Duke | MARGOLIS CENTER for Health Policy

# Thirteenth Annual Sentinel Initiative Public Workshop

November 8, 2021 | 10:00 a.m. – 2:00 p.m. ET
November 9, 2021 | 10:00 a.m. – 2:00 p.m. ET

## Speaker Biographies

**Steve Anderson** is currently the Director of the Office of Biostatistics and Epidemiology (OBE) at the FDA Center for Biologics Evaluation and Research (CBER). He provides leadership for all CBER statistical, epidemiological and risk assessment programs. In 2001, he was hired by CBER as the Associate Director for Risk Assessment to establish a program in quantitative risk assessment for biologic products including vaccines, blood products and others. Since his arrival at FDA he has led numerous important risk assessment projects and epidemiological studies. He led the first studies at FDA using Centers for Medicare & Medicaid Services (CMS) data to estimate blood utilization in inpatient and outpatient setting. He has conducted collaborative studies using the FDA Sentinel system and CMS data to evaluate the safety of blood products and vaccines and worked to integrate use of these data systems into CBER's regulatory processes to improve biologic product safety evaluations and surveillance. He launched the CBER Biologics Effectiveness and Safety (BEST) System to expand and enhance CBER access to new and better data sources, methods, tools, expertise and infrastructure to conduct surveillance and epidemiologic studies for biologic products. Dr. Anderson earned a Master's Degree in Public Policy (MPP) at Georgetown University and while there developed the first quantitative risk assessment for antimicrobial resistant pathogens in cattle. Dr. Anderson received his PhD from the University of Cincinnati where he worked on biochemistry, drug resistance and ion pumps, pathogenicity and genomics of unique tropical disease pathogens. He has published a number of articles in biologic product safety, risk assessment, epidemiology, infectious diseases, biologics safety, and genomics and protein structure/targeting.

**Robert Ball MD, MPH, ScM** is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research, FDA. Dr. Ball shares in the responsibilities for leading OSE staff evaluating drug and biologic product safety and effectiveness using Real World Evidence, including managing the Sentinel System. From 2008 to 2013, Dr. Ball served as the Director, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research (CBER), FDA where he led statistical and epidemiological evaluation of vaccines, blood, cell, tissue, and gene therapy products. He started his FDA career as a medical epidemiologist in CBER in 1998 and oversaw post-market safety surveillance for all US licensed vaccines from 2001-2008.

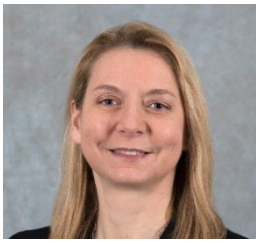
**Michael Blum, MD, MPH** is currently Deputy Director, Office of Pharmacovigilance and Epidemiology in FDA CDER. He is a pediatric infectious diseases specialist. Dr. Blum worked as a medical reviewer in the CDER Division of Anti-Infective Drug Products, followed by over 20 years in the pharmaceutical industry in a variety of vaccine and safety leadership positions. He has experience in industry and the FDA with the use of real-world data to assess the safety of drugs and biologics and currently leads COVID-19 scientific activities within the CDER Office of Surveillance and Epidemiology.

**Patricia ("Trish") Bright** earned a Master's Degree and Ph.D. in Epidemiology from the University of North Carolina (Chapel Hill). She was a Faculty Member at the Johns Hopkins School of Medicine from 2003 to 2010, where she helped run clinical trials assessing therapeutic approaches to prevent maternal-to-child HIV transmission in developing countries. She began working at the FDA in 2010 as a Commissioner's Fellow. In 2012, she joined the Division of Epidemiology in the Center for Drug Evaluation and Research (CDER)'s Office of Surveillance and Epidemiology (OSE). She worked in the Division of Epidemiology as both a primary reviewer and as a Team Lead. More recently, she joined the OSE's Regulatory Science and Applied Research (RSAR) Division and has been serving as Acting Sentinel Program Lead to assist with Sentinel's Coordination.

