Setting Priorities for Methods Research and Development for Active Medical Product Surveillance

Participant Biographies

Robert Ball, MD, MPH, ScM is the director, Office of Biostatistics and Epidemiology (OBE), Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA) where he leads CBER's statistical and epidemiological evaluation of the safety and effectiveness of biologic products. Prior to this appointment, Dr. Ball served as a medical epidemiologist and chief, vaccine safety branch in OBE where he helped direct CBER's epidemiological and surveillance activities related to vaccine safety. He is an author on more than 90 scientific publications and his current research interests include improving methods for identification, evaluation and prevention of adverse effects of biologic products. Prior to joining the FDA in 1998, Dr. Ball provided clinical care in the United States and Philippines and conducted research in decompression sickness prevention and treatment as a U.S. Navy medical officer. Dr. Ball received his BS in Mathematics and MD from Georgetown University. He interned at the U.S. Naval Hospital Bethesda, completed his MPH and residency in occupational and environmental medicine at the Uniformed Services University of the Health Sciences, and received the ScM degree in infectious disease epidemiology and vaccine science and policy from Johns Hopkins School of Public Health.

Josh Benner, PharmD, ScD is a research director at the Engelberg Center for Health Care Reform and a fellow in Economic Studies at Brookings, where his work focuses on improving the safety, effectiveness and value of health care interventions. He directs a portfolio of activities related to the infrastructure and methods for developing better evidence, including medical product safety surveillance, comparative effectiveness research, and clinical research and development. Prior to joining Brookings, Dr. Benner was senior principal in health economics and outcomes research at IMS Health, where he led studies on the utilization and value of medicines, including prospective trials, retrospective studies in administrative and medical records databases, patient surveys, and economic modeling. Dr. Benner completed an AHRQ post-doctoral fellowship in health services research at the Division of Pharmacoepidemiology & Pharmacoeconomics, Brigham and Women's Hospital. He holds a doctor of pharmacy degree from Drake University and a doctor of science in health policy and management from the Harvard University School of Public Health.

Jeffrey S. Brown, PhD is an assistant professor 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. 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 drug and vaccine safety surveillance using automated health care 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.

Aloka Chakravarty, PhD is director, division of biometrics VII which focuses on quantitative safety evaluation of drugs and biologics across its full life-cycle. She has been leading this division since its inception in October 2009. Dr. Chakravarty joined the Center for Drug Evaluation and Research (CDER) in 1992 and brings to her current position considerable experience in CDER, having previously supported oncology, anti-infective, dermatologic, dental and ophthalmologic, hematologic, medical imaging and radiopharmaceutical products and special pathogens areas of the drug review program. She has served as a staff fellow, senior statistical reviewer, acting team leader, and as deputy director of division of biometrics IV. As the staff director for biologic therapeutic statistical staff, she led the transition of biologic therapeutic products from CBER to CDER

in 2003. Dr. Chakaravarty has also served on detail as the acting director, division of surveillance, Office of Surveillance and Compliance in the Center for Veterinary Medicine. Most recently, she was the division director, division of biometrics V, supporting oncology drug and biologic products, imaging and hematology products. Dr. Chakravarty participated in the CDER Leadership Development Program and has received many CDER awards, including the Excellence in Leadership Award in 2000, FDA Award of Merit in 2008 and FDA Scientific Achievement Award in 2010. She received her PhD in Statistics from Temple University, and MStat from Indian Statistical Institute. Dr. Chakravarty served as an adjunct faculty in department of statistics, Foundation for Advanced Education in the Sciences, National Institutes of Health. She is an internationally recognized thought leader in the area of surrogate markers and biomarkers in drug development and has presented and published widely on it. Her research interests include design of clinical trials, surrogate endpoint methodology, biomarkers, interim analysis, Bayesian methodology, safety evaluation and statistical computing.

COL Trinka Coster, MD is director of the Pharmacovigilance Center in the United States Army Office of the Surgeon General. At the Center, her work focuses on providing military leadership with timely and actionable drug safety surveillance information. COL Coster is an internist and clinical pharmacologist by training. Her assignments in the military have included directing a clinical trials unit at the U.S. Army Institute of Infectious Diseases that conducted Phase 1 and Phase Clinical trials, overseeing product development of combat casualty care military products, and most recently developing the newly established Army's Pharmacovigilance Center. She is also actively involved in new initiatives that are exploring methods to develop decision supports systems for her Pharmacovigilance Center using Structured Product Label information and using semantic web technology.

Lesley Curtis, PhD is associate professor of medicine in the Duke University School of Medicine and works primarily in the Center for Clinical and Genetic Economics. 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. She is a co-investigator for the AHRQ-sponsored Cardiovascular Center for Education and Research on Therapeutics (CERTS), the director of the Duke DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) center, and co-leads the Data Core for FDA's Mini-Sentinel program.

