ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

Sentinel Initiative Public Workshop
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Biographies

Patrick Archdeacon, MD, is a medical officer in the Office of Medical Policy with the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). His work at the Office of Medical Policy includes involvement in the Clinical Trials Transformation Initiative (a public-private partnership that identifies practices to increase the quality and efficiency of clinical trials) and the Sentinel Initiative (a system that will draw on existing automated healthcare data from multiple sources to actively monitor the safety of medical products continuously and in real time). Dr. Archdeacon originally joined FDA in 2008 as a medical officer in the Division of Special Pathogens and Transplant Products in the Office of New Drugs. He attended medical school at Columbia University's School of Physicians and Surgeons. Prior to joining FDA, he completed his training in internal medicine at the New York Presbyterian Hospital and in nephrology and transplant nephrology at the University of North Carolina.

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 research director of the Therapeutics Research and Infectious Disease program at DPM and director of scientific operations for the U.S. Food and Drug Administration's (FDA) Mini-Sentinel project. Dr. Brown 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 multi-institutional drug and vaccine safety surveillance using automated healthcare administrative and claims data, including the application of sequential analytic and data mining methodologies. His research portfolio also holds work in health policy, health economics, outcomes research. Dr. Brown holds a master's degree in economics from Tufts University and a PhD in social policy from Brandeis University.

Melissa Butler, PhD, PharmD, MPH, BCPS, is a pharmacist with research interests in comparative effectiveness, pharmacoepidemiology, quality of care, health disparities, and health policy at Kaiser Permanente. Dr. Butler received her bachelor of science and doctor of pharmacy degrees from Philadelphia College of Pharmacy, where she minored in economics. After pharmacy school she trained at Harvard Vanguard/Harvard Pilgrim as a managed care pharmacy resident and at the University of Illinois at Chicago (UIC)/Pharmacia as a drug therapy outcomes fellow. Dr. Butler achieved and maintains her certification as board certified pharmacotherapy specialist. She also holds a masters of public health in health policy and administration from UIC and a PhD in pharmaceutical sciences with specialization in pharmaceutical outcomes and policy from the Eschelman School of Pharmacy at the University of North Carolina, Chapel Hill. Prior to starting at Kaiser Permanente, Dr. Butler worked as a

consultant with the outcomes research company Xcenda and as a pharmacist in various health care settings.

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. 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. Dr. Chrischilles is principal investigator of the Iowa Developing Evidence to Inform Decisions about Effectiveness (Iowa DEcIDE) Center and co-investigator on a pragmatic trial in the NIH Common Fund's Health Care Systems Research Collaboratory.

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.

Ralph I. Horwitz, MD, MACP, is senior vice president for Clinical Evaluation Sciences at GlaxoSmithKline (GSK), and Harold H. Hines, Jr. professor emeritus of medicine and epidemiology at Yale University. Dr. Horwitz trained in internal medicine at institutions (Royal Victoria Hospital of McGill University and the Massachusetts General Hospital) where science and clinical medicine were connected effortlessly. These experiences as a resident stimulated a deep interest in clinical research training which he pursued as a fellow in the Robert Wood Johnson Clinical Scholars Program at Yale under the direction of Alvan R. Feinstein. He joined the Yale faculty in 1978 and remained there for 25 years as co-director of the Clinical Scholars Program and later as chair of the department of medicine. Before joining GSK, Dr. Horwitz was chair of Medicine at Stanford and dean of Case Western Reserve Medical School. Dr. Horwitz' research interests are in the methods used to study the strategies of clinical care. He has published widely on methods for the etiology, diagnosis, prognosis and treatment of disease. He is an elected member of the Institute of Medicine of the National Academy of Sciences; the American Society for Clinical Investigation; the American Epidemiological Society; and the Association of American Physicians (he was president in 2010). He was a member of the Advisory Committee to the National Institutes of Health Director (under both Drs. Elias Zerhouni and Francis Collins). Dr. Horwitz served on the American Board of Internal Medicine and was chairman in 2003. He is a master of the American College of Physicians.

