dr. Robert M. Califf was confirmed earlier this year as the 25th Commissioner of Food and Drugs.

As Commissioner, Dr. Califf oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products.

Dr. Califf has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

This is Dr. Califf's second stint as Commissioner. He also served in 2016 as the 22nd Commissioner. Before assuming the position at that time, he served as the FDA's Deputy Commissioner for Medical Products and Tobacco.

Prior to rejoining the FDA in 2022, Dr. Califf was head of medical strategy and Senior Advisor at Alphabet Inc., contributing to strategy and policy for its health subsidiaries Verily Life Sciences and Google Health. He joined Alphabet in 2019, after serving as a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and was the founding director of the Duke Clinical Research Institute.

Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco and a fellowship in cardiology at Duke.

Frank B. Hu, M.D., MPH, Ph.D.

Fredrick J. Stare Professor of Nutrition and Epidemiology
Chair, Department of Nutrition
Harvard TH Chan School of Public Health
Professor of Medicine
Harvard Medical School & Brigham & Women's Hospital



Dr. Frank Hu is Chair of Department of Nutrition, Fredrick J. Stare Professor of Nutrition and Epidemiology at Harvard T.H. Chan School of Public Health, and Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital. Dr. Hu's major research interests include epidemiology and prevention of obesity and cardiometabolic diseases through diet and lifestyle; gene-environment interactions; nutritional metabolomics; and nutrition transitions in low- and middle-income countries. Currently, he is Director of *Boston Nutrition and Obesity Research Center* Epidemiology and Genetics Core and co-Director of the *Program on Obesity Epidemiology and Prevention* at Harvard. He has published a textbook on Obesity Epidemiology (Oxford University Press) and >1000 peer-reviewed papers with an H-index of 290. He served on the *Institute of Medicine* (IOM) Committee on Preventing the Global Epidemic of Cardiovascular Disease, the NIH Obesity Guideline Expert Panel, American Heart Association Nutrition Committee, and the 2015 Dietary Guidelines Advisory Committee, USDA/HHS. He has served on the editorial boards of *Lancet Diabetes & Endocrinology*, *Diabetes Care*, and *Clinical Chemistry*. Dr. Hu was elected to the *National Academy of Medicine* in 2015.

Raj Madabushi, Ph.D.

Associate Director, Guidance and Scientific Policy
Office of Clinical Pharmacology, OTS/CDER/FDA



Rajanikanth (Raj) Madabushi has over 15 years of regulatory experience. As a Pharmacometrics Reviewer and Clinical Pharmacology Team Lead, Dr. Madabushi has played a key role in the advancement and application of quantitative clinical pharmacology approaches for regulatory decision making and addressing various drug development issues. He currently serves as the Associate Director, Guidance and Scientific Policy in the Immediate Office of Office of Clinical Pharmacology. Dr. Madabushi is also the CDER Point-of-Contact for the MIDD Paired Meeting Program and the Rapporteur for ICH M12 Expert Working Group – Drug Interaction Studies. Dr. Madabushi received his Ph.D. in Pharmaceutical Sciences from Birla Institute of Technology and Sciences (BITS), Pilani, India.

David J. Greenblatt, M.D.

Louis Lasagna Endowed Professor
Tufts University School of Medicine



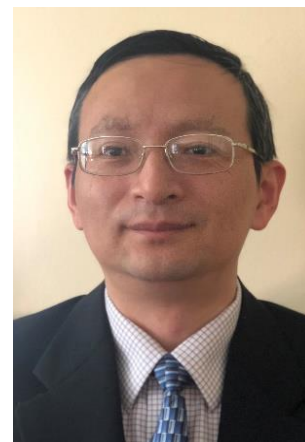
A native of Newton, Massachusetts, Dr. Greenblatt is a Magna Cum Laude graduate of Amherst College (1966), where he was senior class president and co-captain of the varsity football team. He graduated from Harvard Medical School in 1970, then trained in internal medicine at the Montefiore Hospital, New York City (1970-1971), and on the Harvard Medical Service at Boston City Hospital (1971-1972). Following a Fellowship in Clinical Pharmacology at Massachusetts General Hospital, under the mentorship of Dr. Jan Koch-Weser (1972-1974), he stayed on to head their Clinical Pharmacology Unit (1975-1979).