Gerald J. Dal Pan, MD, MHS became the director of the Office of Surveillance and Epidemiology (known then as the Office of Drug Safety) in U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) in November 2005. Prior to that, he was the director of the Division of Surveillance, Research, and Communication Support in CDER's Office of Drug Safety, a position he held since December 2003. He received his medical degree from Columbia University, and his master's degree in clinical epidemiology from Johns Hopkins University. He trained in internal medicine at the Hospital of the University of Pennsylvania, and in neurology at Johns Hopkins Hospital. He is board certified in internal medicine and neurology. He was an instructor in the neurology department at Johns Hopkins. He next worked for Guilford Pharmaceuticals in Baltimore, and then for HHI Clinical Research and Statistical Services in Hunt Valley, MD. He joined the FDA in July 2000 as a medical officer in the Division of Anesthetic, Critical Care, and Addiction Drug Products.

Frank DeStefano, MD, MPH is the director of the Immunization Safety Office of the Centers for Disease Control and Prevention (CDC). He is a graduate of Cornell University and the University of Pittsburgh School of Medicine. He received training in public health and preventive medicine in the Epidemic Intelligence Service and preventive medicine residency at CDC. He obtained a Masters of Public Health degree at Johns Hopkins University School of Hygiene and Public Health. He has had extensive epidemiologic research experience at CDC, the National Institutes of Health, and at non-governmental research organizations. His areas of research have included immunizations, autism and other developmental disabilities, reproductive health, veterans' health, diabetes, cardiovascular diseases, and other chronic diseases. Dr. DeStefano is an author on over 140 publications in leading scientific and medical journals. For the past 15 years Dr. DeStefano has had a focus on

vaccine safety. He currently serves on the Food and Drug Administration Vaccines and Related Biological Products Advisory Committee (VRBPAC).

Susan Ellenberg, PhD is a professor of biostatistics and the associate dean for clinical research at the University of Pennsylvania. Dr. Ellenberg's research interests have focused on issues in the design and analysis of clinical trials, and assessment of medical product safety. Particular areas of interest include efficient trial designs, interim monitoring and the operation of data monitoring committees, evaluation of surrogate endpoints, ethical issues in clinical research, special issues in trials of cancer and AIDS therapies, and of vaccines. She is an associate editor of *Clinical Trials* and of the *Journal of the National Cancer Institute*. Dr. Ellenberg is a fellow of the American Statistical Association, the American Association for the Advancement of Science, the Society for Clinical Trials, and an elected member of the International Statistical Institute. She has served as president of the Society for Clinical Trials and the Eastern North American Region of the International Biometric Society, has chaired the Statistics Section of the AAAS and will serve as chair of the board of trustees for the National Institute of Statistical Sciences beginning in 2011. Her book on clinical trials data monitoring committees, co-authored with Drs. Thomas Fleming (University of Washington) and David DeMets (University of Wisconsin), was named Wiley Europe Statistics Book of the Year for 2002.

Clifford Goodman, PhD is a senior vice president and principal at The Lewin Group, a health care policy and human services consulting firm based in Falls Church, Virginia. He has 30 years of experience in such areas as health technology assessment, evidence-based health care, comparative effectiveness research, and studies pertaining to health care innovation, regulation, and payment. He directs studies and projects for an international range of government agencies; pharmaceutical, biotechnology, and medical device companies; health care provider institutions; and professional, industry, and patient advocacy groups. Dr. Goodman is senior staff for the Lewin Group Center for Comparative Effectiveness Research. He is the chair of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) for the Centers for Medicare & Medicaid Services. He has testified to Congress on issues pertaining to Medicare coverage of health care technology. Dr. Goodman is vice president (and president elect) of the professional society Health Technology Assessment International (HTAi), and is a fellow of the American Institute for Medical and Biological Engineering. He did his undergraduate work at Cornell University, received a master's degree from the Georgia Institute of Technology, and earned his doctorate from the Wharton School of the University of Pennsylvania.

Thomas Gross, MD is currently the acting director of the Office of Surveillance and Biometrics at the Center for Devices and Radiological Health of the U.S. Food and Drug Administration (FDA). Prior to coming to FDA, 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 is board certified in pediatrics, general preventive medicine, and clinical pharmacology.

Abraham G. Hartzema is professor and eminent scholar at the University of Florida in the Department of Pharmacy Health Care Administration. He is the Perry A. Foote Chair in Health Outcomes Research, and professor in Epidemiology and Biostatistics in the College of Public Health and the College of Medicine. In the year 2007, he was awarded the University of Florida Foundation Research award. Dr. Hartzema has widely published on various aspects of prescription drug safety, including several books on pharmacoepidemiology. His most recent book entitled "Pharmacoepidemiology and Therapeutic Risk Management" was published in the year (2008) by Harvey Whitney Book Publishers. Co-edited with Hugh Tilson (UNC-Chapel Hill) and Arnold Chan (Harvard University) the book reflects the new therapeutic risk management paradigm as implemented by the FDA. He has served on the scientific board of the FIP; and on editorial boards, including *Medical Care, Annals of Pharmacotherapy, the International Journal of Pharmacy Practice, Pulmonary Circulation* and others. He has been the chair of several Data Safety and Monitoring Boards. He has also served on the University of Florida Graduate Council, and grant review panels for AHRQ, DSEN, NIH, and NIHBL. He currently serves on the United States Pharmacopeia: Nomenclature, Safety and Labeling Expert Committee. Dr. Hartzema's current research funded by the Agency

