



**COVID-19 Evidence Accelerator:
What We've Learned, Where We're Headed
Thursday, October 20, 2022
1-4 PM ET**

Speaker Bios

Keynote Speakers

Robert M. Califf, MD, MAAC

Commissioner of Food and Drugs, U.S. Food and Drug Administration



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. 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.

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.

Namandjé N. Bumpus, PhD

Chief Scientist, U.S. Food and Drug Administration



Dr. Namandjé N. Bumpus was named as the FDA's Chief Scientist on June 30, 2022. The Office of the Chief Scientist supports the research foundation, science, and innovation that underpins the FDA's regulatory mission. It does this through a broad framework that encompasses scientific collaborations, laboratory safety, the transfer of FDA inventions to the private sector, scientific integrity in FDA policy- and decision-making, the professional development of regulatory scientists, and its core research component—the

FDA's National Center for Toxicological Research—which generates the vital data that the FDA requires for its regulatory decision-making and development of sound regulatory policy.

Before joining the FDA, Dr. Bumpus was the E.K. Marshall and Thomas H. Maren Professor and chair of the Department of Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine. She served previously as associate dean for basic research in the Johns Hopkins University School of Medicine. She earned a bachelor's degree in biology at Occidental College in 2003, a doctorate in pharmacology at the University of Michigan in 2007 and completed a postdoctoral fellowship in molecular and experimental medicine at The Scripps Research Institute in La Jolla, CA in 2010.

Dr. Bumpus currently serves as president-elect of the American Society for Pharmacology and Experimental Therapeutics. She previously served as chair of the NIH Xenobiotic and Nutrient Disposition and Action study section.

Amy P. Abernethy, MD, PhD
President of Clinical Studies Platforms, Verily



Dr. Amy Abernethy is the President of Clinical Studies Platforms at Alphabet's Verily, where she has responsibility for the company's Baseline program and other initiatives to support clinical trials and real-world evidence (RWE) studies. Before joining Verily, Dr. Abernethy was Principal Deputy Commissioner and Acting Chief Information Officer of the US Food & Drug Administration. Prior roles include serving as CMO/CSO of Flatiron Health and multiple roles at Duke University, where she was Professor of Medicine. Dr. Abernethy went to the University of Pennsylvania and then Duke University Medical School, and received her PhD from Flinders University in Australia.

Panelists

Sara Brenner, MD, MPH
Associate Director for Medical Affairs and Chief Medical Officer for In Vitro Diagnostics, Center for Devices and Radiological Health, U.S. Food and Drug Administration



Dr. Sara Brenner is a preventive medicine and public health physician serving as the Chief Medical Officer for In Vitro Diagnostics and Associate Director for Medical Affairs in the Center for Devices and Radiological Health at the U.S. Food and Drug Administration (FDA) where she advises leadership on regulatory premarket and post-market compliance and surveillance as well as broader initiatives to promote and protect public health across the medical technology landscape.

Since February 2020, Dr. Brenner has been supporting the National COVID-19 Response at multiple levels, focused on diagnostics, data, and leveraging technology across the interagency response. Since May 2020, Dr. Brenner has also been serving as the Diagnostic Data Lead on the U.S. Department of Health and Human Services (HHS) Data Strategy and Execution Workgroup (DSEW).

Prior to joining FDA, Dr. Brenner served as a Senior Policy Advisor in the White House Office of Science and Technology Policy (OSTP) with a broad portfolio in biomedical science, technology, and human health.

Dr. Brenner received her medical degree from the University of Iowa Carver College of Medicine, her master's degree in public health from the SUNY Albany School of Public Health (Health Policy and Administration), and a bachelor's degree in genetics (minor in philosophy) from Iowa State University. She trained in Internal Medicine at Evanston Northwestern in Chicago and Preventive Medicine and Public Health at the New York State Department of Health and SUNY Albany School of Public Health.

Aloka G. Chakravarty, PhD

Director, Data Analytics and Senior Statistical Advisor, Office of the Commissioner



Dr. Aloka Chakravarty is currently the Director of Data Analytics and Senior Statistical Advisor in the Office of the Commissioner, FDA for real-world data and evidence activities related to collaborations on COVID-19 and others. She is also working on select strategic data initiatives at FDA with the Chief Data Officer.

Prior to that, she was the Deputy Director of the Office of Biostatistics in CDER, FDA. She is an internationally recognized thought leader in multi-regional clinical trials, safety evaluation, real world data and evidence, surrogate markers and biomarkers in drug development. Dr. Chakravarty served as an Adjunct Faculty in the Department of Statistics, FAES, NIH and has been on Advisory Board of multiple academic institutions.