Dr. Greenblatt has been on the Faculty of Tufts University School of Medicine (TUSM) and the Staff of Tufts Medical Center (TMC) since 1979. He is a senior faculty member in the Graduate Program in Pharmacology & Experimental Therapeutics, and has previously served as Chair of the Department of Pharmacology and Experimental Therapeutics at TUSM, Program Director and Associate Program Director of the institution's Clinical/Translational Research Center, and Chair of the Institutional Review Board. He is Editor-in-Chief of *Clinical Pharmacology in Drug Development*, and also served as Co-Editor-in-Chief, with Dr. Richard I. Shader, of the *Journal of Clinical Psychopharmacology* from 1981 to 2020. His PubMed listing includes more than 1100 publications, of which 790 are original research reports. He has served as postdoctoral training supervisor or dissertation supervisor for more than 50 trainees, most of whom have gone on to positions as university-based investigators or scientists in industry.

Dr. Greenblatt is Board Certified by the American Board of Clinical Pharmacology (1991), where he is a charter member. A member of the American Society for Clinical Pharmacology and Therapeutics (ASCPT) since 1973, he received the Rawls-Palmer Progress in Medicine Award from that organization in 1980. As a member of the American College of Clinical Pharmacology (ACCP) since the early 1970s, he served as President (1996-1998), and received their McKeen-Cattell Award in 1985, the Distinguished Service Award in 2001, and the Distinguished Investigator Award in 2002. He received the 2005 Research Achievement Award in Clinical Sciences from the American Association of Pharmaceutical Sciences, the Distinguished Faculty Award from TUSM in 2015, and the 2016 Award in Excellence in Clinical Pharmacology from the Pharmaceutical Research and Manufacturers of America Foundation, through ASCPT. Dr. Greenblatt is the recipient of the 2022 Oscar B. Hunter Career Award in Therapeutics from ASCPT, recognizing outstanding career contributions to clinical pharmacology and therapeutics.

Hao Zhu, Ph.D., Mstat

Division Director, Division of Pharmacometrics
Office of Clinical Pharmacology, OTS/CDER/FDA



Dr. Hao Zhu is the director of the Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Science, Center of Drug Evaluation and Research, U.S. Food and Drug Administration. Dr. Zhu received his Ph.D. in Pharmaceutical Sciences and Master in Statistics from the University of Florida. He started his career in modeling and simulation teams in Johnson & Johnson and Bristol-Myers-Squibb. He joined FDA as a pharmacometrics reviewer more than 15 years ago. Dr. Zhu has been a clinical pharmacology team leader for more than 6 years and a QT-IRT scientific lead for 2 years. Then he became the deputy director at the Division of Pharmacometrics. His division reviews the pharmacometrics related submissions and supports pharmacometrics-related policy development.

Amin Rostami-Hodjegan, Ph.D., FCP, FAAPS, FJSSX, FBPS

Professor of Systems Pharmacology and Director of CAPKR,
University of Manchester, UK
CSO, Certara, Princeton, USA



The Institute of Scientific Information (ISI, Clativate) listed Amin as one of the world's most highly cited researchers (under 'Pharmacology & Toxicology') in 2017. Amin is also at 0.06% top rank of the Highly Cited Researchers List by Elsevier for pharmacology (2020). He has published over 300 peer reviewed highly influential scientific articles (>20,000 citations, h-index = 77). The work of Professor Rostami covers wide areas of drug development over the last 30 years, ranging from pharmaceuticals (e.g. bioequivalence) to clinical pharmacology (e.g. mixture pharmacology of drug/metabolites), translational and systems pharmacology (e.g. quantitative proteomics of enzymes and transporter for in vitro to in vivo (IVIVE) scaling).

Amin was co-founder of two spin-off companies from the University of Sheffield (Simcyp Limited and Diurnal PLC). As a leader in the field of physiologically-based pharmacokinetics (PBPK) and quantitative systems pharmacology (QSP), he is internationally recognized for his expertise in IVIVE to predict the behaviour of drugs in human body and understanding the associated inter-individual variabilities. He was one of the founding editors of Pharmacometrics and System Pharmacology, and serves on the Editorial Boards of several other journals.