for Healthcare Research and Quality and the Florida Office of Rural Health, addresses health information technology and medication error prevention in small rural hospitals. He is also principle investigator on grants in Sickle Cell Disease, Hemophilia and Epilepsy. Research areas of interest include the costs of illness for sickle cell disease, the use of transfusions to prevent complications, iron overload and iron chelation, prescribing and utilization of hydroxyurea in sickle cell disease, transition of pediatric to adult care, and empowering patients with sickle cell disease. His theoretical interests are in data mining techniques, developing metrics for the benefit/risk ratio of drugs, methods development for active medical product safety surveillance. Dr. Hartzema was on faculty leave (Sept 2008 – Sept 2009) in the FDA Immediate Office of the Commissioner working on the Congressional mandated Sentinel Initiative. He currently serves as a principle investigator to the Observational Medical Outcomes Project (OMOP), a public-private partnership between the FDA, the Foundations of the National Institute of Health and PhRMA.

Sean Hennessy, PharmD, PhD is associate professor of epidemiology and of pharmacology and senior scholar (core faculty member) in the Center for Clinical Epidemiology & Biostatistics (CCEB) at the University of Pennsylvania. He is a pharmacoepidemiologist with research foci on drug-drug interactions and comparative effectiveness research. He is PI of Penn's Agency for Healthcare Research and Quality (AHRQ)-funded Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Center, PI of Penn's center in the Food and Drug Administration-funded Scientific Program to Support Epidemiology Investigations, and lead Co-PI of Penn's AHRQ-funded Center for Education and Research on Therapeutics (CERT). Dr. Hennessy serves on the U.S. Department of Health and Human Services' National Vaccine Advisory Committee's Vaccine Safety Working Group, and has served on the U.S. Food and Drug Administration's Drug Safety and Risk Management Advisory Committee. He is a past president of the International Society for Pharmacoepidemiology, and current chair of the Drug Safety Scientific Section of the American Society for Clinical Pharmacology and Therapeutics (ASCPT). He is editor for the Americas of the journal *Pharmacoepidemiology & Drug Safety,* and co-editor of *Pharmacoepidemiology, 5th edition*, and serves on the editorial board of *Clinical Pharmacology and Therapeutics*.

Jeffrey A. Kelman, MD, MMSc is the chief medical officer for the Center for Medicare at the Centers for Medicare & Medicaid Services (CMS). Dr. Kelman received his AB in 1969 and MMSc in 1971 from Brown University and his doctorate of medicine in 1973 from Harvard Medical School. He is board certified in internal medicine, pulmonary medicine, geriatrics, and medical direction LTC. Dr. Kelman trained at the Peter Bent Brigham Hospital and the National Heart, Lung, and Blood Institute of the National Institutes of Health. He served as medical director for Collington Episcopal Life Care Center, and as senior medical consultant, Congressional Budget Office, before joining CMS.

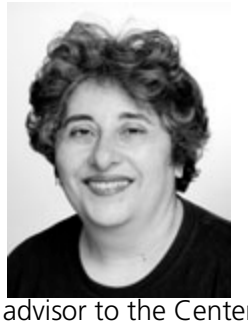
David Knutson recently joined the U.S. Department of Health and Human Services as a senior analyst in the Health Financing Policy Division of the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Prior positions include senior research fellow at the University of Minnesota - Division of Health Policy and Management. His duties included research, teaching, and the development of the Center for Care Organization Research and Development. Previous positions include director of Health Systems Studies at the Park Nicollet Institute, director of provider contracting for two HMOs, director of Emergency Medical Services (EMS) and long-term care regional planning, and executive director of hospital and community-based mental health programs. Mr. Knutson conducts research and development projects related to risk adjustment; performance-based purchasing; insurance markets; and organizational issues associated with chronic illness management. He has served on the Society of Actuaries Risk Adjustment Project Oversight Group. From 2002-2006 he served on the Centers for Medicare & Medicaid Services (CMS) National Advisory Panel on Medicare Education. Since 2006, he has served on the Efficiency Measurement Advisory Panel and consultant for the National Committee on Quality Assurance (NCQA). He led the State of Minnesota's Technical Expert Panel on provider performance e-reporting using the state's all-payer claims data base. Most recently, he served on the Minnesota State Health Insurance Exchange Workgroup. His projects that have been funded by the Robert Wood Johnson Foundation (RWJ), RWJ-Program for Changes in Healthcare Financing and Organization (HCFO), the Society of Actuaries, the Centers for Medicare & Medicaid Services (CMS), the Agency for HealthCare Research and Quality (AHRQ), state Medicaid programs, the Center for Health Care Strategies (CHCS), and the health care systems of the United Kingdom (UK), Sweden, and Germany. Mr. Knutson has a BA in biology and an MS in health economics.

