

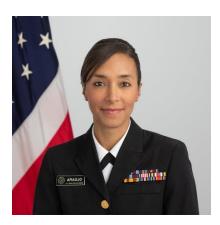


Speaker Biographies

Collaborating to Advance Health Equity for Diabetes and Chronic Kidney Disease (CKD)

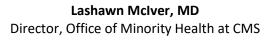
RADM Richardae Araojo, PharmD, MS

Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity



Rear Admiral Richardae Araojo serves as the Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity at the U.S. Food and Drug Administration (FDA). In this role, RADM Araojo provides leadership, oversight, and direction on minority health and health disparity matters for the Agency. RADM Araojo previously served as the Director of the Office of Medical Policy Initiatives in FDA's Center for Drug Evaluation and Research (CDER), where she led a variety of broad-based medical and clinical policy initiatives to improve the science and efficiency of clinical trials and enhance professional and patient labeling. RADM Araojo joined FDA in 2003, where she held several positions in CDER. RADM Araojo received her Doctor of Pharmacy Degree from Virginia

Commonwealth University, completed a Pharmacy Practice Residency at University of Maryland, and earned a Master's degree in Pharmacy Regulation and Policy from the University of Florida.





Dr. LaShawn McIver joined CMS as the Director of the Office of Minority Health in August 2020. In her role, she serves as the principal advisor to the agency on the needs of minority populations, including racial and ethnic minorities, people with disabilities, members of the lesbian, gay, bisexual, and transgender community, individuals with limited English proficiency, and rural populations. She also provides subject matter expertise to CMS on minority health and health disparities and gives recommendations on how to address them. Before joining CMS, Dr. McIver led Government Affairs & Advocacy (GA&A) efforts at the American Diabetes Association (ADA) as its Vice President of Public Policy & Strategic Alliances and later as its Senior Vice President of all GA&A. During her 9-year tenure with the ADA, she provided strategic direction and oversight of the ADA's advocacy

activities which focused on increasing federal and state funding for diabetes research and programs;





eliminating diabetes disparities; diabetes prevention; and improving the availability of accessible, adequate, and affordable health care. She has also served as the inaugural HIV/AIDS fellow for the Congressional Black Caucus' Center for Policy Analysis and Research and as a program director at the Baltimore City Health Department.

Dr. McIver earned a Medical Degree in International Health & Medicine through the Medical School for International Health in Collaboration with Columbia University's Medical Center and a master's degree of Public Health from the Johns Hopkins University Bloomberg School of Public Health.

Chanel F. Whittaker, PharmD, BCPS, CGP, FASCP Associate Professor, University of Maryland School of Pharmacy



Dr. Whittaker is an Associate Professor of Geriatric Pharmacotherapy at the University of Maryland School of Pharmacy in Baltimore, Maryland. Dr. Whittaker is a Board-Certified Geriatric Pharmacist (BCGP) and Pharmacotherapy Specialist (BCPS). She currently serves as Director of Education and Training with the Peter Lamy Center on Drug Therapy and Aging and the PGY-2 Geriatric Pharmacy Residency Program. She also completed a fellowship with the Stanford Geriatric Education Center in Ethnogeriatrics to gain experience with developing educational programs to equip health care professionals to address the health care needs of culturally diverse older adults. Her practice, teaching and research expertise include geriatric pharmacotherapy, chronic disease state management

and health literacy/health communication.

Dr. Whittaker has practiced in a number of ambulatory care clinics providing medication management services to older adults with multimorbidity and patients with Chronic Kidney Disease for over 10 years. Her current practice sites include an interprofessional GeriPact and Renal Clinic at the Baltimore VA

Dr. Whittaker has contributed to geriatric pharmacy through service to ASCP's National Pharmacy Educators and Research Council, the Commission for Certification in Geriatric Pharmacy as well as other interprofessional committees on a state and local level.

Andrea Furia-Helms, MPH
Director, Office of Patient Affairs, FDA.



Andrea Furia-Helms is the Director of the Office of Patient Affairs (formerly Patient Affairs Staff) in the Office of Clinical Policy and Programs, Office of the Commissioner. In her role, she collaborates with patient communities, the FDA medical product Centers and other offices to incorporate patient and caregiver perspectives in cross-cutting regulatory meetings. Ms. Furia-Helms spent over ten years in the FDA's Office of Health and Constituent Affairs where she directed the FDA Patient Representative Program and coordinated patient engagement activities for the agency.





Prior to FDA, Ms. Furia-Helms was Director of the *Back to Sleep* (now *Safe to Sleep*) campaign, a public-private partnership to educate communities on Sudden Infant Death Syndrome (SIDS), at the National Institutes of Health. She developed SIDS outreach initiatives for African American, American Indian and Latino communities.

