ENGELBERG CENTER for Health Care Reform at BROOKINGS

Sentinel Initiative Public Workshop
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Biographies

Jeffrey Brown, PhD, MA, is an assistant professor in the Department of Population Medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is a health services researcher with expertise in pharmacoepidemiology and drug safety, with primary research activities involving the development of new methodologies to facilitate multi-institutional medical product safety surveillance using electronic health data, including the application of sequential analytic and data mining methodologies. His expertise is in developing the infrastructure, systems and tools to establish interoperability to enable multi-site distributed querying of health data. He is Director of Scientific Operations for the FDA's Mini-Sentinel project, and has leadership responsibility for network development, implementation, and operation in several other large-scale distributed networks, including the NIH Collaboratory, NCI Cancer Research Network, the ONC MDPHnet project, and the PCORI National Clinical Research Network. Dr. Brown is also the lead architect of PopMedNet, an open-source software platform that facilitates the creation and operation large-scale interoperable distributed health data networks. PopMedNet was selected by the ONC S&I Framework community as a key component in the reference implementation for the ONC Query Health Initiative that is tasked with developing the standards and reference architecture for distributed querying of EHRs to support quality measurement, public health surveillance, and research. Dr. Brown holds a master's degree in economics from Tufts University and a PhD in social policy from Brandeis University. Jeff is an 8-time national champion and 3-time world champion in Ultimate Frisbee.

Robert M. Califf, MD, is the vice chancellor for clinical research, director of the Duke Translational Medicine Institute (DTMI), and professor of medicine in the division of cardiology at the Duke University Medical Center. Dr. Califf leads a large, multifaceted organization focused on the transformation of how discoveries are translated into improved medical care. Prior to his role at DTMI, he was the founding director of the Duke Clinical Research Institute, a premier academic research organization. He is the editor-in-chief of American Heart Journal, the oldest cardiovascular specialty journal. As director of DTMI, funded in part by a National Institutes of Health Clinical and Translational Science Award (CTSA), Dr. Califf's contribution includes service as the first co-chair of the Principal Investigators Steering Committee of the CTSA. He has served on the Cardiorenal Advisory Panel of the Food and Drug Administration (FDA) and the Pharmaceutical Roundtable of the Institute of Medicine (IOM). He is currently a member of the IOM Forum in Drug Discovery, Development, and Translation and sits on a subcommittee of the Science Board of the FDA. During his tenure as a founding director of the Coordinating Center for the Centers for Education & Research on Therapeutics, a public-private partnership among the Agency for Healthcare Research and Quality, the FDA, academia, the medical-products industry, and consumer groups, he focused on research and education to advance and optimize the use of medical products. He currently serves as the co-chair of the Clinical Trials Transformation Initiative, a public-private

partnership focused on improving the clinical trials system, and as the chair of the Clinical Research Forum, an organization of academic health and science system leaders focused on enhancing the effectiveness of the clinical research enterprise.

Elizabeth A. Chrischilles, PhD, is a professor in the Department of Epidemiology and holds the Pomerantz Chair in Public Health in the University of Iowa College of Public Health. Dr. Chrischilles is a co-leader of the Mini-Sentinel Protocol Core. She is also leading a Mini-Sentinel protocol-based assessment of thromboembolic events after immunoglobulin administration. Her research involves using healthcare administrative databases to address drug safety and effectiveness questions, particularly for patients with multiple chronic conditions. She is also involved in cluster-randomized trials of team management interventions, prospective follow-up of prognostic cohorts, linkage of claims data to prospective registries and cohorts, and leading a research team that is investigating multiple uses of an internet-based personal health record designed with older adults.

Lesley H. Curtis, PhD, is professor in medicine at the Duke University School of Medicine and works primarily in the Duke Clinical Research Institute. A health services researcher by training, Dr. Curtis oversees a portfolio of projects that use observational data to address questions related to clinical and comparative effectiveness, pharmacoepidemiology, health care delivery, and epidemiological trends. Dr. Curtis has considerable experience analyzing Medicare claims data, large clinical registries, and prescription drug data, and has led the linkage of large clinical registries with longitudinal Medicare claims data. In addition, Dr. Curtis has been responsible for the linkage of those data with longitudinal cohorts in the Cardiovascular Health Study, the Framingham Heart Study, the Jackson Heart Study, and the Multi-Ethnic Study of Atherosclerosis (MESA). Experienced in facilitating large-scale multi-institutional research through the use of distributed health data networks, Curtis co-leads the Data Core for the FDA's Mini-Sentinel Initiative, co-leads the Electronic Health Record Core for the NIH's Health Care Systems Collaboratory, and co-leads the Standardization & Interoperability Task Force for the Patient-Centered Outcomes Research Initiative's National Clinical Research Network.