Xavier Kurz, MD, PhD, MSc graduated in 1982 as a medical doctor at the University of Liege, Belgium. He specialized in tropical medicine and worked for several years in public health projects in Africa and Asia. He obtained an MSc (1991) and a PhD (1997) in Epidemiology and Biostatistics at McGill University, Montreal, Canada. He joined the Department of Pharmacology of the University of Liege, where he developed and conducted pharmacoepidemiological and pharmacoeconomic studies on vascular disorders and dementia. In 1995, he joined the Belgian Centre for Pharmacovigilance (Ministry of Health) as a scientific expert. He joined the Pharmacovigilance and Risk Management Sector of the European Medicines Agency (EMA) in September 2005. As signal detection scientific advisor and project leader, he has coordinated the EMA activities for the benefit-risk monitoring of Influenza A/H1N1 pandemic vaccines in Europe. On behalf of EMA, he also coordinates the PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium) project, a public-private partnership of 31 participants, carried-out within the framework of the Innovative Medicines Initiative of the European Commission. He is Principle Scientific Advisor of the ENCePP (European Network of Centres forPharmacoepidemiology and Pharmacovigilance) project.

S. Lawrence Kocot, JD, LLM, MPA serves as a visiting fellow in the Economic Studies program and deputy director of the Engelberg Center for Health Care Reform at Brookings. Mr. Kocot is also senior counsel at SNR Denton LLP. Mr. Kocot was interim president and CEO and currently serves on the Board of Directors of the Partnership for a Healthier America. Previously, he was senior advisor to the Administrator of the Centers for Medicare & Medicaid Services at the U.S. Department of Health and Human Services. In this capacity, he was involved in a wide range of health care policy issues and operations related to Medicare and Medicaid. Mr. Kocot is former chairman and currently a member of Virginia's Commonwealth Health Research Board; he was appointed by Virginia Governor Mark R. Warner and reappointed by Virginia Governor Tim Kaine. Prior to his government service, he spent nearly a decade at the National Association of Chain Drug Stores, where he was senior vice president and general counsel. Mr. Kocot received his BA and MPA degrees from the University of Massachusetts at Amherst. He earned his JD and LLM degrees at the Georgetown University Law Center.

David Madigan, PhD is professor and chair 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 and of the Institute of Mathematical Statistics. He has just finished a term as editor-in-chief of *Statistical Science*.

Danica Marinac-Dabric, MD, PhD is director, division of epidemiology, Office of Surveillance & Biometrics, Center for Devices and Radiological Health (CDRH), FDA. Previously, she served as a Cchief of epidemiology in the division of mostmarket surveillance at CDRH. A physician and epidemiologist by training, Dr. Marinac-Dabic leads the CDRH Post-Approval Studies Program in charge of oversight of all FDA mandated postmarket studies of medical devices. Dr. Marinac-Dabic also oversees the CDRH Epidemiologic Research Program charged with advancing the methods and infrastructure for evidence development and appraisal with application to medical device regulatory science. Under her leadership FDA Medical Device (MDEpiNet) Initiative was launched in 2010 to identify evidence gaps and questions, datasets, and approaches for conducting robust analytic studies to improve understanding of clinical outcomes and performance of medical devices through strategic consortium with academic centers. Dr. Marinac-Dabic is author of several book chapters, manuscripts and presentations on various topics of medical device epidemiology and surveillance.



Marianthi Markatou, PhD, MA holds a BSc in Mathematics and Physics, and an MA and PhD in Statistics. She is a research scientist with the healthcare transformation research group, T.J. Watson Research Center, IBM, and an adjunct professor of statistical sciences, Cornell University, New York. Before joining IBM Research, Dr. Markatou was a full professor in the department of biostatistics, Mailman School of Public Health and affiliate professor, department of biomedical informatics, Columbia University, New York (and an approved PhD dissertation sponsor in both departments). Dr. Markatou has had two extended stays with the U.S. government; during 2001-03, she was directing statistics at the National Science Foundation and during 2009-10, she was a scientific advisor to the Center of Biologics Evaluation and Research of the U.S. Food and Drug Administration. Dr. Markatou's research interests are at the interface of statistics, computational sciences (machine learning and data mining) and biological and medical sciences, including the theory and applications of statistical distances, problems in model assessment and selection, classification and clustering, robustness, surveillance methods using large databases, pharmacovigilance, biomarker development, and comparative effectiveness and safety research. Dr. Markatou is an elected fellow of the American Statistical Association, an elected member of the International Statistical Institute and a faculty fellow of the Institute of Social and Economic Research and Policy (ISERP), Columbia University. Currently, she is an associate editor of the theory and methods section of the *Journal of the American Statistical Association*, *Biology Direct's* section on mathematical biology, and *Sankhya*, the Indian Journal of Statistics

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 (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 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.

Jennifer Clark Nelson, PhD is an associate investigator in the biostatistics unit at Group Health Research Institute (GHRI) and an assistant professor of biostatistics at the University of Washington. Dr. Nelson's research focuses on statistical methods for vaccine and drug safety and effectiveness studies. She is particularly interested in addressing challenges in sequentially-monitored post-licensure vaccine and drug safety surveillance when using large observational databases. Dr. Nelson provides statistical leadership within the national Centers for Disease Control and Prevention (CDC) sponsored Vaccine Safety Datalink (VSD) project and as senior statistician and co-lead of the Mini-Sentinel Coordinating Center Methods Core for the U.S. Food and Drug Administration (FDA). As part of both those efforts, she is leading the development, evaluation, and wider implementation of safety surveillance methods for a variety of medical products, including drugs, devices, and biologics. She is also an invited member of the vaccines sub-committee of the International Society for Clinical Biostatistics, established to facilitate collaboration among statisticians working on vaccine research worldwide.

