REAGAN-UDALL FOUNDATION FOR THE FDA

Implementing the RAISE Action Framework

Public Meeting
July 16, 2024; 2PM - 3PM (eastern time)

Presenters & Panelists

Allen Hsiao, MD, FAAP, FAMIA
Chief Health Information Officer
Yale School of Medicine & Yale New Haven Health System

Dr. Allen Hsiao is Professor of Biomedical Informatics & Data Science, of Pediatrics and of Emergency Medicine at the Yale School of Medicine and serves as the Chief Health Information Officer (CHIO) for the Yale School of Medicine and Yale New Haven Health System and Vice Chair for the Department of Biomedical Informatics & Data Science. He received his BA in Biomedical Ethics and MD from Brown University, then completed residency training in Pediatrics at Yale before completing fellowships and board certifications in Pediatric Emergency Medicine and Medical Informatics. He has served on numerous medical informatics-related committees for the Hospital and University, as well as nationally for groups such as the American Academy of Pediatrics, Health Information Management Systems Society, and the National Association of Children's Hospitals and Related Institutions.

Lenel James, MBA, FHL7
Business Lead, Health Information Exchange and Innovation
Blue Cross Blue Shield Association

Mr. Lenel James is the Business Lead for Health Information Exchange and Innovation at Blue Cross Blue Shield Association (BCBSA), on the Health Information Technology (HIT) team. He has been with the Association for over 20 years and is the principal HIT and standards advisor for internal BCBSA proof-of-concept projects with technology partners and BCBS Plans on the effective use of industry standards and innovative use of technology.

Mr. James has been the BCBSA HL7 voting representative for 19 years. He has been the payer advisor champion for multiple HL7 FHIR Accelerators including the Da Vinci Project, for value-based care health data exchange, the Gravity Project, for Social Determinants of Health, and is a founding member of the FHIR-At-Scale Taskforce, for FHIR standard scalability. He has served as co-chair for the HL7 EHR (Electronic Health Records) Workgroup and the HL7 Payer User Group and currently participates in numerous workgroups. He also has co-authored multiple HL7 standards.

In addition to his extensive standards development organization involvement, Mr. James has received industry recognition. In 2006, he received the "Award of Merit" from WEDI (Workgroup for Electronic Data

Interchange) and was named the HL7 "Member of the Year." In 2019, he received the HL7 John Quinn Fellowship Award, for more than 15 years of leadership and increasing payer community engagement in HL7. As part of his 35+ years of experience in clinical information systems, and information technology strategic planning, Mr. James also spent five years as the Acting Director of Clinical Systems for the IT Department of the third largest public hospital in the USA – giving him both a health system and payer perspective on the challenges for the health care industry.

As part of his history of community engagement, Mr. James was a member of the Executive Committee of the Great Lakes Regional Health Equity Council (RHEC-V). The RHEC was part of an HHS Office of Minority Health initiative, the National Program for Action to End Healthcare Disparities, where he co-chaired the Social Determinates of Health Committee. He also co-founded and co-chaired the Cross-RHEC Community Health Worker Coalition (representing four regions across over 25 states).

Mr. James holds a BS degree from SIU-Edwardsville and MBA from the University of Illinois. He was appointed to NCVHS in 2023, serving on the Subcommittee on Standards.

Anjum Khurshid, MD, PhD
Associate Professor, Department of Population Medicine at Harvard Medical School & Harvard Pilgrim Health Care Institute
Chief Data Scientist, Sentinel Operations Center

Dr. Anjum Khurshid is an Associate Professor at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is the Chief Data Scientist for the Sentinel Operations Center, a national drug surveillance program. Dr. Khurshid was previously the Co-Chief, Health Informatics, Data Science and Epidemiology Division, Department of Population Health and Associate Professor at Dell Medical School, The University of Texas at Austin. He has served on the United States' Federal Advisory Committee for Health Information Technology, a congressionally mandated advisory body, and as a patient engagement advisor to the Patient Centered Outcomes Research Institute, Washington DC. He is a Fellow of the American Medical Informatics Association and on the editorial board of Blockchain in Health Today.

Dr. Khurshid earned his medical degree from King Edward Medical University, Lahore and his Masters in Public Affairs and PhD in Public Policy from the University of Texas at Austin.