Gregory Daniel, PhD, MPH, RPh, is a Fellow in Economic Studies and managing director for evidence development and innovation in the Engelberg Center for Health Care Reform at the Brookings Institution. In this position, Dr. Daniel oversees and provides strategic direction regarding the Center's evidence development and biomedical innovation portfolio, including medical product safety surveillance, regulatory science and FDA policy issues, comparative effectiveness research, and other biomedical innovation policies. Dr. Daniel was previously vice president, Government and Academic Research at HealthCore (subsidiary of WellPoint, Inc) where he led a division responsible for providing research services in the areas of pharmacoepidemiology, drug, vaccine, and biologic safety evaluations, comparative effectiveness research, and health economics and outcomes research. His research has utilized electronic health insurance claims data integrated with clinical data including laboratory results, electronic hospital data, paper-based and electronic medical record data, and registries. Dr. Daniel is a registered pharmacist and holds a PhD in Pharmaceutical Economics, Policy, and Outcomes Research with a minor in Epidemiology from the University of Arizona, a MPH specializing in biostatistics, a MS in Pharmaceutical Administration, and a BS in Pharmacy, all from The Ohio State University.

Bruce Fireman, MA, is a biostatistician and research scientist at the Division of Research, Kaiser Permanente Northern California. His research interests include assessment of the effectiveness and safety of vaccines and drugs. He usually works with population-based data, comparing the effectiveness of alternative treatments and alternative ways of delivering healthcare. He has evaluated disease management programs care and primary care teams. He has collaborated with Kaiser Permanente clinicians and administrators in efforts to improve healthcare**.**

Sally Greenberg joined the National Consumers League as Executive Director on October 1, 2007. The League's focus is on five key priority areas: fraud, child labor, LifeSmarts, health care, especially the safe use of medications and medication adherence, and food safety and nutrition. Ms. Greenberg has testified numerous times before Congress on consumer protection issues, including on product safety, fraud, excessive fees on car rentals, consumer rip-offs in calling cards and in support of protections for farmworker children. She is the primary spokesperson for the NCL on a variety of issues. Ms. Greenberg came to NCL from Consumers Union, where she worked from 1997-2007 on product liability and food safety issues, along with auto and product safety. Previously, she worked at the U.S. Department of Justice Foreign Claims Settlement Commission and prior to that, she spent a decade serving as the Eastern States Civil Rights Counsel for the Anti-Defamation League, based in Boston. Ms. Greenberg was president of the Women's Bar Association of Massachusetts and the Women's Bar Foundation, and served on several gubernatorial commissions in Massachusetts. She also served for many years on the board of directors of the Alliance for Justice, and HALT, an organization whose mission is the protection of the rights of consumers in their interactions with lawyers and the legal system. Ms. Greenberg is a member of the Reagan-Udall Foundation Board, a nonprofit established by Congress to support the mission of the FDA and help equip the agency with the highest caliber regulatory science and technology. She also serves on the board of the Keystone Center, which helps leaders in health, energy, environment and education battle contentious issues with a consensus-based approach. She also served for over a decade on the board of directors of Trillium Asset Management, the oldest and largest investment management firm dedicated to socially responsible investing.

Thomas P. Gross, MD, MPH, is currently the Director of the Office of Surveillance and Biometrics at the Center for Devices and Radiological Health of the Food and Drug Administration. Prior to coming to FDA in the late 1980s, Dr. Gross worked as an Epidemic Intelligence Service Officer with the Centers for Disease Control and Prevention and earned a Master of Public Health degree from the Johns Hopkins School of Hygiene and Public Health. He also served in the Commissioned Corps of the U.S. Public Health Service (Captain, retired) and is board certified in Pediatrics, General Preventive Medicine, and Clinical Pharmacology.