Michael D. Nguyen, MD is a medical officer in the U.S. Food and Drug Administration's (FDA) office of biostatistics and epidemiology at the Center for Biologics Evaluation and Research (CBER). At CBER, he serves as the project officer for Mini-Sentinel's Postlicensure Rapid Immunization Safety Monitoring (PRISM) program and focuses his efforts on postmarketing vaccine safety surveillance. 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.

Sharon-Lise Normand, PhD is professor of health care policy (biostatistics) in the department of health care policy at Harvard Medical School and professor in the department of biostatistics at the Harvard School of Public Health. Her research focuses on the development of statistical methods for health services and outcomes research, primarily using Bayesian approaches, including causal inference, provider profiling, item response theory analyses, latent variables analyses, multiple informants analyses, and evaluation of medical devices in randomized and non-randomized settings. She serves on several task forces for the American Heart Association and the American College of Cardiology, was a consultant to the U.S. Food and Drug Administration's Circulatory System Devices Advisory Panel after serving a four-year term on the panel, is a member of the Medicare Evidence Development and Coverage Advisory Committee, and is Director of Mass-DAC, a data coordinating center that monitors the quality of all adult cardiac surgeries and coronary interventions in all Massachusetts' acute care hospitals. Dr. Normand has served on several editorial boards including *Biometrics*, *Statistics in Medicine*, *Health Services and Outcomes Research Methodology*, *Psychiatric Services*, and *Cardiovascular Quality and Outcomes*. She was the 2010 president of the Eastern North American Region of the International Biometrics Society and is vice chair of the Patient Centered Outcomes Research Institute's Methodology Committee. Dr. Normand earned her PhD in biostatistics from the University of Toronto, holds a master's of science as well as a bachelor's of science degree in statistics, and completed a post-doctoral fellowship in Health Care Policy at Harvard Medical School. She is a fellow of the American Statistical Association, a fellow of the American College of Cardiology, a fellow of the American Heart Association, and an associate of the Society of Thoracic Surgeons.

Robert O'Neill, PhD is the director of the Office of Biostatistics (OB) in Office of Translational Sciences in the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration. His office provides biostatistical and scientific computational leadership and support to all programs of CDER. Prior to October 1998 he was director of the Office of Epidemiology and Biostatistics, responsible also for the post-market safety surveillance of new drugs. In 1989-1990, Dr. O'Neill was a visiting professor at the Department of Research, University Medical School, Basel, Switzerland, where he developed and presented numerous lectures and created a course series "Topics in Therapy Evaluation and Review (TITER)" for European pharmaceutical scientists, which was the model for the European Course In Pharmaceutical Medicine (ECPM), a degree granting graduate program. He is a fellow of the American Statistical Association (1985), a member of several professional societies, a past member of the board of directors of the Society for Clinical Trials, the 2002 recipient of the Marvin Zelen Leadership Award in Statistical Science, and the 2004 Lowell Reed Lecture Awardee from the American Public Health Association.

J. Marc Overhage MD, PhD currently serves as the chief medical information officer for Siemens Healthcare. Prior to joining Siemens, Dr. Overhage was chief executive officer of the Indiana Health Information Exchange and director of medical informatics for the Regenstrief Institute. Dr. Overhage is a general internist with 20 years of practice in ambulatory, inpatient and emergency department settings. He led development, implementation and evaluation of clinical information systems including CPOE, clinical decision support and health information exchange. He has published over 100 scholarly articles and gives approximately 50 presentations annually. He serves on the National Committee for Vital and Health Statistics, the HIT Standards Committee and on the board of directors of the National Quality Form. Dr. Overhage is a fellow of the Institute of Medicine, the American College of Medical Informatics and the American College of Physicians. Dr. Overhage holds a doctorate in biophysics and an MD, both from the Indiana University School of Medicine.

Richard Platt, MD, MSc is a professor and chair of the department of population medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is principal investigator of the U.S. Food and Drug Administration's (FDA) Mini-Sentinel program and of contracts with FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to conduct post-marketing studies of drugs' and biologics' safety and effectiveness. He chaired the FDA's Drug Safety and Risk Management Advisory Committee, and is a member of the Association of American Medical Colleges' Advisory Panel on Research and the Institute of Medicine Roundtable on Evidence-Based Medicine. 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 has 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 (AHRQ) HMO Research Network Center for Education and Research in Therapeutics, the AHRQ HMO Research Network DEcIDE Center, the CDC Eastern Massachusetts Prevention Epicenter, and FDA contracts to conduct post-marketing studies of drugs' and biologics' safety and effectiveness.

