ENGELBERG CENTER for Health Care Reform at BROOKINGS

Distributed Data Networks for Active Medical Product Surveillance
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Participant Biographies

Mark McClellan, MD, PhD
Director, Engelberg Center for Health Care Reform and Leonard D. Schaeffer Chair in Health Policy Studies, The Brookings Institution

As director of the Engelberg Center at Brookings, Mark McClellan's work focuses on promoting high-quality, innovative and affordable health care. A doctor and economist by training, he also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare and Medicaid Services (CMS) and former commissioner of the Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, as well as an associate professor of economics and medicine at Stanford University.

Elizabeth B. Andrews, PhD, MPH
Vice President, Pharmacoepidemiology and Risk Management, RTI Health Solutions

Elizabeth Andrews is the vice president of pharmacoepidemiology and risk management at RTI Health Solutions within RTI International, an independent, not-for-profit research institute. She provides consultation to pharmaceutical companies on therapeutic risk management, and serves as principal investigator on research programs that evaluate drug safety and compliance with risk management programs. Her epidemiologic experience includes safety studies using electronic medical records and claims databases, and coordinating studies across multiple databases. She is also an adjunct associate professor of epidemiology at the University of North Carolina School of Public Health and School of Pharmacy, a member of the editorial board of the *Journal of Pharmacoepidemiology and Drug Safety*, and co-editor of the textbook *Pharmacovigilance*. Previously, Dr. Andrews served as vice president of worldwide epidemiology at a large pharmaceutical company. She also managed the Statewide Regionalized Perinatal Care program and directed the non-Medicaid health care reimbursement programs for the State Health Department of North Carolina. Dr. Andrews is fellow, past president, and current board member of the International Society for Pharmacoepidemiology.

Jeffery S. Brown, PhD
Department of Population Medicine, Harvard Medical School and the Harvard Pilgrim Health Care Institute

Jeffrey S. Brown is a lecturer in the department of population medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is also director of the HMO Research Network Center for Education and Research in Therapeutics (CERT) Data Coordinating Center housed at DPM, as well as research director of the Therapeutics Research and Infectious Disease program. He is a health services researcher with expertise in pharmacoepidemiology and drug safety,

with primary research activities involving the development of new methodologies and techniques to facilitate drug and vaccine safety surveillance using automated healthcare claims and encounter data. This includes application of new sequential analytic and data mining methodologies using observational data, as well as new methods and approaches for facilitating multi-institutional research using such data. His research portfolio also holds work in health policy, health economics, and outcomes research. Dr. Brown holds a master's degree in economics from Tufts University and a PhD in social policy from Brandeis University. He is a seven-time national champion and three-time world champion in Ultimate Frisbee, and the men's ultimate frisbee coach at Tufts University.

James Baggs, PhD
Epidemiologist, Immunization Safety Office, Centers for Disease Control and Prevention

James Baggs is an epidemiologist in the Immunization Safety Office at the Centers for Disease Control and Prevention, where he works on the Vaccine Safety Datalink (VSD) project. Within the VSD, he participates as both a data manager and an epidemiologist; he has been involved in the continuing development of the VSD, its distributed data model, and the development of active surveillance in near real time, as well as working on a number of research studies within the project. Previously, Dr. Baggs worked as an epidemiologist for the State of Washington. He received his doctoral degree from the Rollins School of Public Health at Emory University in 1999, where he concentrated on studies of HIV genetic variation.

Mary L. Durham, PhD
Vice President for Health Research, Kaiser Permanente and Director, Center for Health Research

Mary L. Durham is vice president of health research for Kaiser Permanente and director of the Center for Health Research – Northwest, Hawaii, and Southeast. In addition to her leadership roles, Dr. Durham conducts her own National Institutes of Health-funded research on workplace health and translational research. She is also the associate director of the Oregon Clinical and Translational Research Institute, and was previously a commissioner for Oregon's Senate Commission for Health Care Access and Affordability. In tandem with her distinguished health research career, Dr. Durham has worked with state and federal lawmakers in crafting policy-level decisions across a wide range of topics such as privacy, mental health law, genetics, research, and human subjects protection. She has held diverse roles, from providing expert testimony to the President's National Bioethics Advisory Commission to consulting for the World Health Organization. Dr. Durham has served on the boards of the Association for Health Services Research (Academy Health), Group Health Community Foundation, and Kaiser Permanente Health Care Alternatives. She is a professor in the department of public health and preventive medicine at the Oregon Health & Science University, and adjunct professor in the department of sociology at Portland State University. Dr. Durham is also a former commissioner of the American Bar Association, where she served on the Commission on Mental and Physical Disability Law.