Dr. Chakravarty has received numerous awards, including the FDA Award of Merit and Dr. Frances O. Kelsey Drug Safety Excellence Award. She received her doctoral degree in Statistics from Temple University, and M. Stat from Indian Statistical Institute. Dr. Chakravarty is a Fellow of the American Statistical Association and an Associate Editor of Statistics in Biomedical Research.

Anand Chokkalingam, PhD

Executive Director and Head, Real-World Evidence Virology, Gilead Sciences



Dr. Anand Chokkalingam is Executive Director and Head of Real-World Evidence for Gilead's Virology Therapeutic Area, encompassing HIV, viral hepatitis, and emerging infections including COVID-19. At Gilead he has also led Clinical Development teams for COVID-19 and HCV, and prior to that served as Head of Epidemiology for Gilead's Liver Disease portfolio.

Dr. Chokkalingam is also an Associate Adjunct Professor of Epidemiology at the UC Berkeley School of Public Health. He came to Gilead in 2013 after eight years on faculty at UC Berkeley. He has worked previously for several biotech and molecular diagnostics companies including Syva/Syntex, Celera, and Tethys. He has a bachelor's degree in Biochemistry from UC Berkeley and a doctoral degree in Epidemiology from the University of Maryland Baltimore, and completed post-doctoral training at the U.S. NCI's Division of Cancer Epidemiology and Genetics.

Jacqueline Corrigan-Curay, JD, MD

Principal Deputy Center Director, Center for Drug Evaluation and Research



Dr. Jacqueline Corrigan-Curay is the Principal Deputy Center Director in FDA's Center for Drug Evaluation and Research (CDER). Most recently, she served as the Acting Center Deputy Director for Operations, directing center and agency-level priority and initiative programs and leading GDUFA III reauthorization negotiations.

Previously, Dr. Corrigan-Curay was director of CDER's Office of Medical Policy (OMP). In that role, she led the development, coordination, and implementation of medical policy programs and strategic initiatives. She worked collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes.

Nancy Dreyer, PhD, MPH

Chief Scientific Officer Emerita, IQVIA Real World Solutions



Dr. Nancy Dreyer is the Chief Scientific Officer Emerita for IQVIA Real World Solutions, Adjunct Professor of Epidemiology at the University of North Carolina at Chapel Hill, President of Dreyer Strategies LLC, and a Trustee of Brandeis University. Well-known for her thought leadership, she is a Fellow of both the International Society of

Pharmacoepidemiology and the Drug Information Association. She has helped advance the use of real-world evidence for regulatory purposes, influencing the content of recent guidelines by regulators in the US, Europe, and China, each of which cite one or more of her publications. Her substantial executive and field experience in pharmacoepidemiology, occupational and environmental health have helped hone her pragmatic views.

Nicolle Gatto, PhD, MPH

Chief Science Officer, Aetion, Inc



Dr. Nicolle Gatto has over 20 years of pharmacoepidemiological and regulatory experience across industry and academia. She is the Chief Science Officer and leads the Scientific Research and Strategy team at Aetion, Inc, a technology company that provides analytic software and research services to the healthcare industry including biopharma, regulators, and payers. In this role, she serves as a senior scientific expert on methodological and regulatory-related studies across therapeutic areas, and partners with biopharma

companies and decision-making bodies, such as regulatory agencies and Health Technology Assessment agencies (HTAs).

Prior to Aetion, Dr. Gatto worked at Pfizer where she oversaw Vaccines and Oncology Epidemiology and led a team to design and implement post-authorization safety and effectiveness studies, and pre-approval studies to support development and regulatory decision-making across Pfizer's portfolio. She is a Fellow of the International Society for Pharmacoepidemiology, and an Adjunct Assistant Professor of Epidemiology at Columbia University and Tulane, where she has taught courses in pharmacoepidemiology, causal inference and confounding control methods. She

has a bachelor's degree in biology from University at Albany, State University of New York, a master's degree in Public Health from the New York University School of Education, and a doctoral degree in Epidemiology from the Columbia University Mailman School of Public Health.

Adrian Hernandez, MD, MHS

Executive Director, Duke Clinical Research Institute, and Vice Dean of the Duke University School of Medicine



Dr. Adrian Hernandez, MD, MHS, is Executive Director, Duke Clinical Research Institute, and Vice Dean of the Duke University School of Medicine.