Judy Racoosin, MD, MPH is the Sentinel Initiative scientific lead at the U.S. Food and Drug Administration (FDA). In that role, she leads efforts to develop the scientific methodologies needed to enable FDA to conduct active surveillance in automated health care data sources such as administrative claims databases and electronic health record systems. Dr. Racoosin has worked at the FDA on pre- and post-market safety issues and safety policy for more than 14 years. Previously, she was the senior safety policy advisor in the Center for Drug Evaluation and Research's (CDER) Office of the Center Director. She was also a reviewer and team leader on the safety team in CDER's Divisions of Neurology Products and Psychiatry Products for nine years. Dr. Racoosin graduated magna cum laude from the University of Maryland School of Medicine and completed a residency in internal medicine at the University of Chicago Hospitals. Following her residency, she earned an MPH from the University of Illinois at Chicago School of Public Health. She is also board-certified in clinical pharmacology.

Jane Reese-Coulbourne, MS, ChE is the executive director of the Reagan-Udall Foundation for the U.S. Food and Drug Administration (FDA). Created by Congress, the Foundation supports the mission of the FDA by identifying, funding, and supporting public private partnerships and projects that will provide the highest caliber science and technology, to enhance the safety and effectiveness of FDA regulated products. Ms. Reese-Coulbourne's background includes experience in patient advocacy, industry and government. As an employee of the Procter & Gamble Company for more than 10 years, she worked in production operations, chemical engineering, government regulation, new technology and product/brand start-ups. Later working with other Fortune 500 companies, she consulted in strategic planning, reengineering/restructuring, new technology plans and start-ups, and total quality management in unionized manufacturing and utility operations. Her diagnosis of breast cancer led to her interest in health research and patient advocacy, serving as executive vice president of the National Breast Cancer Coalition, and then as a consultant to the director of the National Cancer Institute (NIH), as well as to leaders in not-for-profit advocacy organizations, foundations, and biotechnology /pharmaceutical companies. Projects have included strategic planning, branding, organizational turnarounds, and philanthropic planning as well as community and patient advocacy involvement in clinical trial initiatives, company-patient advocacy strategy and pre-approval drug initiatives such as expanded access programs. Ms. Reese-Coulbourne holds a BS in Chemistry from the University of Mary Washington and an MS in Chemical Engineering from the University of Virginia.

Marsha Reichman, PhD is scientific lead for surveillance programs in the Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research (CDER), CDER lead for Sentinel Initiative Implementation and chair of the CDER Sentinel Steering Committee at the U.S. Food and Drug Administration (FDA). 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 Program, and surveillance research coordinator for the Program. She was also NCI lead on

the development of SEER*DMS, a distributed, unified data management system for SEER Cancer Registries. Her research interests include use of observational data for medical surveillance, and survival statistics, and head and neck cancers.

Mary Beth Ritchey, PhD is the associate director for postmarket surveillance studies in division of epidemiology, Office of Surveillance and Biometrics, at the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). In addition to her efforts regarding this program of postmarket studies mandated under section 522 of the Act, she is one of two CDRH representatives for the FDA Sentinel methodology group and the technical lead for the Medical Device Epidemiology Network (MDEpiNet). Dr. Ritchey has bachelor's degrees in chemistry/pharmacology and nursing, and she earned her master of science in public health and PhD from the University of North Carolina at Chapel Hill.

Melissa Robb, RN joined the Center for Drug Evaluation and Research's (CDER), Office of Medical Policy at the U.S. Food and Drug Administration (FDA) in 2009. She is the project director for the Agency's Sentinel Initiative. The Initiative's goal is to create a national, integrated, electronic system for monitoring medical product safety, augmenting the Agency's current postmarket surveillance capabilities. In 2002, CDR Robb began her career with the Agency as a project manager in FDA's division of cardiovascular and renal products within CDER. She has also worked as a denior program management officer in the Office of Critical Path Programs within the Office of the Commissioner. Prior to joining the FDA and the United States Public Health Service Commissioned Corps, CDR Robb was active duty in the United States Air Force and served at Andrews Air Force base in Maryland. She is a registered nurse and received her degree at Purdue University's School of Nursing in 1997. She has also received a regulatory affairs certification from the University of California, San Diego and a certification in patient and product safety from the University of Southern California.

Estelle Russek-Cohen, PhD is the acting division director in the Division of Biostatistics in the Center for Biologics Evaluation and Research (CBER) in the Office of Biostatistics and Epidemiology at the U.S. Food and Drug Administration (FDA). She came to CBER in February 2010 as deputy division director. Before that she was a team leader in the diagnostic devices branch of the division of biostatistics, in FDA's Office of Surveillance and Biometrics at the Center for Devices and Radiological Health. Dr. Russek-Cohen received a PhD in biostatistics from the University of Washington, Seattle. Dr. Russek-Cohen was a professor in the University of Maryland's Biometrics Program for 26 years and director of the Biometrics Program for her last five years at College Park when she retired in 2004 and came to FDA. At Maryland, she regularly collaborated with scientists and epidemiologists on infectious disease research. She also spent a year of sabbatical leave and several summers at the Biometric Research Branch of the National Cancer Institute working on statistical issues in clinical trials. Her current interests in statistics include the assessment of safety of CBER regulated products and statistical issues in personalized medicine. She is a fellow of the American Statistical Association.