Vik Kheterpal, MD
Principal, CareEvolution, Inc.

Vik Kheterpal is principal of CareEvolution, Inc., a leading provider of secure interoperability solutions. The company markets HIEBus™, a health information exchange technology platform to enable edge applications to share clinical information in a secure, reliable, and incremental manner. Dr. Kheterpal is very active in the interoperability and health information technology landscape. He is a member of the eHealth Initiative and serves on its Transforming Care Delivery and Policy working groups, as well as a member of the Healthcare Information and Management Systems Society's (HIMSS) Emergency Responder Task Force and the joint HIMSS/American Health Information

Management Association work group on health information exchange privacy and security. Previously, Dr. Kheterpal served as the global general manager and vice president for clinical information systems for GE Healthcare, where he led GE's clinical IT initiatives. Dr. Kheterpal received his doctorate in medicine from the University of Michigan at Ann Arbor, where he also earned a bachelor's degree in biomedical sciences.

Terri Madison, PhD, MPH
President, i3 Drug Safety

Terri Madison is president and founding leader of i3 Drug Safety, where her responsibilities include business and scientific leadership for safety services provided by the pharmacovigilance and clinical epidemiology teams. Previously, Dr. Madison served as senior vice president of global operations at i3 Statprobe, a global data services CRO. With more than 20 years of biopharmaceutical industry experience, including eight years at Parke-Davis Pharmaceutical Research and 11 years at STATPROBE, Dr. Madison has substantial experience in data collection, analysis, and reporting across multiple therapeutic areas in all phases of research, and often serves in a consulting capacity to both internal and external clients. Her core areas of research interest and expertise includes pregnancy surveillance; risk management; and the design, conduct, and analysis of observational cancer studies, for which she has worked with both state and national cancer registries to evaluate both social and biological factors associated with prognosis. Dr. Madison received her doctorate in epidemiology from the University of Michigan, and a master's in public health from the University of Michigan School of Public Health.

Kenneth D. Mandl, MD, MPH
Associate Professor, Harvard Medical School and Director, Intelligent Health Laboratory at the Children's Hospital Informatics Program

Kenneth D. Mandl is an associate professor in the Harvard Medical School Center for Biomedical Informatics and affiliated faculty at the Harvard-MIT Division of Health Sciences and Technology, as well as director of the Intelligent Health Laboratory at the Children's Hospital Informatics program. He is also an attending physician in pediatric emergency medicine. Additionally, he co-directs the Centers for Disease Control and Prevention (CDC) Center of Excellence in Public Health Informatics, and is a member of the Advisory Committee to the director of the CDC. A pioneer in both consumer informatics and population health monitoring, Dr. Mandl has innovated and published extensively in the areas of personally controlled health records, disease outbreak detection, public health surveillance, and national health information infrastructure. Recognized for his teaching and research, he has received the Barger Award for Excellence in Mentoring at Harvard Medical School and the Presidential Early Career Award for Scientists and Engineers, the highest honor bestowed by the U.S. government to outstanding scientists and engineers. Currently, he is working to translate biosurveillance approaches to address issues in pharmacovigilance.

Wilson D. Pace, MD
Director, American Academy of Family Physicians National Research Network, and Director, State Networks of Colorado Ambulatory Practices and Partners

Wilson D. Pace is the director of the American Academy of Family Physicians National Research Network, and director of the State Networks of Colorado Ambulatory Practices and Partners. Additionally, he is the Green-Edelman Chair for practice-based research and professor of family medicine at the University of Colorado, Denver. As the director of both a national practice-based research network and a consortium of practice-based research networks within Colorado, Dr. Pace's research has focused on practice reorganization, electronic data collection techniques and advancing translational research methodologies. He is the principal architect of the Distributed Ambulatory Research in Therapeutics Network (DARTNet), a consortium of health care

organizations and research networks that seek to combine available electronic health data, practice-based research techniques and quality improvement activities to support comparative effectiveness research using both observational and pragmatic clinical trial methods. He also serves as the principal investigator, co-investigator or in an advisory capacity to a number of health information technology, behavioral change and disease specific research projects.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI
President, Clinical Services and Chief Medical Officer, Hospital Corporation of America

Jonathan B. Perlin is president, clinical services and chief medical officer of the Hospital Corporation of America (HCA), where he provides leadership for clinical services and improving performance at HCA's 163 hospitals and more than 600 outpatient centers and physician practices. Before joining HCA in 2006, Dr. Perlin was under secretary for health in the U.S. Department of Veterans Affairs. Nominated by the President and confirmed by the Senate as the senior-most physician in the federal government and chief executive officer of the Veterans Health Administration, Dr. Perlin led the nation's largest integrated health system to recognition for full implementation of electronic health records and benchmark quality. He serves on numerous boards and commissions, including the Joint Commission, Meharry Medical College, and the National eHealth Collaborative. He also chairs the Health IT Standards Committee for the U.S. Department of Health and Human Services. Dr. Perlin has faculty appointments at Vanderbilt University as adjunct professor of medicine and biomedical informatics and at Virginia Commonwealth University as adjunct professor of health administration.