**Robert M. Califf, MD, MACC,** is the is the Sr. Advisor for Verily and Google Health. Prior to this Dr. Califf was the vice chancellor for health data science for the Duke University School of Medicine; director of Duke Forge, Duke's center for health data science; and the Donald F. Fortin, MD, Professor of Cardiology. He served as Deputy Commissioner for Medical Products and Tobacco in the U.S. Food and Drug Administration (FDA) from 2015-2016, and as Commissioner of Food and Drugs from 2016-2017. A nationally and internationally recognized leader in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf is a graduate of Duke University School of Medicine. Dr. Califf was the founding director of the Duke Clinical Research Institute and is one of the most frequently cited authors in biomedical science.

**Gianmario Candore** is a statistician by training who has been working at the European Medicines Agency since 2009. Over the last years he has been involved in different projects on observational research and is now leading the real word data transformation to support regulatory decision-making. He is also co-chair of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP®).

**Daniel Arthur Caños, PhD, MPH,** is the Director of the Office of Clinical Evidence and Analysis (OCEA) in the FDA Center for Devices and Radiological Health (CDRH). Prior to joining OCEA in 2019, Daniel was the Director of the Evidence Development Division (EDD) in the Centers for Medicare and Medicaid Services (CMS) Coverage and Analysis Group (CAG) and was on a part time detail within the FDA CDRH. The EDD work included National Coverage Analyses (NCAs) and National Coverage Determinations (NCDs) involving Coverage with Evidence Development and review of FDA approved Investigational Device Exemption studies for CMS coverage determination. Before joining CAG in 2016, Daniel was an Associate Director in the FDA CDRH Division of Epidemiology. He originally joined FDA in 2008. He received a BA in Psychology from the University of Cincinnati, MPH from the George Washington University, and PhD in Epidemiology from the University of North Carolina at Chapel Hill.



**Patrizia Cavazzoni** is the Director at the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA).

Dr. Cavazzoni received her medical degree at McGill University and completed a residency in Psychiatry and a fellowship in mood disorders at the University of Ottawa. She subsequently joined the faculty of medicine at the University of Ottawa as an assistant professor, where she was engaged in clinical work, teaching, and research on genetic predictors of mood disorders, authoring numerous peer-reviewed scientific publications. Following this, Dr. Cavazzoni worked in the pharmaceutical industry for several years, and held senior leadership positions in clinical development, regulatory affairs and safety surveillance.

Dr. Cavazzoni is certified by the American Board of Neurology and Psychiatry, a Fellow of the Canadian Royal College of Physician and Surgeons, a member of the Canadian College of Neuropsychopharmacology and recipient of the American College of Psychiatrists' Laughlin Fellowship.

**Dr. Noelle Cocoros** is a Research Scientist at the Harvard Pilgrim Health Care Institute and is the Lead Epidemiologist for the FDA's Sentinel System Operations Center. Dr. Cocoros has a background in infectious disease epidemiology, pharmacoepidemiology, and public health surveillance. Her expertise in novel uses of electronic health data for research, evaluation, and surveillance ranges from pandemic response to pragmatic clinical trials. She received a doctorate in epidemiology from the Boston University School of Public Health.

**Catherine Cohet** joined the European Medicines Agency's Data Analytics and Methods Task Force in 2020, after several years holding various pharmacoepidemiology positions in the pharmaceutical industry (GlaxoSmithKline Vaccines and Sanofi Pasteur MSD). She has extensive experience generating and evaluating RWE across all phases of medicines development, with a focus on post-authorisation vaccine monitoring. She is currently part of the ICH Expert Group which will develop a guideline on principles of planning and designing pharmacoepidemiological studies using RWD in the context of drug safety assessment. Catherine previously worked in the public health sector as an epidemiologist, at the Centre for Public Health Research and the Malaghan Institute of Medical Research in Wellington, New Zealand, as well as the WHO International Agency for Research on Cancer in Lyon, France, and received her PhD from the University of Strasbourg, France. Her research interests include methodological and governance aspects of RWE generation; regulatory science; and understanding biological mechanisms behind the safety and efficacy of medicines.

**John Concato** is Associate Director for Real-World Evidence Analytics in the Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), FDA. As an internist and epidemiologist, Dr. Concato seeks to enhance policies related to drug development and regulatory review; his responsibilities include a focus on real-world evidence (RWE) and involve work developing internal Agency processes, interacting with external stakeholders, supporting RWE demonstration projects and guidance development, and serving as the Chair of the RWE Subcommittee. Prior to joining FDA, his career focused on generating research as an independent investigator, research center director, and Professor of Medicine at Yale University School of Medicine and the U.S. Department of Veterans Affairs (VA); he also was one of two founding principal investigators of the VA Million Veteran Program

genomic mega-biobank. He received MD and MS degrees from New York University and an MPH degree from Yale University.