Patrick Ryan, ME is associate director of analytical epidemiology at Johnson & Johnson Pharmaceutical Research and Development, where he leads 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, a public-private partnership managed by the Foundation for the National Institutes of Health and chaired by the U.S. Food and Drug Administration. As part of this effort, he is conducting methodological research to assess the appropriate use of observational health care data to identify and evaluate drug safety issues.

Thomas Scarnecchia, MSc is an accomplished life-science technology leader with significant experience as a senior executive, company officer, and technologist within the biopharmaceutical industry. Mr. Scarnecchia is CTO at Digital Aurora, a management consulting firm focused on information technology strategy and initiative management in the life science industry. He serves as executive director of the Observational Medical Outcomes Partnership, a public-private partnership for the FNIH. Prior to Digital Aurora, he was the vice president of corporate informatics at Millennium Pharmaceuticals. He provided overall strategy and leadership for Millennium's R&D

Informatics organization including computational sciences and knowledge management. Mr. Scarnecchia was previously a member of the management board at R.W. Johnson Pharmaceutical Research Institute, a Johnson & Johnson Company. There he held various senior leadership positions including vice president of information management and technology. His life-sciences experience includes leadership roles at Janssen Research Foundation and Lederle Laboratories. He holds a master of science degree in computer science and a bachelor of science degree in biology, both from Pace University.

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 at the Brigham and Women's Hospital. He is principal investigator of the BWH DEcIDE research center on comparative effectiveness research and the DEcIDE methods center, both funded by AHRQ, and PI 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 health care databases. Dr. Schneeweiss is past president of the International Society for Pharmacoepidemiology and is a 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 FDA Drug Safety and Risk Management Advisory Committee and member of multiple scientific advisory boards. He received his medical training at the University of Munich Medical School and his doctoral degree in pharmacoepidemiology from Harvard.

Rachel Sherman, MD, MPH is the associate director for Medical Policy in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA), where she is responsible for developing, coordinating, and implementing the Center's medical policy programs and strategic initiatives. She oversees the regulation of prescription drug promotion and advertising; provides leadership and scientific advice in clinical trial implementation and policy issues related to human subject protection; and is leading the implementation of the Agency's Sentinel Initiative and the development of FDA biosimilars policy. Since 1998, she has held a series of senior management positions, including deputy office director for the Office of Drug Evaluation I, deputy office director of the Office of Medical Policy in CDER, and associate commissioner for Clinical Programs. She also spent five years managing the development and implementation of FDA's Critical Path Initiative. Dr. Sherman is a board certified internist and infectious disease subspecialist. She received her BA in mathematics from Washington University, her MD from Mt. Sinai School of Medicine, and her MPH from The Johns Hopkins School of Hygiene and Public Health.

Azadeh Shoaibi is an epidemiologist, and she joined the Sentinel Initiative Core team at the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) in September 2010. Before joining CDER, she worked at the FDA Center for Devices and Radiological Health (CDRH) since 2004 where she performed pre-market and post-market evaluation, surveillance, and research on a variety of medical devices with a focus on in vitro diagnostic devices. Her prior research experience was in the areas of epidemiology of HIV and other sexually transmitted infections, malaria parasites genomics, and radiosensitizers effect on cell cycle regulation and cancer. She holds a master's degree in epidemiology from University of California Los Angeles and a master's degree in molecular microbiology and immunology from John Hopkins University. She is currently completing her doctoral degree in epidemiology at University of Maryland Baltimore.

Judy A. Staffa, PhD, RPh is currently the director, division of epidemiology II in the U.S. Food and Drug Administration's (FDA) Office of Surveillance and Epidemiology (OSE). She directs the regulatory review work of epidemiologists in CDER, and also helps to direct staff in conducting epidemiologic research and surveillance using a variety of population-based data. Dr. Staffa received her bachelor's degree in pharmacy from the University of Connecticut, and practiced community pharmacy prior to receiving her training in public health. She earned a master's degree in behavioral sciences from the Harvard School of Public Health, followed by a doctoral degree in epidemiology from the Johns Hopkins Bloomberg School of Public Health.

Prior to joining FDA in 1999, she was a researcher at the Degge Group for ten years, conducting numerous pharmacoepidemiologic studies using both administrative claims data and electronic medical records data.

Paul Stang, PhD is senior director of epidemiology at Johnson & Johnson, as well as co-principal investigator for the Foundation for the National Institutes of Health's Observational Medical Outcomes Partnership (OMOP), a public-private partnership whose aim is to engage in a program of study to objectively assess the performance, value, and impact of observational data and methods in monitoring the safety and benefit of medications. Dr. Stang has held a number of positions over the past 20 years in epidemiology and pharmacoepidemiology. Previously, Dr. Stang was a vice president at Cerner Corporation, which he joined after co-founding and serving as the chief scientific officer of Galt Associates, a health care consulting and informatics start-up that was acquired by Cerner. He previously served in positions at other health care companies, universities, and academic medical centers including the State University of New York-Stony Brook and the University of North Carolina at Chapel Hill. He holds adjunct faculty appointments at a number of institutions and is an elected fellow of the International Society for Pharmacoepidemiology. Dr. Stang has published widely in epidemiology, health outcomes, productivity, and communications.