As the Senior Vice President of Research & Development (SVP) and Chief Scientific Officer at Certara, he facilitates the incorporation and integration of the latest advances in translational modelling to biosimulation platforms offered by Certara to its clients, with the aim of accelerating the development and regulatory approval of safer drug products and bringing them to the patients

Alison Edelman, M.D., MPH

Professor Obstetrics and Gynecology
Division Director of Complex Family Planning (CFP)
CFP Fellowship Director at Oregon Health & Science University (OHSU)



Alison Edelman is a Professor of Obstetrics and Gynecology, the Division Director of Complex Family Planning (CFP) and CFP Fellowship Director at Oregon Health & Science University (OHSU). She completed her medical training at OHSU and was the very first fellow in Complex Family Planning (2001). She completed a Master in Public Health at the University of Washington (2003). Dr. Edelman is an active clinician-scientist with intra- and extra-mural research funding. Her work has focused on management of contraceptive induced menstrual changes, emergency contraception, and obesity and contraceptive efficacy. Dr. Edelman is also the Oregon site PI for the NICHD Contraceptive Clinical Trials Network which helps to develop new female methods of contraception. Given the success of the female site at OHSU, activities have expanded to trials in development of male methods of contraception. A complete list of her publications can be found at: <http://www.ncbi.nlm.nih.gov/sites/myncbi/alison.edelman.1/bibliography/41144878/public/?sort=date&direction=ascending>

For close to 20 years, Dr. Edelman has been a global technical consultant in sexual and reproductive health (SRH) with extensive incountry experience in LAC, Asia, and Africa as well as assisting with humanitarian emergency SRH response needs. Additionally, she was appointed in 2022 to the UN/WHO Scientific Technical Advisory Group of the Department of Sexual and Reproductive Health and Research (3 year term; only 2 members can be from North or South America). She has a number of additional leadership positions in the field including Lead Editor of the Cochrane Fertility Regulation Review Group, Associate Editor of the journal, *Contraception*, member of the expert working group for the Centers for Disease Control Medical Eligibility Criteria (MEC) for Contraceptive Use as well as the Selective Practice Guidelines for Contraceptive Use and a member of the World Health Organization's steering committee for the WHO MEC. She recently completed her time as the Chair of ACOGs Committee on Gynecology Practice Bulletins (4-2021). She is continuing to work with ACOG to support the transformation of their guidance to meet IOM standards and to support ACOG COVID-19 gynecology-related FAQs.

Michel M.R.F. Struys, M.D., Ph.D., FRCA

Professor and Chair, Department of Anesthesiology
University of Groningen-University Medical Center Groningen, The Netherlands
Professor, Department of Basic and Applied Medical Sciences
Ghent University, Gent, Belgium



Michel M.R.F. Struys, M.D., Ph.D., FRCA is Professor and Chair at the Department of Anesthesiology, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands. He is also affiliated as Professor to the Department of Basic and Applied Medical Sciences, Ghent University, Gent, Belgium. He is a board certified anesthesiologist and clinical pharmacologist in Belgium and the Netherlands. His main research interest is in clinical pharmacokinetics and pharmacodynamics, drug administration technology, and drug effect monitoring. He co-authored more than 250 scientific publications and various books and book chapters. He is Director for Grants and International relations for the British Journal of Anaesthesia, Associate Editor for Anesthesiology and incoming chair of the Scientific Committee, European Society of Anaesthesiology and Intensive Care. His main clinical interest is in anesthesia for oncological and abdominal surgery.

Varsha Mehta (Bhatt-Mehta), Pharm.D., M.S., FCCP

Senior Staff Fellow

OCP-Pediatrics, OTS, CDER, FDA

Dr. Mehta (Bhatt-Mehta) is a Senior Staff Fellow in Pediatrics in the Office of Clinical Pharmacology (OCP) within the Office of Translational Sciences (OTS) at the Center for Drug Evaluation and Research (CDER), Federal Food and Drug Administration (FDA) where she has worked since March 2021. Prior to starting at the FDA, Dr. Mehta was a Clinical Professor of Pharmacy, Pediatrics and Communicable Diseases at the University of Michigan for nearly 32 years with a primary clinical focus on neonatal and pediatric critical care pharmacotherapy. She is currently also Professor Emerita at the University of Michigan.