William H. Maisel, MD, MPH, is Chief Scientist and Deputy Center Director for Science at FDA's Center for Devices and Radiological Health (CDRH). He is responsible for providing leadership in the development, implementation, execution, management and direction of the Center's broad national and international biomedical science programs. Prior to joining FDA, Dr. Maisel was Associate Professor of Medicine at Harvard Medical School with more than 15 years of clinical experience as a Board-certified cardiologist. He is former Chair of the FDA Circulatory System Medical Device Advisory Committee and is a former member of the Center for Medicare and Medicaid Services Coverage Advisory Committee. Dr. Maisel received his undergraduate degree in biology from MIT, his medical degree from Cornell

Medical College, and his Masters in Public Health from the Harvard School of Public Health. He has published more than 120 research manuscripts, book chapters, and scientific abstracts on regulatory science, device innovation, and medical device safety and effectiveness.

Kim McCleary is director of Strategic Initiatives at FasterCures, a center of the Milken Institute determined to remove barriers to medical progress. At FasterCures, Ms. McCleary leads the charge on key programmatic areas including how the U.S. Food and Drug Administration (FDA) evaluates risk and benefit for patients, and medical innovation and how we determine value and reimbursement. Prior to joining FasterCures' staff, Ms. McCleary was president and chief executive officer of the Chronic Fatigue and Immune Dysfunction Syndrome (CFIDS) Association of America from 1991 until June 2013. She has earned a reputation as an articulate patient advocate, a keen policy strategist, a diplomatic bridge builder and a dedicated servant leader. She has worked with leaders throughout the executive and legislative branches to develop, implement and oversee effective policy. She helped found the Chronic Pain Research Alliance and joined with other leaders and Pfizer to establish the Campaign to End Women's Pain in 2010. Ms. McCleary led the Partnering to End Pain project, which was selected by Sanofi U.S. as a finalist in the 2012 Collaborate | Activate Innovation Challenge. She has participated in every opportunity organized by the FDA to shape its Patient-Focused Drug Development Initiative, including a range of consultations leading up the first of the 20 PFDDI workshops focused on CFS and ME held in April 2013. With leaders in the narcolepsy community, she helped to design and launch the Unite Narcolepsy initiative to educate, engage and empower narcolepsy patients and their advocates to participate effectively in the PFDDI meeting held in September 2013.Ms. McCleary is a graduate of the University of North Carolina at Chapel Hill.

Mark McClellan, MD, PhD, is a senior fellow and director of the Initiative on Value and Innovation in Health Care at the Brookings Institution. Within Brookings, his work focuses on promoting quality and value in patient centered 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 & Medicaid Services (CMS) and former commissioner of the U.S. 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 chairs the FDA's Reagan-Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and was an associate professor of economics and medicine at Stanford University.

Karen Midthun, MD, is the director of the Center for Biologics Evaluation and Research (CBER), at the U.S. Food and Drug Administration (FDA). CBER regulates vaccines, allergenics, blood and blood products, and cellular, tissue, and gene therapies. Its responsibilities include oversight of the investigational phases of product development, decisions regarding licensure, and post-licensure surveillance activities. Dr. Midthun previously served as the deputy director of CBER and the director of the Office of Vaccines Research and Review within CBER. Before joining the FDA in 1993, Dr. Midthun was on the faculty of the Department of International Health at the Johns Hopkins Bloomberg School of Public Health, where she was involved in the clinical

development of investigational vaccines and was an attending physician at the Johns Hopkins Hospital. Dr. Midthun received her bachelor's degree from the Massachusetts Institute of Technology and her medical degree from the George Washington University School of Medicine. She trained as a resident in internal medicine at Johns Hopkins Hospital and as a fellow in infectious diseases at Johns Hopkins Hospital and the National Institute of Allergy and Infectious Diseases. She is a Fellow of the Infectious Diseases Society of American and a member of the American College of Physicians.

Richard Moscicki, MD, joined the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), as Deputy Center Director for Science Operations in April 2013. A nationally recognized expert in clinical research and development, Dr. Moscicki is bringing his extensive scientific expertise and executive leadership skills to Center operations and direction and to effective development and implementation of CDER programs. Before joining CDER, Dr. Moscicki served as senior vice president (SVP), Head of Clinical Development at Genzyme Corporation. He joined Genzyme in 1992 as Medical Director, becoming Chief Medical Officer and SVP of Biomedical and Regulatory Affairs in 1996 and holding that post until 2011. During that time, Dr. Moscicki was responsible for worldwide global regulatory and pharmacovigilance matters and oversaw all aspects of clinical research and medical affairs for the company. Dr. Moscicki received his medical degree from Northwestern University Medical School. He is board certified in internal medicine, diagnostic and laboratory immunology, and allergy and immunology. He completed his residency in Internal Medicine, followed by a four-year fellowship at Massachusetts General Hospital (MGH) in Clinical immunology and immunopathology. He remained on staff at MGH in Clinical Immunology and on the faculty of Harvard Medical School from 1979 until 2013.