Miriam Sturkenboom, PhD, MSc is a professor in analysis of observational data at the departments of Medical Informatics and Epidemiology of the Erasmus University Medical Center in the Netherlands. She is a pharmacist who received her PhD with honors in pharmacoepidemiology and MSc in epidemiology from the Harvard School of Public Health. She worked with the Boston Collaborative Drug Surveillance Database in the United States, the National Research Council in Italy, and Erasmus University, and teaches pharmacoepidemiology in several countries. Under her guidance, the Integrated Primary Care Information (IPCI) medical record 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 project coordinator of several EC-funded studies on drug safety signal detection and safety testing (SOS, ARITMO, EU-ADR) and manages work packages in several other EC-funded studies dealing with distributed data models in the area of vaccine safety (VAESCO) and drug use in children (TEDDY, GRIP and ARPEC). She is chair of the database resources working group and elected member of the Steering Committee of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance that is coordinated by the European Medicines Evaluation Agency. She is immediate past president of the International Society of Pharmacoepidemiology, co-chair of International Society for Pharmacoepidemiology's task force on common data models, and is a scientific advisor of various regulatory agencies, companies, and institutions.

Darren Toh, ScD is an instructor in the department of population medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute. He is currently the Director of the Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH) activities in Mini-Sentinel. Dr. Toh's research has focused on the comparative safety and effectiveness of medical products. His experience has spanned a wide range of research areas, from estimating the time-varying treatment effects of therapeutics in longitudinal studies with complex exposure patterns, to the safety of medications during pregnancy. Dr. Toh is currently leading or participating in several studies that are funded through the HMO Research Network's Center for Education and Research on Therapeutics (CERT), the Mental Health Research Network, and the Cardiovascular Research Network. He also oversees the HMORN CERT and DEcIDE Coordinating Center.

Alexander M. Walker, MD, DrPH is a principal at World Health Information Science Consultants, LLC (WHISCON), and adjunct professor of Epidemiology at Harvard School of Public Health. At Harvard, he was formerly a professor and chair of the Department of Epidemiology. At WHISCON, he oversees research strategy. Dr. Walker's work encompasses the safety of drugs, devices, vaccines, and medical procedures. Recent studies include post-marketing safety studies for approved drugs, natural history of disease studies to provide context for Phase III clinical trials, studies of the impact of drug labeling and warnings on prescribing behavior, and determinants of drug uptake and discontinuation. Additional areas of research and expertise include health effects of chemicals used in the workplace and statistical methods in epidemiology. Dr. Walker is on the editorial board of *Pharmacoepidemiology and Drug Safety* and is on the board of directors of the

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Emily Welebob RN, MS has over 15 years of experience in electronic healthcare records, and consulting related to both inpatient and ambulatory settings, with a specialized focus on patient safety and quality and health information exchange to support communities and the continuity of care. Currently she is the research program manager working with the Foundation for the National Institutes of Health on the Observational Medical Outcomes Partnership. She has published, lectured and researched in the areas of clinical informatics and healthcare information technologies. She was the project director working with eHealth Initiative (eHI) on the "Collaboration Between Communities and The Life Sciences Industry to Understand Secondary Uses of Healthcare Data for Safety Activities." Formerly, she was a vice president of program delivery at eHI, and managed knowledge delivery functions of both the eHealth Initiative and its Foundation, leading state and regional health information exchange initiatives, and providing technical assistance and policy development for states, regions, and communities across the United States. Prior to her work with eHI, Ms. Welebob was a director at First Consulting Group (FCG), a consulting group for healthcare providers, health plans, government healthcare, pharmaceutical and life sciences organizations. She played a principal role in the development of patient safety services at FCG in developing, leading, and managing services and projects inclusive of patient safety, medication management, and advanced clinical information systems, including computerized physician order entry. Prior to her healthcare consulting work, Ms. Welebob was a registered nurse for 10 years with experience in nursing leadership, and delivering patient care in intensive care, trauma, and emergency departments. Her educational background includes a bachelor of science in nursing from Marymount University, Arlington, Virginia and a master of science, nursing informatics, from the University of Maryland, Baltimore, Maryland.

Janet Woodcock, MD is the director, Center for Drug Evaluation and Research (CDER), 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.

Gwen Zornberg, MD, ScD is acting associate director, regulatory science staff of the U.S. Food and Drug Administration's Office of Surveillance and Epidemiology. Her work focuses on promoting and integrating high quality regulatory science to better detect and characterize drug product safety signals. A physician and epidemiologist by training, her career has spanned public service, industry and academia. She was previously adjunct assistant professor in the department of epidemiology at the Harvard School of Public Health, associate director of the Harvard Longwood Psychiatry Residency Training Program, and director of residency education at the Massachusetts Mental Health Center, and served as chair of healthcare of the New York City Board of Correction.

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