**Francesca (Fran) Cunningham, PharmD,** is the Director of the Center for Medication Safety, Associate Chief Consultant, and Program Director of Outcomes Assessment at the U.S. Department of Veterans Affairs (VA) Pharmacy Benefits Management Services (PBM). Dr. Cunningham was the driving force behind the successful effort of PBM to establish reliable methods for merging the VA prescription database with other large VA-related databases to evaluate the safe and appropriate use of medications in the Veteran population. Her focus has been on assessing new agents where safety data is lacking (post-marketing surveillance) and older drugs when a newly emerging signal requires evaluation. Dr. Cunningham designed the VAMedSAFE program. Under her direction, the program has become a comprehensive pharmacovigilance program and an essential tool in evaluating drug and vaccine safety in VA. Dr. Cunningham's group has worked independently and with other researchers to perform several drug safety and pharmacoepidemiologic studies. Dr. Cunningham serves as VA's federal interagency liaison for medication and vaccine safety. She sits on several internal and external Boards (as a member or interagency liaison) focusing on medication and vaccine safety, emphasizing post marketing surveillance and pharmacovigilance. Her work has led to national awards including the *Mark A. Wolcott National Award for Leadership in Healthcare: Medication Safety* and the *Arthur S Fleming Award* for her medication safety work.

**Gerald J. Dal Pan, MD, MHS** currently serves as the Director of the Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research, where since 2005 he has been responsible for the Center's programs in adverse event surveillance and analysis, pharmacoepidemiology, risk management, and medication error prevention. In this capacity, he is involved in both the premarket and postmarket regulation of drugs and therapeutic biologics, and in the implementation of the drug safety provisions of the Food and Drug Administration Amendments Act and other initiatives. He is a member of the World Health Organization Advisory Committee on the Safety of Medicinal Products, and has served on working groups of the Council of International Organization of Medical Sciences (CIOMS) and the International Council on Harmonisation (ICH). He received his MD from Columbia University College of Physicians and Surgeons and his Master of Health Science in Clinical Epidemiology from the Johns Hopkins University School of Hygiene and Public Health. He completed residency training in Internal Medicine at the Hospital of the University of Pennsylvania and in Neurology at the Johns Hopkins Hospital. He is board certified in both Internal Medicine and Neurology. He joined FDA in 2000 as a medical reviewer in the Center's Office of New Drugs. Before working at FDA, he was a faculty member in the Department of Neurology at Johns Hopkins and worked in the pharmaceutical industry.

**Asif Dhar** is the FDA Sentinel Community Building and Outreach Center Principal Investigator. He is also Vice Chair and US Life Sciences and Health Care (LSHC) Industry Leader for Deloitte LLP leading the overall strategic direction for the life sciences and health care practices, including audit, consulting, tax, and advisory services. He has personally built practices and solutions to advance the use of real world data, address challenges in regulatory sciences, advance digital health and serves clients around the World.

**Richard Forshee** leads the Analytics and Benefit-Risk Assessment Team and the High Performance Integrated Virtual Environment Team for the Office of Biostatistics and Epidemiology (OBE) in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. Recently he was appointed as the Acting Deputy Director for OBE. He works on a wide range of issues related to the risks and benefits of blood and blood products, vaccines, and human cell and tissue products. Dr. Forshee has won numerous awards including the FDA Service Award and the CBER Hope Hopps Memorial Award, and he has published more than 70 scientific articles. Before joining the FDA, he was the Director of the Center for Food, Nutrition, and Agriculture Policy at the University of Maryland, College Park.

**Josh Gagne** is Vice President and Global Head of Epidemiology at Johnson and Johnson. Over the last 15 years, his research has centered on the development, evaluation, and application of methods for generating post-approval comparative safety and effectiveness evidence for new medical products. He was previously an Associate Professor of Medicine in the Division of Pharmacoepidemiology and Pharmacoeconomics at the Brigham and Women's Hospital and Harvard Medical School, and an Associate Professor in the Department of Epidemiology at the Harvard T.H. Chan School of Public Health. At Harvard Chan, he directed the school's Program in Pharmacoepidemiology. He also served as the founding Operations Chief and Lead Epidemiologist of the Sentinel Innovation Center. He is currently an Adjunct Associate Professor in the Department of Epidemiology at Harvard Chan and serves on the editorial boards of Pharmacoepidemiology and Drug Safety and of Drug Safety.