Christine S. Lee, PharmD, PhD
Acting Associate Commissioner for Minority Health
Office of Minority Health and Health Equity, FDA

Dr. Christine S. Lee serves as the Acting Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity (OMHHE) in the Office of the Commissioner at the U.S. Food and Drug Administration. In this role, Dr. Lee provides leadership, oversight, and direction on minority health and health disparity matters for the agency and leads collaborative strategic initiatives that advance health equity, including OMHHE's Enhance Equity Initiative and the Racial and Ethnic Minority Acceleration Consortium for Health Equity (REACH) Initiative.

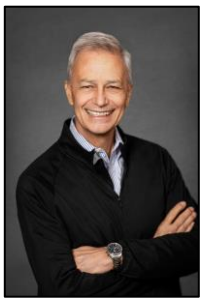
Dr. Lee began her FDA career in 2013 at the Center for Drug Evaluation and Research, where she held roles in Professional Affairs and Stakeholder Engagement, the Office of Surveillance

and Epidemiology, and the Office of Compliance. Prior to joining the FDA, Dr. Lee worked at the Office of the Assistant Secretary for Health in the U.S. Department of Health and Human Services. Dr. Lee received her Pharm.D. from the University of Buffalo and her Ph.D. in Pharmaceutical Outcomes and Policy from the University of Florida.

Carla Rodriguez-Watson, PhD, MPH
Director of Research
Reagan-Udall Foundation for the FDA

Dr. Carla Rodriguez-Watson is the Director of Research for the Reagan-Udall Foundation for the FDA. Dr. Rodriquez-Watson is focused on continuously developing and enhancing a portfolio of work that leverages real-world data and experiences to inform and conduct clinical and post-market drug safety and effectiveness studies. Projects include those focused on developing and advancing frameworks and tools to systematically describe data sources and methods for use in pre- and post-market studies of product safety and effectiveness; as well as the Innovation in Medical Evidence, Development and Surveillance (IMEDS) Program – where such tools can be leveraged. IMEDS leverages a distributed network and tools developed by the FDA's Sentinel initiative to design and execute post-market drug safety studies in a network of 9 healthcare systems representing 111 M persons. Dr. Rodriguez-Watson brings her extensive background in public health surveillance and health outcomes research to this work. She earned her doctoral degree in Epidemiology from the University of Washington School of Public Health, her master's degree in Public Health from Columbia University Mailman School of Public Health, and her bachelor's degree from Rutgers University.

Darryl Sleep, MD
Head, Global Public Health
Amgen



Dr. Daryl Sleep is the Head of Global Public Health within the Office of the Chief Medical Officer. Global Public Health focuses on Access to Healthcare, Clinical Trial Diversity and Representation, and the advancement of health equity globally.

Dr. Sleep has over 40 years' experience across multiple therapeutic areas. He joined Amgen in 2018 as senior vice president, Global Medical and Chief Medical Officer, leading Amgen's Medical Organization before transitioning to lead the newly formed Global Public Health Organization in 2024.

Before joining Amgen, he was SVP, Head of U.S. Medical Office and U.S. Medical Affairs at Takeda Pharmaceuticals. During his eight years at Takeda, Sleep held several senior leadership positions in R&D from translational early clinical development to global clinical science and therapeutic area leadership, driving strategic development of Takeda's pipeline and driving transformation within the R&D organization.

Prior to Takeda, he held several clinical and medical leadership positions in Global Pharmaceutical R&D at Abbott Pharmaceuticals from 2000 to 2010. Sleep received his bachelor of medicine and bachelor of surgery (MBBCh) degree from the University of the Witwatersrand Medicine School, South Africa, in 1983.

Sleep specialized in urology, completing his urology training at the University of Witwatersrand, receiving the Fellowship of the College of Surgeons (FCS) from The Colleges of Medicine, South Africa. He served as Head of Urology at the Johannesburg Academic Hospital before being appointed as Professor of Urology at the

University of Pretoria and Academic Head of the Department of Urology at Kalafong Academic Hospital, in Pretoria, South Africa.

Susan C. Winckler, RPh, Esq.
Chief Executive Officer, Reagan-Udall Foundation for the Food and Drug Administration

Susan C. Winckler is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post in May of 2020, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, industry leaders, and consumers with a neutral forum to address domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, she served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations, and allied groups. Ms. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her juris doctorate *magna cum laude* from Georgetown University Law Center. She is an APhA Fellow, an elected member and Chair of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025), a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council.