Ms. Furia-Helms has a B.A. in psychology from Framingham State University, a B.S. degree in community health education from University of Maryland, and a Master of Public Health from The George Washington University.

Richard Knight, MBA

President of the American Association of Kidney Patients (AAKP) Board of Directors



Richard A. Knight is a former hemodialysis patient who received a kidney transplant approximately fourteen years ago. Mr. Knight received his MBA from the University of Virginia Darden School of Business and his BA in Accounting from Hampton University. He is a member of the NIH National Diabetes and Digestive and Kidney Diseases (NIDDK) Advisory Council. Mr. Knight was appointed to the Scientific Registry of Transplant Recipients (SRTR) Review Committee and is a member of the Steering Committee and Co-Chair of the Community Engagement Committee for NIDDK's Kidney Precision Medicine Project. He has served as a member of six

Technical Expert Panels (TEPs) for the Centers for Medicare and Medicaid Assistance (CMS). Knight has a background in public policy and Congressional operations based on his professional experience on Capitol Hill, where he served in various roles, including communications, policy, and Legislative Director. His advocacy work as a kidney transplant patient is international in scope. He is a Lecturer at Bowie State University's College of Business.

Ann Bullock, MD

Director, Division of Diabetes Treatment and Prevention, Indian Health Service



Ann Bullock is a Board-certified family physician who has worked for the Indian Health Service for over 30 years. She served in various clinical and administrative roles with the Eastern Band of Cherokee Indians in Cherokee, NC from 1990-2009. Since 2009, Dr. Bullock has worked for the IHS Division of Diabetes Treatment and Prevention, first as its clinical subject matter expert and then as its Director. Dr. Bullock has been an author on numerous journal articles as well as IHS diabetes treatment guidelines, clinical tools, and best practices. In addition to diabetes, Dr. Bullock's interests include the effects of chronic stress, trauma, historical trauma, as well as poverty and food insecurity on risk for chronic disease and other adverse life outcomes. Dr. Bullock is an enrolled member of the Minnesota Chippewa Tribe.





Rana Malek, MD Clinical Associate Professor, University of Maryland School of Medicine



Dr. Rana Malek is an Associate Professor of Medicine at the University of Maryland School of Medicine. She is the Fellowship Program Director for Endocrinology, Diabetes and Metabolism and has held various leadership roles in undergraduate medical education.

Dr. Malek earned a Doctor of Medicine from the University of Maryland School of Medicine. She completed her Internal Medicine residency at the J. Willis Hurst Internal Medicine Residency Program at Emory University and her Endocrinology, Diabetes, and Metabolism fellowship at the National Institutes of Health Inter-Institute Endocrinology Fellowship.

Dr. Malek is invested in the recruitment and development of future endocrinologists who are trained to address health disparities in their patient populations. She has integrated health equity as a core element of the fellowship curriculum to train fellows in the social determinants of health, identification of health disparities, care for incarcerated people, and improving resource utilization in uninsured and underinsured individuals. In recognition of her teaching accomplishments, she has received multiple teaching awards.

Dr. Malek is a general council member for the Association of Program Directors in Endocrinology, Diabetes, and Metabolism (APDEM) and is co-chair of the APDEM sub-committee on Diversity, Equity, and Inclusion. In this role she is leading efforts on integrating health equity into endocrinology fellowships nationwide.

Patrick Gee, PhD Kidney Health Initiative (KHI) Patient Family Partnership Council (PFPC) members



Patrick Gee graduated from American University School of Public Affairs in 2012 with a Doctorate of Philosophy in Justice, Law, & Criminology. Patrick is a former Peritoneal/Hemodialysis patient due to suffering from Diabetic Kidney Disease. Patrick has been a Post-Kidney Transplant Recipient since April 2017. Patrick is also a retired Major/Chief of Security from the Virginia Department of Corrections; and currently serves as the Founder & C.E.O. of iAdvocate, Inc., a non-profit Faith-based Health & Wellness organization. He is also an Ordained Minister at Mountain Movers Ministry in Richmond, VA.

As an advocate for those living with Chronic Kidney Disease, He is very engaged with several kidney organizations such as Kidney Health Initiative Patient Family Partnership Council; NephCure Health Equity Steering Committee; American Association of Kidney Disease Board of

Directors, and American Society of Nephrology (A.S.N.) Diabetes Kidney Disease-Collaborative Task Force, to name a few





Christine Lee, PharmD, PhD Strategic Research Engagement Lead, FDA OMHHE



Christine Lee received her PharmD from the University of Buffalo and her PhD in Pharmaceutical Outcomes and Policy from the University of Florida.