Judy Racoosin, MD, MPH
Scientific Lead, Sentinel Initiative, Office of the Commissioner, Food and Drug Administration

In February 2009, Judy Racoosin joined the Food and Drug Administration's (FDA) Sentinel Initiative as its scientific lead, after having worked at the FDA on pre- and post-market safety issues and safety policy for 13 years. Dr. Racoosin received her MD from the University of Maryland School of Medicine in 1992 and completed a residency in internal medicine at the University of Chicago Hospitals in 1995. In 1996, Dr. Racoosin earned an MPH from the University of Illinois at Chicago. She is also board-certified in clinical pharmacology.

Patrick Ryan, ME
Manager, Statistical and Quantitative Sciences, GlaxoSmithKline Research and Development

Patrick Ryan is a manager in statistical and quantitative sciences at GlaxoSmithKline Research and Development, where he has led several efforts to develop and apply exploratory analysis methods to better understand the effects of medicines. He also currently serves as the co-investigator of the Observational Medical Outcomes Partnership (OMOP) – a public-private partnership managed by the Foundation for the National Institutes of Health and chaired by the Food and Drug Administration. As part of this effort, he is conducting methodological research to assess the appropriate use of observational healthcare data to identify and evaluate drug safety issues.

Miriam CJM Sturkenboom, PhD
Professor, Department of Medical Informatics, Erasmus University Medical Center

Miriam Sturkenboom is a professor in analysis of observational research at the department of medical informatics of the Erasmus University Medical Center in the Netherlands. She is also a pharmacist and received her PhD with honors in pharmacoepidemiology. She works with the Boston Collaborative Drug Surveillance Database in the USA, the National Research Council in Italy, and Erasmus University, and teaches pharmacoepidemiology in several countries. Under her guidance, the IPCI database has become a well-known and valuable data source for epidemiological research. Her current research interest is to study drug and vaccine safety in large populations through the creation of national and international networks of databases and novel tools from biomedical sciences for effectively analyzing such linked databases. Dr. Sturkenboom is chair of the database resources working group of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance that is coordinated by the European Medicines Evaluation Agency, and is past president of the International Society of Pharmacoepidemiology. She has also published over 140 journal articles in peer-reviewed journal articles in the field of (pharmaco)epidemiology.

Marcus Wilson, PharmD
President, HealthCore

Marcus Wilson is president of HealthCore, a wholly owned subsidiary of WellPoint, Inc. HealthCore utilizes the vast real world research environment provided by WellPoint's national reach and local depth to provide research services focused on clinical effectiveness, health economics and safety evaluation of various healthcare interventions. The results of the studies offer clarity that empowers a broad array of healthcare decision makers to act with precision to improve quality, safety and affordability. In addition to his leadership position with HealthCore, he also serves as co-chair of eHealth Initiative's Workgroup on Using Health IT for Research on Comparative Effectiveness and Outcomes, and on a number of relevant WellPoint committees including the Strategy & Innovations Council, the Information Management Steering Committee, the Public Policy Steering Committee, and the Enterprise Regulatory Council. He is a past member of the board of directors of the International Society for Pharmacoeconomics & Outcomes Research and is a reviewer for multiple journals. His publications, including book chapters, span various clinical, safety and health outcomes topics.

Janet S. Wright, MD, FACC
Senior Vice President for Science and Quality, American College of Cardiology

Janet S. Wright is the senior vice president for science and quality at the American College of Cardiology (ACC). Her division encompasses clinical guidelines, performance measures, health policy statements, and appropriate use criteria; quality improvement projects like Door to Balloon (D2B) and Hospital to Home (H2H); and the National Cardiovascular Data Registry. Dr. Wright served on the ACC's Board of Trustees and chaired the Task Force on Performance Assessment, Recognition, Reinforcement, Reward, and Reporting. She is a member of the National Committee for Quality Assurance's Physician Program Committee and is on the board of the Center for Information Therapy, a non-profit organization committed to the provision of personalized health information during each healthcare encounter. From its inception in December 2003, Dr. Wright also served as a member of the Independent Citizens' Oversight Committee, a 29-person board charged with administering the California Institute for Regenerative Medicine.