David Madigan, PhD, is professor and chair of the Department of Statistics at Columbia University in New York City. He received a bachelor's degree in mathematical sciences and a PhD in statistics, both from Trinity College Dublin. He has previously worked for AT&T Inc., Soliloquy Inc., the University of Washington, Rutgers University, and SkillSoft, Inc. He has over 100 publications in such areas as Bayesian statistics, text mining, Monte Carlo methods, pharmacovigilance and probabilistic graphical models. He is an elected Fellow of the American Statistical Association, the Institute of Mathematical Statistics, and the American Association for the Advancement of Science. He has just finished a term as editor-in-chief of *Statistical Science* and is the current editor of *Statistical Analysis and Data Mining*.

Mark McClellan, MD, PhD, is director of the Engelberg Center for Health Care Reform and Leonard D. Schaeffer Chair in Health Policy Studies at the Brookings Institution. At the Center, his 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 & Medicaid Services 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.

Jennifer Nelson, PhD, is an associate investigator in the Biostatistics Unit at Group Health Research Institute (GHRI) and an affiliate associate professor of biostatistics at the University of Washington. She received her PhD from the Department of Biostatistics at the University of Washington in 1999. Dr. Nelson's research focuses on methods to assess drug and vaccine safety and effectiveness, and she has published over 35 studies in this area. She is particularly interested in addressing methodological challenges in post-licensure drug and vaccine safety studies that use large observational health care databases. Dr. Nelson provides national leadership as the methods core

co-lead and senior statistician for the U.S. Food and Drug Administration's (FDA) Mini-Sentinel Initiative, a pilot project to facilitate development of an active surveillance system for monitoring the safety of all FDA-regulated medical products. She has also served as methodology committee chair for the Centers for Disease Control and Prevention (CDC) sponsored Vaccine Safety Datalink (VSD) project, a national collaboration involving 10 managed care organizations that has monitored immunization safety in the U.S. since 1990. In 2009, Dr. Nelson earned the VSD's Margarette Kolczak Award for outstanding contributions in biostatistics and epidemiology in the field of vaccine safety. She is also an invited member of the Vaccines Sub-Committee of the International Society for Clinical Biostatistics (ISCB), a group established to facilitate collaboration among statisticians working in vaccine research and to disseminate statistical methods for vaccine research worldwide.

Michael D. Nguyen, MD, is the deputy 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 postmarketing 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.

Samuel Nussbaum, MD, is executive vice president, Clinical Health Policy, and chief medical officer for WellPoint, Inc. He is the key spokesperson and policy advocate for WellPoint and is responsible for the company's public health policy programs. He oversees corporate medical and pharmacy policy and clinical quality programs to ensure the provision of proven effective care. Dr. Nussbaum currently serves on the boards of the National Quality Forum (NQF), the OASIS Institute, New England Healthcare Institute (NEHI), and BioCrossroads, and has participated in numerous Institute of Medicine activities, including serving on the Roundtable on Value & Science-Driven Health Care. Dr. Nussbaum is a professor of clinical medicine at Washington University School of Medicine and serves as adjunct professor at the Olin School of Business, Washington University. He has served as president of the Disease Management Association of America, chairman of the National Committee for Quality Health Care, chair of America's Health Insurance Plan's (AHIP) Chief Medical Officer Leadership Council, as a member of the AHIP Board, and on the Secretary of Health and Human Services' Advisory Committee on Genetics, Health, and Society. Dr. Nussbaum received the 2004 Physician Executive Award of Excellence from the American College of Physician Executives and Modern Physician magazine and has been recognized by Modern Healthcare as one of the "50 Most Influential Physician Executives in Healthcare" in 2010 and 2011. Prior to joining WellPoint, Dr. Nussbaum served as executive vice president, Medical Affairs and System Integration, of BJC Health Care, where he led integrated clinical services across the health system and served as president of its medical group. He earned his medical degree from Mount Sinai School of Medicine. He trained in internal medicine at Stanford University Medical Center and Massachusetts General Hospital and in endocrinology and metabolism at Harvard Medical School and Massachusetts General Hospital, where he directed the Endocrine Clinical Group. As a professor at Harvard Medical School, Dr. Nussbaum's research led to new therapies to treat skeletal disorders and new technologies to measure hormones in blood.