Dr. Lee is an expert in social and behavioral sciences, decision analysis, and human behavioral theories. She is also classically trained in measurement, psychometrics, focus group testing and outcome analysis.

She is a leader in in driving national impact in reducing adverse drug events across the healthcare industry, an expert in coalition-building and partnership development within public and private sectors and an expert in translating quantitative and qualitative research to drive informed policy, educational interventions and communication strategies.

Dr. Christine Lee serves as the Lead for Strategic Research Engagement for the Office of Minority Health and Health Equity (OMHHE) in the Office of the

Commissioner at the U.S. Food and Drug Administration. She leads minority health and health disparity focused research and develops strategic partnerships to advance the health of diverse populations. Prior to joining OMHHE, Dr. Lee's work included structuring unstructured FDA materials as well as social media data to inform regulatory decision making. Dr. Lee aims to develop research and strategic innovations that advance the health for all populations.

Milena Lolic, MD, MS Lead Medical Officer, FDA



Dr. Lolic joined FDA in 2008 as a Medical Officer in the Office of New Drugs. She was involved in drug development and approvals of new drugs, development of new guidances, and regulatory training for medical officers. Since the beginning of 2016, Dr. Lolic has been a member of the Professional Affairs and Stakeholder Engagement staff. Her primary responsibility is the Drug Trial Snapshot initiative aimed at increasing demographic transparency of clinical trials.

Prior to coming to FDA, Dr. Lolic was an Assistant Program Director of the Hospitalist service at University of Maryland St. Joseph Medical Center in Towson, Maryland.

Dr. Lolic received her medical and master's degrees from University of Belgrade, Yugoslavia. She completed a research fellowship at George Washington University and an internal medicine residency at Greater Baltimore Medical Center, where she served as Chief resident. Dr. Lolic is a board-certified internist.



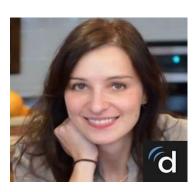


Rekha Kambhampati, MD, MHS Medical Officer, FDA



Rekha Kambhampati, MD, MHS is a board-certified nephrologist and Medical Officer in the Center for Drug Evaluation and Research, Office of New Drugs, Division of Cardiology and Nephrology at the Food and Drug Administration. She was awarded her Doctor of Medicine from Drexel University College of Medicine in Philadelphia, PA. She completed her residency in Internal Medicine at Rutgers-Robert Wood Johnson School of Medicine in New Brunswick, NJ and her Nephrology fellowship at Johns Hopkins University School of Medicine in Baltimore, MD. Given her strong interest in public health, she completed a Master of Health Sciences in Clinical Epidemiology at the Johns Hopkins Bloomberg School of Public Health, with a research focus on health disparities in chronic kidney disease.

Andreea Lungu, MD Medical Officer, FDA



Dr. Andreea Lungu graduated from the Gr T Popa School of Medicine in Iasi, Romania. She completed a residency in Internal Medicine at the Long Island Jewish Medical Center — Albert Einstein College of Medicine, and Cambridge Hospital, followed by a fellowship in Endocrinology and Metabolism at the National Institutes of Health. After fellowship, Dr Lungu was a staff clinician and instructor at Joslin Diabetes Center/Beth Israel Medical Center, and an Assistant Professor in the Department of Diabetes and Endocrinology at University of Massachusetts School of Medicine.

Dr Lungu joined the FDA in 2014 when she became a Medical Officer in the Division of Division of Metabolism and Endocrinology Products, now Division of Diabetes, Lipids and Obesity. Dr. Lungu's work as a primary medical officer has encompassed a wide array of regulatory issues regulatory issues, including representing the Division in two Endocrinologic and Metabolic Drugs Advisory Committees.





Jovonni Spinner, DrPH, MPH, CHES Senior Public Health Advisor, FDA



Jovonni Spinner is an award-winning public health strategist and thought leader with a deep passion for improving health equity across the lifespan through research, communication, multi-sector partnerships, and leadership coaching. She creates culturally-competent programming, shines at telling public health stories, and gives voice to those rarely heard; all the while providing programmatic strategic direction to stakeholders.

She is a Senior Public Health Advisor at the Food and Drug Administration's Office of Minority Health and Health Equity, overseeing

the strategic direction of the outreach and communications team. She has led state and national health equity driven programs like the *Diversity in Clinical Trials Initiative* and *Community Health Worker Health Disparities Initiative*, which have reached millions of consumers to help them make informed health decisions, obtain services, and advocate for healthier communities.