Dr. Mehta's research interests include use of clinical and regulatory science principles to study of safe and effective drug therapies in pediatric and neonatal patients. She is also an educator engaged in experiential instruction of pharmacy students and fellows. Dr. Mehta is an active member of many national organizations lending her professional services to further the causes of these organizations. She has published over 100 scientific papers, abstracts, and book chapters in peer-reviewed scientific journals. She has traveled internationally to deliver scientific presentations in the UK, Europe, and Singapore.

Dr. Mehta's interest in Pediatric Drug Development (PDD) spans over more than two decades. Her clinical research program and experience in clinical trial design inspired her deeper involvement in PDD including research in regulatory science, pediatric clinical trial design and pediatric drug development.

Daniel Gonzalez, Pharm.D., Ph.D.

Associate Professor, Division of Pharmacotherapy and Experimental Therapeutics

UNC Eshelman School of Pharmacy, The University of North Carolina at Chapel Hill

Daniel Gonzalez, Pharm.D., Ph.D., is an Associate Professor in the Division of Pharmacotherapy and Experimental Therapeutics of the UNC Eshelman School of Pharmacy. He has an adjunct appointment within the Department of Pediatrics at the UNC School of Medicine. He joined the UNC Eshelman School of Pharmacy in 2014 after completing a postdoctoral fellowship through the UNC-Duke Collaborative Clinical Pharmacology T32 Postdoctoral Training Program. Gonzalez received his Pharm.D. and Ph.D. from the University of Florida College of Pharmacy in 2008 and 2012, respectively. Gonzalez is a licensed pharmacist in North Carolina and Florida.



Gonzalez's experiences have afforded a highly collaborative and multidisciplinary research program focused on advancing pediatric public health by promoting the safe and effective use of drugs in children. His research interests include pediatric clinical pharmacology and the application of mathematical modeling and simulation techniques to characterize the pharmacokinetics and pharmacodynamics of drugs, guide drug dosage selection, and improve drug safety in children. Gonzalez's research program is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), and he has published >95 peer-reviewed publications and >40 abstracts. He has served as the major advisor for 6 Ph.D. students and 15 postdoctoral fellows.

Michael Neely, M.D., MSc, FCP

Chief, Division of Infectious Diseases
Director, Laboratory of Applied Pharmacokinetics and Bioinformatics
The Saban Research Institute
Children's Hospital Los Angeles (CHLA),
Professor and Clinical Scholar, Department of Pediatrics
Keck School of Medicine, University of Southern California



Dr. Michael Neely is a Professor of Pediatrics and Clinical Scholar in the Department of Pediatrics at the Keck School of Medicine of the University of Southern California. He is a Board-certified pediatric infectious disease specialist physician with more than 20 years of experience in patient care, research, and mentoring of approximately 50 visiting scholars, fellows, and post-docs in clinical pharmacology and pharmacometrics. He serves as the Chief of Infectious Diseases at the Children's Hospital of Los Angeles (CHLA) and the director of the CHLA Laboratory of Applied Pharmacokinetics and Bioinformatics. Dr. Neely's lab created and maintains the Pmetrics population modeling and simulation package for R and the BestDose software to optimize individual patient dosing through applied pharmacometric techniques. Dr. Neely has recently expanded his lab to include hollow fiber capabilities, focusing on optimizing treatment of serious infections in pediatric patients such as Mycobacterium abscessus, Staphylococcus aureus, and resistant Gram-Negative bacteria. His research has been continually funded by the NIH since 2007, with additional funding from FDA and private foundations. He lectures and conducts pharmacometric workshops internationally and has published over 160 peer-reviewed publications and ten book chapters.

Jackie Gerhart, Ph.D., MBA, M.S.

Associate Director, Clinical Pharmacology, Global Product Development,
Pfizer



Dr. Jackie Gerhart recently joined Pfizer as an Associate Director in Clinical Pharmacology in Global Product Development, where she supports Pfizer's COVID-19 assets, including PAXLOVID. She previously worked in GlaxoSmithKline's Drug Metabolism and Pharmacokinetics supporting the respiratory preclinical portfolio. Dr. Gerhart completed her Ph.D. in Pharmaceutical Sciences at the University of North Carolina at Chapel Hill's Eshelman School of Pharmacy, where her research focused on using model and simulation techniques to optimize drug dosing in pediatric populations, particularly children with obesity. She also received her MBA in Finance from the University of North Carolina Kenan-Flagler Business School and her B.S. and M.S. degrees in Biomedical Engineering from Drexel University.