Michael D. Nguyen, MD, is the acting director of the Division of Epidemiology in the U.S. Food and Drug Administration's (FDA) Office of Biostatistics and Epidemiology at the Center for Biologics Evaluation and Research (CBER). He serves as the CBER center lead for the Mini-Sentinel program and is involved in postmarket safety surveillance of vaccines, blood components, and blood-derived products. Prior to working at the FDA, he completed his training in pediatrics and served as an officer in the Epidemic Intelligence Service at the Centers for Disease Control and Prevention.

Richard Platt, MD, MSc, is a professor and chair of the Department of Population Medicine at Harvard Medical School and executive director of the Harvard Pilgrim Health Care Institute. He is principal investigator of the U.S. Food and Drug Administration (FDA) Mini-Sentinel program, of contracts with FDA's Center for Drugs Evaluation and Research and Center for Biologics Evaluation and Research to conduct post-marketing studies of drugs' and biologics' safety and effectiveness. He chaired the FDA's Drug Safety and Risk Management Advisory Committee, is a member of the Association of American Medical Colleges' Advisory Panel on Research and the Institute of Medicine Roundtable on Value & Science-Driven Health Care. Dr. Platt was co-chair of the Board of Scientific Counselors of the Centers for Disease Control and Prevention's (CDC) Center for Infectious Diseases. Additionally, he chaired the National Institutes of Health study section, Epidemiology and Disease Control 2, and the CDC Office of Health Care Partnerships steering committee. Dr. Platt is also principal investigator of a CDC Center of Excellence in Public Health Informatics, the Agency for Healthcare Research and Quality HMO Research Network DEcIDE Center, and a CDC Prevention Epicenter.

Marsha Reichman, PhD, is senior advisor and scientific lead for Surveillance Programs in the Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research (CDER), and CDER Lead for the Sentinel Initiative at the U.S. Food and Drug Administration (FDA). She also chairs the CDER Sentinel Steering Committee. A biostatistician, epidemiologist and molecular biologist by training, Dr. Reichman came to the FDA in 2010 from the National Cancer Institute (NCI) where she was acting director of the Cancer Statistics Branch, including the SEER Cancer Surveillance Program, and surveillance research coordinator for the Surveillance Research Program in the Division of Cancer Control and Population Sciences (DCCPS). In DCCPS, Dr. Reichman was also NCI lead on the development of SEER*DMS, a distributed, unified data management system for SEER Cancer Registries, and co-founder of the Informatics Committee of the Division. As a Senior Staff Fellow at NCI, Dr. Reichman was primary investigator on a metabolic study of alcohol consumption in pre-menopausal women that demonstrated, for the first time, alcohol effects on estrogen blood levels and metabolism. Previously, she directed the Survey Research Group at Northrop Grumman Health IT. Dr. Reichman's research interests include use of observational data for medical surveillance, health disparities, survival statistics, and head and neck cancers. She received her bachelor's degree in mathematics and biology from Barnard College, PhD in Cell and Molecular Biology from MIT, and master's degree in mathematical statistics from University of Maryland.

Michael Rosenblatt, MD, is executive vice president and chief medical officer at Merck. He represents the voice of the patient and medicine inside Merck and is the company's primary external advocate on medical issues. Dr. Rosenblatt previously was dean of Tufts University School of Medicine and the George R. Minot Professor of Medicine at Harvard Medical School. He served as the president of Beth Israel Deaconess Medical Center. He was also director of the Harvard-MIT Division of Health Sciences and Technology. Prior to these leadership positions, he was senior vice president for research at Merck where he co-led the worldwide development team for alendronate (FOSAMAX®), Merck's bisphosphonate for osteoporosis and bone disorders. From 1981 to 1984, he served as chief of the Endocrine Unit at the Massachusetts General Hospital. Dr. Rosenblatt is the recipient of the Fuller Albright Award for his work on parathyroid hormone and the Vincent du Vigneaud Award in peptide chemistry and biology, and the Chairman's Award from Merck. Committed to innovation, he has served on the board of directors and scientific advisory boards of several biotechnology companies. Dr. Rosenblatt was elected to the American Society of Clinical Investigation and the Association of American Physicians, is a fellow of the American Association for the Advancement of Science and the American College of Physicians, and served as the president of the American Society of Bone and Mineral Research. He has served as a consultant to the U.S. President's Council of Advisors on Science and Technology. Dr. Rosenblatt received his undergraduate degree summa cum laude from Columbia University and his MD magna cum laude from Harvard Medical School. He trained in internal medicine and endocrinology at the Massachusetts General Hospital.