She is an alum of Virginia Commonwealth University, Emory University, and Morgan State University.

Tesheia Harris, MBA, MHS

Deputy Director and Chief Operating Officer of YCCI and the Associate Director for Clinical Research for Yale School of Medicine



Tesheia Harris, MBA, MHS, is Deputy Director and Chief Operating
Tesheia Harris, MBA, MHS, is Deputy Director and Chief Operating Officer
of YCCI and the Associate Director for Clinical Research for Yale School of
Medicine, where she provides leadership and direction in the area of
clinical research. Her career has focused on the development of clinical
research programs and support infrastructure. Prior to assuming her
current position, she held positions as Assistant Dean for Clinical
Research at the University of Vermont College of Medicine and Director
of Clinical Trials at the University of Wisconsin-Madison. She has served
as a consultant for several academic centers interested in establishing
clinical research programs and as a grant reviewer for the National

Institutes of Health.

Ms. Harris is nationally recognized for her expertise in the design and setup of clinical research programs and as such has been an invited speaker at many national and international conferences. She has served as Chair and co-Chair for several National Clinical and Translational Science Award (CTSA) Consortium Groups/Committees. She sits on the external scientific advisory boards for the CTSAs at New York, Washington, and Rockefeller Universities, the Universities of Buffalo, Colorado, Florida, Rochester, and Washington and at University College London Hospitals' Biomedical Research Centre.





Charmaine Rochester-Eyeguokan PharmD, CDCES (CDE), BCACP

Professor, University of Maryland School of Pharmacy



Dr. Charmaine Rochester graduated from Howard University College of Pharmacy in 1996 with a Doctorate in Pharmacy (PharmD), then pursued a Postgraduate Year-1 (PGY1) Residency at the Medical University of South Carolina and a postgraduate Year-2 (PGY2) Residency at the University of Mississippi Medical Center. She is a certified diabetes care and education specialist (CDCES) and a Board-Certified Ambulatory Care Pharmacist (BCACP).

She currently practices as a clinical pharmacist at the Center for Diabetes and Endocrinology, University of Maryland Medical Center, and she the Clinical Director of the P³ eHealth Services (Diabetes clinic) at the University of Maryland School of Pharmacy. She has practiced with endocrinologists in an interdisciplinary team approach under collaborative protocols for almost 20 years.

Qi Liu, PhD, MStat, FCP

Senior Science Advisor
Office of Clinical Pharmacology, Office of Translational Sciences
Center for Drug Evaluation and Research, U.S. Food and Drug Administration



Dr. Qi Liu is a Senior Science Advisor in the Office of Clinical Pharmacology (OCP), CDER, FDA. During her career at the FDA, Dr. Liu contributed to over 200 NDA/sNDA reviews, 20 BLA/sBLA reviews, and numerous IND reviews to support drug development. She has also worked on many research projects and built collaborations to advance regulatory sciences and promote innovations. She co-authored over 40 manuscripts and presented on many topics at FDA Advisory Committee meetings and scientific conferences. She worked on several working groups for FDA guidance documents and Manual of Policies & Procedures (MAPP) development. She also leads OCP's Innovative Data Analytics program. Dr. Liu is a Fellow of the American College of Clinical

Pharmacology. She is also on the editorial board of the American Association of Pharmaceutical Scientists Journal, Clinical Pharmacology and Therapeutics, and Clinical and Translational Science. Dr. Liu is interested in the application of clinical pharmacology principles, innovative tools (e.g., modeling/simulation, machine learning, digital health tools), big data and real-world evidence to facilitate drug development and advance precision medicine.

Before joining FDA, Dr. Liu was a senior pharmacokineticist at Merck & Co. Inc. She obtained her Ph.D. degree in Pharmaceutics and a concurrent Master's degree in Statistics from the University of Florida. In addition, she has a Master's degree in Pharmaceutics and a Bachelors' degree in Clinical Pharmacy from West China University of Medical Sciences





Jenna Norton, PhD, MPH

Associate Director, Division of Kidney, Urologic, and Hematologic Diseases



Jenna Norton brings a public health perspective to the Division of Kidney, Urologic and Hematologic Diseases (KUH) at NIDDK. Jenna serves as Associate Director of the NIDDK's National Kidney and Urologic Science Translation Program. In this role, she guides NIH efforts relating to kidney and urologic conditions to implement public health focused research that views health in the context of an individual's social and physical environment and to disseminate and implement research findings in clinical and community settings. Jenna is passionate about understanding the role of social determinants of health in kidney diseases and urologic conditions, and through her work, she aims to increase recognition of and research into the role social determinants play in health and disease, particularly in relation to racial, ethnic and socioeconomic health disparities.