Dr. Hernandez is a cardiologist who has research interests in improving cardiovascular health and accelerating clinical evidence through outcomes research, clinical trials, comparative effectiveness and health policy. He had led multiple large-scale patient-centered research programs, registries and clinical trials aimed at improving health across multiple conditions such as NIH's Health System Collaboratory and the PCORI-funded PCORnet®, the National Patient-Centered Clinical Research Network. Dr. Hernandez leads multiple programs to address COVID-19, including the Healthcare Worker Exposure Response and Outcomes (HERO) registry and HERO-TOGETHER (post-vaccination safety study), and ACTIV-6, a platform treatment trial for repurposed medications. He has authored over 700 peer-reviewed publications.

Harvey Kaufman, MD

Senior Medical Director, Medical Informatics, Quest Diagnostics



Dr. Harvey Kaufman is a Senior Medical Director, Medical Informatics at Quest Diagnostics. In that capacity Harvey leads the Information Ventures health informatics analyst team. He also leads Quest's Health Trends efforts. Harvey joined the company in 1992 as Medical Director in Cambridge, Massachusetts. He was the first Chief Laboratory Officer for Quest Diagnostics, the first Six Sigma Quality leader and the first medical director

of Hospital Services, Business Development, International and Clinical Trials, as well as Health and Wellness. Harvey has been involved with Quest Diagnostics Health Trends™ since its inception in 2005 and has provided medical support for many of our informatics activities. He earned a medical degree from the Boston University School of Medicine, a master's degree in molecular biology from MIT and an MBA in marketing from NYU's Stern School of Business

Sandy Leonard, MPH

Senior Vice President, Partnerships and Real-World Data Solutions, HealthVerity



Sandy Leonard leads the teams responsible for driving strategic partner relationships, growing HealthVerity's government engagements as well as the team that brings real world data expertise and technical solutioning to HealthVerity's many clients. All of this is to enable evidence generation and innovative research solutions, leveraging HealthVerity's industry-leading technology and network of data partners.

Prior to HealthVerity, Sandy was the Vice President, Medical Evidence and Observational Research at AstraZeneca where she led a global team of RWE scientists and study delivery professionals who together delivered impactful evidence for the entirety of the AstraZeneca portfolio.

Throughout her career, Sandy has developed and implemented key corporate strategies focused on the development and application of evidence throughout the healthcare system, including the evolution of evidence generation capabilities, establishing RWE strategy and collaboration initiatives. Sandy holds an undergraduate degree in Psychology from the University of Wisconsin – Madison and has a master’s degree in Public Health, from the University of Tennessee – Knoxville.

Nancy Lin, PhD

Director of Epidemiology, Real-World Solutions, IQVIA



Dr. Nancy Lin is the Director of Epidemiology, Real World Solutions at IQVIA. In her current role, she provides senior scientific oversight and input on the design and execution of global observational and minimally interventional studies. Dr. Lin’s interests include application and considerations for the use of electronic health care data (e.g., claims, EHR) and enriched approaches to enhance assessment of medical product use, safety, and effectiveness to support healthcare decisions. Prior to joining IQVIA, Dr. Lin was Vice President, Real World Insights and Evidence at Health Catalyst, following a position as Senior Scientist - Epidemiology at Optum, where she served as the site principal investigator for Optum participating in the FDA Sentinel Initiative. She received a doctoral degree in Epidemiology and a master’s degree in Epidemiology from the Harvard School of Public Health.

Vincent Lo Re III, MD, MSCE

Associate Professor of Medicine, Division of Infectious Diseases, University of Pennsylvania



Dr. Vincent Lo Re is a tenured Associate Professor of Medicine in the University of Pennsylvania Division of Infectious Diseases, Senior Scholar in the Penn Center for Clinical Epidemiology and Biostatistics, and Senior Investigator in the Penn Center for Real-World Evidence and Safety of Therapeutics. Dr. Lo Re leads an NIH-funded research program focused on infectious diseases epidemiology and pharmacoepidemiology. He also maintains an active clinical practice devoted to the care of patients with infectious diseases, particularly HIV and chronic viral hepatitis. In addition to his clinical and research efforts, he is Co-Director of Penn’s Master of Science in Clinical Epidemiology degree program and has been an active member of the International Society for Pharmacoepidemiology, serving as a member of the Board of Directors, Scientific Program Chair for the 35th International Conference for Pharmacoepidemiology in August 2019, and President (2021-2022). He is also Regional Editor for the Americas of *Pharmacoepidemiology and Drug Safety*.

Peter Marks, MD, PhD

Director, Center for Biologics Evaluation and Research



Dr. Peter Marks is the Director of the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. The center is responsible for assuring the safety and effectiveness of biological products, including vaccines, allergenic products, blood and blood products, and cellular, tissue, and gene therapies.).