**George Hripcsak, MD, MS,** is Vivian Beaumont Allen Professor and Chair of Columbia University's Department of Biomedical Informatics and Director of Medical Informatics Services for NewYork-Presbyterian Hospital/Columbia Campus. He is a board-certified internist with degrees in chemistry, medicine, and biostatistics. Dr. Hripcsak's research focus is on the clinical information stored in electronic health records and on the development of next-generation health record systems. Using nonlinear time series analysis, machine learning, knowledge engineering, and natural language processing, he is developing the methods necessary to support clinical research and patient safety. He leads the Observational Health Data Sciences and Informatics (OHDSI) coordinating center; OHDSI is an international network with thousands of researchers. Dr. Hripcsak is a member of the National Academy of Medicine, the American College of Medical Informatics, the International Academy of Health Sciences Informatics, and the New York Academy of Medicine. He has published over 400 papers.

**Bradley Layton, PhD,** is a Senior Research Epidemiologist at RTI Health Solutions with considerable experience in the design, conduct, analysis, and reporting of epidemiologic studies. With over 10 years of experience in the field of pharmacoepidemiology, his experience and publications span a wide range of substantive areas, including renal, cardiovascular, men's health, vaccines, and pregnancy, and incorporate multidatabase and multinational studies. Dr. Layton also has experience with epidemiologic methods, lecturing to clinical and public health audiences about observational study design, large database utilization, and propensity score analysis. Dr. Layton received his master's and doctorate degrees in epidemiology from the Department of Epidemiology in the Gillings School of Global Public Health, University of North Carolina at Chapel Hill,

focusing in pharmacoepidemiology. Dr. Layton also is an active member of the International Society of Pharmacoepidemiology (ISPE), and currently serves as the chair of the ISPE Vaccine Special Interest Group.

**Thomas MaCurdy, PhD,** is a Senior Research Director at Acumen LLC who serves as the Director of the BEST Data Coordination Center and who has directed a continual series of FDA projects over the past 15 years focused on monitoring and assessing the safety and effectiveness of biologics and drugs regulated by the FDA. This collaboration with the FDA has produced numerous epidemiological studies published in leading professional journals and the development and operationalization of robust near real-time surveillance systems used to monitor the safety of such products as the dispensing of the influenza vaccine each year. In addition to his position at Acumen, Dr. MaCurdy is a Professor of Economics at Stanford University, Senior Fellow at the Hoover Institution, and a Senior Fellow at the Stanford Institute of Economic Policy Research, with an extensive publication record in both professional journals and public policy venues.

**Richard Platt, MD, MSc** is Professor and Chair of the Harvard Medical School Department of Population Medicine at the Harvard Pilgrim Health Care Institute. He is principal investigator of the FDA's Sentinel System that studies of the safety and effectiveness of marketed medical products. Dr. Platt also leads the NIH Health Care Systems Research Collaboratory's Distributed Research Network and is co-principal investigator of a CDC Prevention Epicenter. He is a member of the National Academy of Medicine's Leadership Consortium for a Value & Science-Driven Learning Health System, and co-chairs its CER Innovation Collaborative.

**Sebastian Schneeweiss, MD, ScD,** is a Professor of Medicine and Epidemiology at Harvard Medical School and Chief of the Division of Pharmacoepidemiology, Department of Medicine, Brigham and Women's Hospital.

His research focuses on assessing the effectiveness and safety of biopharmaceuticals in clinical practice. He has developed analytic methods to improve the accuracy of estimating causal treatment effects of new drugs using complex digital healthcare databases. His work is published in >500 articles and is used for regulatory and coverage decision making around the globe. He is funded by NIH, PCORI, IMI, and FDA where he is also a voting consultant. He is Principal Investigator of the FDA Sentinel Innovation Center and co-leads the RCT-DUPLICATE initiative to understand when and how real-world evidence studies can reach causal conclusions.