Alexander (Sander) Vinks, Ph.D., Pharm.D. FCP

Professor of Pediatrics and Pharmacology,
University of Cincinnati, College of Medicine
Cincinnati Children's Research Foundation Endowed Chair
Director, Division of Clinical Pharmacology
Cincinnati Children's Hospital Medical Center



Dr. Vinks serves as the Program Director of the *Eunice Kennedy Shriver* National Institutes of Child Health & Human Development (NICHD) Pediatric Clinical Pharmacology T32 training program at Cincinnati Children's. He is Co-Director of Cincinnati Children's Genetic Pharmacology Service, and Scientific Director for pharmacy research in the Division of Patient Services. He also directs a multidisciplinary Pharmacometrics Center of Excellence and spearheads a precision therapeutics implementation program. Dr. Vinks is a fellow of the American College of Clinical Pharmacology, and he serves as associate editor of *Clinical Pharmacology & Therapeutics*.

His research interests include pharmacokinetic-pharmacodynamic (PK/PD) modeling, physiologically-based pharmacokinetics (PBPK), pharmacogenetics/genomics, and the application of population and simulation methods to inform clinical trial design as part of model-informed drug development (MIDD) and therapeutic drug management through the implementation of model-informed precision dosing (MIPD) strategies.

Joga Gobburu, Ph.D.

Professor, School of Pharmacy and School of Medicine
Director, Center for Translational Medicine
University of Maryland



Dr. Joga Gobburu is Professor with the School of Pharmacy and the School of Medicine, University of Maryland, Baltimore, MD, USA. He held various positions at the U.S. FDA between 1998 and 2011. He has experience with overseeing the review of 1000s of Investigational New Drug Applications (INDs), over 250 New Drug and Biological Licensing Applications, numerous FDA Guidances, and policies pertaining to drug approval and labeling. At the FDA, he was part of the committee responsible for 21st Review Process and provided input into PDUFA planning.

He received numerous FDA awards such as the Outstanding Achievement Award and recognized with the Senior Biomedical Research Scientist appointment. He also received the Outstanding Leadership Award from the American Conference on Pharmacometrics (2008), the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology (2008), and Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics (2019). He is also a Fellow of AAPS and ACCP. Dr. Gobburu is on the Editorial Boards of several journals. He has published over 100 papers and book chapters.

Gilbert Burckart, Pharm.D.

Associate Director-Pediatrics
Office of Clinical Pharmacology, CDER, FDA

Dr. Gilbert Burckart is presently Associate Director for Pediatrics, Office of Clinical Pharmacology, U.S. Food and Drug Administration. Dr. Burckart has served on the faculties of four universities (Buffalo, Tennessee, Pittsburgh, Southern California) as a Professor of Pharmacy, Pediatrics and Surgery for 33 years prior to coming to the FDA. He moved to the U.S. FDA in 2008, and his duties include the direction of the Pediatric Clinical Pharmacology program within the Office of Clinical Pharmacology, and participation in the FDA's Pediatric Review Committee. His present educational and research program focuses on pediatric drug development studies.

**Jayabharathi Vaidyanathan, Ph.D.**

Associate Director for Therapeutic Review
Division of Cardiometabolic and Endocrine Pharmacology
Office of Clinical Pharmacology, OTS, CDER, FDA

Jaya Vaidyanathan, Ph.D., is the Associate Director for Therapeutic Review in the Division of Cardiometabolic and Endocrine Pharmacology in the Office of Clinical Pharmacology, CDER, FDA. She previously served as a Team Leader supporting review for Diabetes, Lipid Disorders, Obesity and general Endocrinology products. Jaya received her Ph.D. in Pharmaceutical Sciences in 2003 from the Medical University of South Carolina. She has experience supporting drug review across a wide range of therapeutic areas and has represented CDER on several policy and guidance working groups, including Bioavailability and Bioequivalence studies submitted in NDAs or INDs – General considerations, Waiver of in vivo bioavailability and bioequivalence studies for immediate-release solid oral dosage forms based on Biopharmaceutics Classification System (BCS), and indication specific guidances such as developing products for weight management, diabetes, and thyroid products. She is a member of the CDER-BCS committee and the CDER-Regulatory Science & Review enhancement program (RSR) committee.