Dr. Marks received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women’s Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.

Ellen V. Sigal, PhD

Chairperson and Founder, Friends of Cancer Research



Ellen V. Sigal, PhD, is Chairperson and Founder of Friends of Cancer Research (Friends), a think tank and advocacy organization based in Washington, DC that drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients.

Dr. Sigal serves on the Board of the Foundation for the National Institutes of Health, where she chairs its Public Private Partnerships Committee. In 2010, Dr. Sigal was appointed to a six-year term on the Board of Governors of the Patient Centered Outcomes Research Institute (PCORI) as a representative of patients and health consumers.

Additionally, in 2016, Dr. Sigal was named to Vice President Biden’s Cancer Moonshot Blue Ribbon Panel, to the Parker Institute for Immunotherapy Advisory Group, and joined the inaugural board of advisors for the George Washington University’s Milken Institute of Public Health.

Andrew C. von Eschenbach, MD

President, Samaritan Health Initiatives, Inc.



Dr. Andrew C. von Eschenbach currently serves as President of Samaritan Health Initiatives, Inc. and as an Adjunct Professor at University of Texas MD Anderson Cancer Center. He served as the 20th Commissioner of Food and Drugs (2005-09) where he championed an agenda to modernize the FDA. He emphasized innovation by fostering creative projects, including the FDA's Critical Path Initiative, which was designed to bring modern tools of science to the product development process.

Dr. von Eschenbach joined FDA after serving for four years as Director of the National Cancer Institute (NCI) at the National Institutes of Health where he set an ambitious goal to eliminate the

suffering and death due to cancer by rapid acceleration and integration of the discovery-development-delivery continuum.

Dr. von Eschenbach earned a bachelor's degree from St. Joseph's University in Philadelphia and his medical degree from Georgetown University. After completing a residency in urologic surgery at University of Pennsylvania Hospital in Philadelphia, he served as was an instructor at University of Pennsylvania School Of Medicine and completed a Fellowship in Urologic Oncology at the University of Texas MD Anderson Cancer Center. Dr. von Eschenbach joined the Reagan-Udall Foundation for the FDA Board of Directors in 2018.

Moderators

Jeff Allen, PhD

President and CEO, Friends of Cancer Research



Jeff Allen is President and CEO of Friends of Cancer Research (Friends). Friends is an advocacy organization based in Washington, DC that drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients. For more than two decades, Friends has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible.

As a thought leader on many issues related to the Food and Drug Administration, regulatory strategy, and healthcare policy, he is regularly published in prestigious medical journals and policy publications. In addition to participating in major scientific and policy symposiums around the country each year, Jeff has had the honor to be called to testify before Congress on multiple occasions and regularly contributes his expertise to the legislative process.

Prior to joining Friends, Jeff was an endocrinology researcher at the National Institutes of Health. His background in cancer research focused upon molecular changes associated with cancer formation as well as treatments to prevent cancer progression. Jeff received his doctorate degree in Cell and Molecular Biology from Georgetown University and holds a bachelor's degree in Biology from Bowling Green State University.

Carla Rodriguez-Watson, PhD, MPH

Director of Research, Reagan-Udall Foundation for the FDA



Dr. Carla Rodriguez-Watson is the Director of Research at the Reagan-Udall Foundation for the FDA. An epidemiologist, Dr. Rodriguez-Watson's research focus is the use of real-world, big-data for public health surveillance and the epidemiology of viral hepatitis and HIV, influenza, substance abuse, liver and kidney disease.

Prior to joining the foundation, Dr. Rodriguez-Watson was a Research Scientist II at the Mid-Atlantic Permanente Research Institute (MAPRI) of Kaiser Permanente (KP).

Before her focus on clinical epidemiology, Dr. Rodriguez-Watson devoted more than a decade to developing, enhancing, and evaluating active and passive surveillance systems for the New York City Department of Health and Mental Hygiene (DOHMH), the San Francisco Department of Public Health, and Seattle-King County Public Health. She was part of the team that developed the first electronically integrated vital statistics, lead, and immunization registry for the NYC DOHMH, whose jurisdiction included more than 8 million New Yorkers. Her work to further develop and evaluate signals generated by syndromic surveillance systems has been published and presented at national conferences. This surveillance work was the driving force behind her doctoral research to assess the accuracy of syndromic systems to identify laboratory confirmed pediatric influenza, for which she received a CDC dissertation grant award.

Dr. Rodriguez-Watson 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. She is currently associate faculty in the Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health.

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



Susan C. Winckler is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, she served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Winckler directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters. As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), she managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.