**John D. Seeger, PharmD, MPH, DrPH, FISPE** is a pharmacoepidemiologist and Chief Scientific Officer for Epidemiology at Optum, where he has been employed for more than 20 years. He has conducted dozens of studies addressing regulatory drug safety questions across a wide range of drugs, vaccines, and disease conditions. Most of this work has involved the use of health insurance claims databases, and Dr. Seeger's methodologic expertise focuses on research issues encountered in such settings. He has worked extensively with propensity scores that seek to mitigate confounding by collapsing covariates, and he teaches several courses on propensity scores in pharmacoepidemiology. Throughout this work, Dr. Seeger has remained keenly aware of the limitations of research using administrative data and has supplemented the platform

of insurance claims with additional data where appropriate, including laboratory test results, surveys, medical record reviews, and has expanded into research involving electronic health record data.

Dr. Seeger is an Adjunct Assistant Professor of Epidemiology at the Harvard T.H. Chan School of Public Health. He has been active within the International Society of Pharmacoepidemiology (ISPE) and is a Past President and Fellow of the Society.

**Eric S. Weintraub** is an epidemiologist currently working with the Vaccine Safety Datalink at the Centers for Disease Control and Prevention. He holds a Bachelor in Health Sciences from the University of Florida and a Master of Public Heath from Emory University. Eric has over 20 years of experience in the field of vaccine safety ranging from traditional retrospective safety analysis to conducting real-time rapid sequential analysis of vaccines and adverse events. He is currently the project lead for the Vaccine Safety Datalink which is a collaborative project between CDC and 9 integrated health care organizations whose primary mission is to evaluate the safety of licensed and recommended routine vaccinations. In addition, Eric is the CDC lead for the VSD's Rapid Cycle Analysis assessing the safety of COVID-19 vaccines in real time. He has co-authored more than 100 articles on the topics related to vaccine safety.

**Susan C. Winckler, RPh, Esq.** 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, Ms. Winckler served as President of Leavitt Partners Solutions, a national healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Ms. Winckler directly advised CEOs and C-suite executives of life-sciences and pharmaceutical companies, payers, health-care providers, government agencies, employers, and associations on international, federal and state public policy and regulation, business strategy, investments, M&A, and other major business matters. Ms. Winckler also served as Chief Risk Management Officer for the entire Leavitt Partners family of businesses. Before becoming President, her role leading the DC office for Leavitt Partners included serving as Interim Executive Director of the Health Care Transformation Task Force, an alliance of patients, payers, providers, and purchasers committed to moving 75% of their businesses to value-based payment by 2020.

A pharmacist and attorney by training, Ms. Winckler was CEO of the Food & Drug Law Institute, which serves nearly all major law firms' food and drug practices, government regulators, leaders of pharmaceutical, device, food and tobacco companies, and consumers with class-leading legal and regulatory resources, analyses, updates, journals, and conferences. She provided a neutral forum for these stakeholders to address domestic and global food and drug law issues. She also served on FDLI's board.

As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), Ms. Winckler 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 the White House, myriad government entities, and external stakeholders. She was unique among her predecessors in also simultaneously leading FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. In 2007, she led FDA's medical product negotiation with China's then-State Food and Drug

Administration, resulting in the Product Safety Memorandum of Agreement between the two nations. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.

Ms. Winckler earned a BS from the University of Iowa College of Pharmacy and her JD 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. She previously served on the boards of the Partnership for Safe Medicines and the American Society of Pharmacy Law, and on the executive leadership board for the Univ. of Iowa College of Pharmacy.

**Hui-Lee Wong** is Associate Director for Innovation and Development at the Office of Biostatistics and Epidemiology at the Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA). In this capacity, she is actively engaged in the CBER Surveillance Program efforts aimed at advancing CBER surveillance systems. At the US FDA since 2009, her regulatory experience encompasses post market surveillance of biologics, drugs at Center for Drug Evaluation and Research and medical devices at Center for Devices and Radiological Health. She also leads projects in building capacity for pharmacovigilance of vaccines in Democratic Republic of Congo and Kenya. She was seconded to the U.S. Centers for Disease Control and Prevention Ebola Response Team in Sierra Leone in 2015. Prior to US FDA, she completed a post-doctoral fellowship at the U.S. National Institutes of Health and received a Ph.D. in Molecular Epidemiology from the University of Southern California.