Joe V. Selby, MD, MPH, is the first executive director of the Patient-Centered Outcomes Research Institute (PCORI). A family physician, clinical epidemiologist and health services researcher, he has dedicated his career to patient care, clinical research and administration. At PCORI, he works to identify and address strategic issues and opportunities for PCORI and to implement and administer the research agenda authorized by the PCORI Board of Governors. Building on the foundational work of the Board, Dr. Selby leads the continuing development of PCORI as a research organization, overseeing the implementation of its research agenda, its external communications, and its work to establish effective on-going, two-way engagement channels with each of PCORI's key stakeholder groups, beginning with patients. Dr. Selby joined PCORI from Kaiser Permanente, Northern California, where he was a researcher for 27 years,

serving as director of the Division of Research for the last 13 years. In this role, he led a department of more than 50 investigators and 500 research staff working on more than 250 ongoing studies. An accomplished researcher, he has authored more than 220 peer-reviewed articles, primarily in the areas of primary care delivery; diabetes mellitus outcomes and quality improvement; colorectal cancer screening strategies; population management for chronic conditions; and quality measurement. Dr. Selby was elected to membership in the Institute of Medicine in 2009. A native of Fulton, Missouri, he received his medical degree from Northwestern University; his training in family medicine from Contra Costa County Family Medicine Program, Martinez, CA, and his master's in public health from the University of California, Berkeley. He served as a commissioned officer in the Public Health Service with the National Health Services Corp from 1976-1983 and received the Commissioned Officer's Award in 1981. Dr. Selby was appointed PCORI executive director on May 16, 2011.

Azadeh Shoaibi, MS, MHS, joined the Sentinel Initiative team at the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) in 2010. Currently, she is the FDA methods lead of Sentinel and directs the development and implementation of epidemiologic and statistical infrastructure for the Sentinel system. Ms. Shoabi first joined FDA in 2004 and worked at the Center for Devices and Radiological Health (CDRH) where she performed post-market evaluation, surveillance, and research on a variety of medical devices with a focus on in vitro diagnostic devices. She holds a master's degree in epidemiology and a master's degree in molecular microbiology and immunology. Ms. Shoabi is currently a doctoral candidate in epidemiology at University of Maryland, Baltimore. Her prior research and public health experience were in the areas of epidemiology of HIV and other sexually transmitted infections, cell cycle regulation and cancer development, and genomics of malaria parasites.

Janet Woodcock, MD, is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). Dr. Woodcock held various leadership positions within the FDA's commissioner's office, including deputy commissioner and chief medical officer, deputy commissioner for operations, and chief operating officer and director, Critical Path Programs. Previously, Dr. Woodcock served as director of CDER from 1994-2005. She also held other positions at FDA including director, Office of Therapeutics Research and Review and acting deputy director, Center for Biologics Evaluation and Research. A prominent FDA scientist and executive, Dr. Woodcock has received numerous awards, including a Presidential Rank Meritorious Executive Award, the American Medical Association's Nathan Davis Award, and Special Citations from FDA Commissioners. Dr. Woodcock received her MD from Northwestern Medical School, completed further training, and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

Katherine Yih, PhD, MPH, is an epidemiologist in the Harvard Pilgrim Health Care Institute and the Department of Population Medicine at Harvard Medical School. She works in the areas of infectious disease surveillance and post-marketing vaccine safety monitoring, the latter with the FDA-sponsored Post-licensure Rapid Immunization Safety Monitoring (PRISM) system, a component of the Mini-Sentinel pilot project. She holds a PhD in biological sciences from the University of Michigan and a master of public health degree with a concentration in international health from the Harvard School of Public Health.