Laura Higginbotham, M.D., MPH

Lead Physician, Division of Diabetes, Lipid Disorders, and Obesity
CDER, OND, FDA



Dr. Laura Higginbotham is a lead physician and clinical team leader in FDA's Division of Diabetes, Lipid Disorders, and Obesity within Center for Drug Evaluation and Research (CDER)'s Office of New Drugs (OND). She oversees the clinical review and regulation of products intended for the treatment of obesity, including oversight of investigational drugs and approval of new drugs for obesity, and often serves as the cross-discipline team leader (CDTL) who assesses findings from all review disciplines and incorporates them into a summary decision.

Dr. Higginbotham is board certified in preventive medicine and is experienced in the behavioral, medical, and surgical management of obesity. She received her medical degree from the University of Virginia and MPH in Epidemiology from the University of North Carolina. She completed four years of general surgery residency at Emory University, an NIH T32 NRSA fellowship in drug development, and preventive medicine residency at the University of North Carolina.

Kenneth Todd Moore, MA., M.S., FAHA

Scientific Director, Cardiovascular Disease
Cardiovascular & Metabolism Medical Affairs
Janssen Pharmaceuticals



Kenneth 'Todd' Moore joined Janssen Research & Development in 2006. After several years of working as a Clinical Pharmacology Leader, focusing on the design, conduct, and analysis of Phase I clinical trials, he moved to the Cardiovascular & Metabolism (CVM) Medical Affairs department in 2015. Todd is an experienced Scientific Director with a demonstrated history of research in the anticoagulant CV disease therapeutic area, experience with U.S. Food and Drug Administration drug submissions and leading both Clinical and Clinical Pharmacology drug trials.

Todd's publication history includes: 31 Abstracts; 14 Poster presentations; 32 Manuscripts; 8 opinion papers and Letters to the Editor, 2 Book Chapters and 3 Policy Papers. He designed and is currently leading the EMPOWER-PAD program, sponsored by Janssen Pharmaceuticals, which is a free educational and mobile screening platform in the U.S. promoting understanding and screening of Peripheral Artery Disease in underserved communities. Todd is also a member of the J&J Bioethics Board and of the American College of Clinical Pharmacology Public Policy Board. Lastly, He is currently acting as the U.S. Medical Affairs Therapeutic Area Lead for the Resistant Hypertension Disease area.

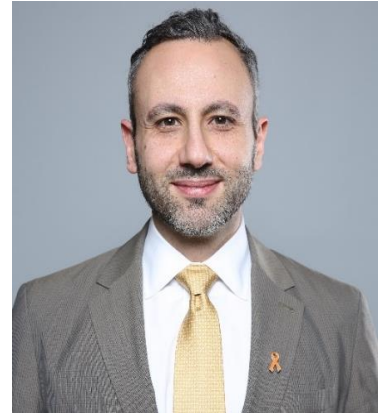
Prior to joining Janssen, Todd was a Sr. Clinical Scientist at Bristol-Myers Squibb R&D, with responsibilities primarily with the Cardiovascular Therapeutic area. He obtained a BA in Biology from the University of Delaware, a MS in Biology - Fairleigh Dickinson University, a MA in Bioethics and Health Policy from Loyola University-Chicago and is currently a Doctoral Candidate in Bioethics at Loyola University-Chicago.

Issam Zineh, Pharm.D., MPH, FCP, FCCP

Director

Office of Clinical Pharmacology, CDER, FDA

Issam Zineh is Director of the Office of Clinical Pharmacology (OCP) at the U.S. Food and Drug Administration (FDA). He has held various leadership positions at FDA including Associate Director for Genomics in OCP (2008-2012) and Co-Director of the CDER Biomarker Qualification Program (2009-2015) and serves on the CDER Medical Policy Council. He is a recognized expert in the fields of drug development and evaluation, clinical pharmacology, pharmacotherapy, and precision medicine. As Director of OCP, Dr. Zineh leads a staff of 260 regulatory, research, program/project management, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.