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.

John Santa, MD, MPH, is the director of the Consumer Reports Health Ratings Center. The Ratings Center focuses on explicit approaches evaluating and comparing health services, products and practitioners. Dr. Santa was the administrator of the Office of Oregon Health Policy and Research from 2000 to 2003. He helped organize and implement an evidence-based approach to prescription drug purchasing that eventually came to be known as the Drug Effectiveness Review Project. He has worked in leadership positions for hospitals, physician groups and health insurers. Dr. Santa has taught in multiple environments including medical school, residency training and graduate courses in Public Health. Dr. Santa received his bachelor's degree from Stanford University in 1972, his MD from Tufts University in 1976 and master's of public health from Portland State University in 2005. He has practiced primary care internal medicine in several settings, most recently at the Portland, Oregon Veterans Affairs Medical Center.

Sebastian Schneeweiss MD, ScD, is associate professor of medicine and epidemiology at Harvard Medical School and vice chief of the Division of Pharmacoepidemiology and Pharmacoeconomics of the Deptartment of Medicine at Brigham and Women's Hospital (BWH). He is principal investigator of the BWH DEcIDE Research Center on Comparative Effectiveness Research and the DEcIDE Methods Center, both funded by AHRQ, and director of the Harvard-Brigham Drug Safety Research Center funded by FDA/CDER. His research is funded by multiple NIH grants and focuses on the comparative effectiveness and safety of biopharmaceuticals and analytic methods to improve the validity of epidemiologic studies using complex healthcare databases particularly for newly marketed medical products. His work is published in high-ranking journals and was featured in *Discover* magazine. Dr. Schneeweiss is past president of the International Society for Pharmacoepidemiology and is Fellow of the American College of Epidemiology, the American College of Clinical Pharmacology, and the International Society for Pharmacoepidemiology. He is voting consultant to the U.S. Food and Drug Administration (FDA) Drug Safety and Risk Management Advisory Committee and member of the methods committee of the Patient Centered

Outcomes Research Institute. He received his medical training at the University of Munich Medical School and his doctoral degree in pharmacoepidemiology from Harvard University.

Darren Toh, ScD, is an assistant professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute. He is currently deputy director of scientific operations for the Mini-Sentinel pilot program. Dr. Toh is a pharmacist and pharmacoepidemiologist with an interest in comparative safety and effectiveness research of medical products. His research has been focused on 1) evaluating the risks and benefits of therapeutics, especially in vulnerable populations such as pregnant women and individuals with multiple comorbidities, and 2) developing and applying robust and secure analytic methods to conduct such studies in large-scale multi-institutional collaboratives. He is also director of the Coordinating Center for the HMO Research Network DEcIDE Center.

Myrl Weinberg, MA, has served as president of the National Health Council (NHC) since 1996. The NHC brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Ms. Weinberg's extensive career has focused on health care delivery, medical research, long-term care, and related issues that affect people with chronic conditions. She has testified repeatedly before Congress and federal regulatory bodies and is a frequent speaker on the patient perspective in health policy. Ms. Weinberg currently serves on the NIH Cures Acceleration Network (CAN) Review Board, Robert Wood Johnson Foundation's Aligning Forces for Quality Program National Advisory Committee and the Center for Information and Study on Clinical Research Participation Board of Advisors. She is a former chair of the International Alliance of Patients' Organization Governing Board.

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.