Jenna is a champion of data standards in research and patient care in order to improve interoperability of data, thereby increasing research efficiency and improving patient outcomes. In collaboration with colleagues at the Agency for Healthcare Research and Quality, she co-leads the Electronic (e-) Care Plan for People with Multiple Chronic Conditions Project, which aims to develop a standards-based e-care plan that can interface with the electronic health record to aggregate critical, patient-centered health and social data and share that data across clinical, community, home and research settings. She co-led work to develop a laboratory measure-based electronic phenotype to identify people with chronic kidney disease from the EHR. Additionally, she represents KUH on the NIH Common Data Elements Task Force and is participating in efforts to advance use of common data elements and other data standards in NIDDK research.

Leonard Pogach, MD, MBA, FACP

National Program Director Diabetes and Endocrinology, Specialty Care Services, Veterans Health Administration



Dr. Pogach was graduated from Hahnemann Medical College (1976), completed an internal medicine residency at Temple University Medical Center (1979), a fellowship in Endocrinology and Diabetes at Boston University Medical Center (1981), and an MBA from Seton Hall University (1999). He joined the East Orange (NJ) Veterans Affairs (VA) Medical Center in 1981, and VA Central Office in 2012. Dr. Pogach was the medical director of the first VA program to achieve ADA Recognition for Diabetes Education in 1989; and has served as the National Program Director for Diabetes since 1993. He has been the lead VA physician (Champion) for the development of VA/DoD Diabetes Guidelines since 1995 and was the

VA representative to the Diabetes Quality Improvement Program that developed NCQA Diabetes Performance Measures (1997). Funded by VA Health Services Research and Development, he and his





research team have published extensively on diabetes outcomes and assessment of quality using large databases. Current initiatives include implementation of a Virtual Medical Center technology to increase access to DSME; use of national databases to prevent hypoglycemia and improve chronic kidney disease management; and integrating diabetes numeracy and shared decision making into everyday diabetes education and clinical practice.

Clydette Powell MD, MPH, FAAP

Designated Federal Officer,
National Clinical Care Commission
Medical Officer, Office on Women's Health
Office of the Assistant Secretary for Health
US Department of Health and Human Services



As Medical Officer, Dr Clydette Powell advises the Director of the Office on Women's Health and supports the technical work of the Congressionally-mandated National Clinical Care Commission, a federal advisory commission established by Public Law 115-80. Dr Powell guides the Commission's evaluation of federal diabetes programs and assures that the best available scientific information informs the deliberations of the Commission on this chronic disease which impacts 115 million Americans and costs the public \$245 billion. Dr Powell serves as the Designated Federal Officer for this 23-member national Commission.

During her five years at Office of Disease Prevention and Health Promotion (ODPHP), Dr Powell was the Director of the Division of Health Care Quality.

She led two HHS National Action Plans: on prevention of health care associated-infections (HAI), and adverse drug events (ADE). To implement these, she oversaw two federal steering committees and three federal interagency working groups, interfacing regularly with federal agencies. She was the ODPHP liaison for Healthy People 2020/2030 objectives for HAIs and ADEs, including opioids. As a core member for the ODPHP Strategic Plan, she contributed to its design and implementation. Dr Powell's 45 years of clinical medicine and public health have established her as a dedicated mentor to ORISE fellows and Preventive Medicine residents.

Dr Powell is triple Board-certified in Preventive Medicine, Psychiatry/Neurology, and Pediatrics. Following her BS degree in Chemistry from Old Dominion University, she received her Doctor of Medicine degree from The Johns Hopkins University School of Medicine. She completed her six-year residency at the University of Pittsburgh Medical Center. The University of California School of Public Health awarded her a Master of Public Health (MPH) degree in epidemiology. Dr Powell holds unrestricted medical licenses in the District of Columbia and the Commonwealth of Virginia. As a pediatric neurologist, she has consulted for a local federally qualified health center, Children's National Medical Center, and globally through telemedicine.

Prior to HHS, Dr Powell served for 15 years as Medical Officer in the Office of Health, Infectious Disease and Nutrition, within the Bureau for Global Health, at the US Agency for International Development. She





had lead responsibilities for TB/HIV programs in Afghanistan, Pakistan, Brazil, Zimbabwe, and Haiti. She served as Country Health Lead for Zimbabwe and for Nepal. She served on the Afghanistan-Pakistan Task Force, the Fragile States team, and a USAID human trafficking work group. Dr Powell is Associate Professor of Pediatrics at The George Washington University School of Medicine and Health Sciences, and at Virginia Commonwealth University. Past academic appointments include University of California and Harvard University School of Medicine.