Jan Schlender, Ph.D.

Head Systems Pharmacology & Medicine Team 2

Research & Development, Pharmaceuticals

Bayer AG

Jan Schlender is heading a system pharmacology group at Bayer. In addition, he is a pharmacometric lead in clinical development programs. He joined Bayer as a Ph.D. student and continued as a modeling & simulation scientist in 2016. At Bayer, he was and is primarily engaged in pharmacokinetic, pharmacodynamic, systems biology and pharmacology modelling. During his time at Bayer, Jan supervised six Ph.D. students and a PostDoc. He built a scientific track record on quantitative approaches for special population groups. Jan studied Pharmacy at the University of Bonn and the National Taiwan University. He obtained an additional master in drug research at the University of Bonn with a research fellowship at the University of Florida and obtained his Ph.D. with Bayer Technology Services in affiliation with the University of Bonn.

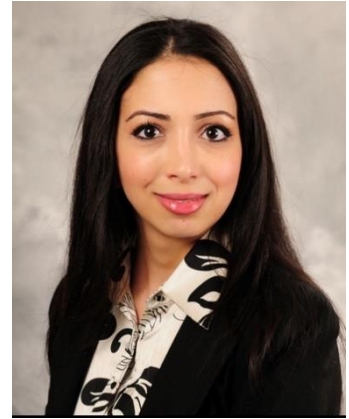


Amal Ayyoub, Ph.D.

Team Leader

Office of Clinical Pharmacology-Pediatrics, CDER, FDA

Amal Ayyoub received a Bachelor of Pharmacy with honors from the University of Jordan, and a Doctorate in Clinical Pharmaceutical Sciences from the College of Pharmacy with a minor in Biostatistics from the College of Public Health at the University of Iowa where she served as the lead scientist performing pharmacometrics and clinical pharmacology analyses in the development of Pyramax; a first anti-malarial to be granted a positive scientific opinion from the European Medicines Agency (EMA). Dr. Ayyoub joined the Office of Clinical Pharmacology at FDA in 2016 where she currently serves as a Team Leader. Dr. Ayyoub is a member of the Editorial Board of the Journal of Clinical Pharmacology (JCP), the Chair of the Education Task Force for the ACCP/ISoP Scientific Interest Group, and a Clinical Assistant Professor at the University of Maryland for the purpose of precepting students in the Experiential Learning Program.



Althea Cuff, M.S.

Senior Regulatory Project Manager

EPPM, Office of Clinical Pharmacology, CDER, FDA

Althea Cuff is a Senior Regulatory Project Manager in the Executive Programs and Project Management (EPPM) staff in the Office of Clinical Pharmacology (OCP) at the Food and Drug Administration.

Prior to joining FDA in 2007, Althea served as a Medical Technologist/Laboratory Manager at various hospitals in the Washington DC, area, to include Howard University, Children's National Medical Center, Holy Cross Hospital, and the Walter Reed National Medical Center. She received her Bachelor of Science in Clinical Laboratory Science from Howard University and a Master of Science degree in Bioscience/Regulatory Affairs from Johns Hopkins University.

Since joining at FDA, Althea has served in a number of regulatory positions in the Office of New Drugs Quality Assessment, Office of Surveillance and in the Office of New Drugs.



James Polli, Ph.D.

Professor and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics, University of Maryland School of Pharmacy

James Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption. His two main research interests are 1) maximizing oral bioavailability through formulation and chemical approaches and 2) developing public quality standards for oral dosage forms. He has served as advisor to 24 Ph.D. graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI; www.cersi.umd.edu) and the Center for Research on Complex Generics (CRCG; www.complexgenerics.org), each an FDA-funded collaborative agreement with the Agency. He is Director of the online M.S. in Regulatory Science program (www.pharmacy.umaryland.edu/regulatoryscience).

He is a fellow of the American Association for Pharmaceutical Scientists and until recently served as an editor of its flagship journal *Pharmaceutical Research* for 12 years. He is a member of the University of Maryland General Clinical Research Center Advisory Committee and the University of Maryland institutional review board (IRB). He is a member of the Scientific Advisory Board of Simulations Plus.

