Public Workshop: Ensuring Access to Effective Patient Medication Information

Participant Biographies

Rachel E. Behrman, MD, MPH is director in the Office of Medical Policy in the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA). She is responsible for developing, coordinating, and implementing medical policy programs and strategic initiatives, including those focused on clinical trial modernization, policy issues related to human subject protection, and good clinical practices. Dr. Behrman began her career with the FDA in the Division of Antiviral Drug Products and has served in numerous positions, most recently as associate commissioner for Clinical Programs and director of the Office of Clinical Programs. Dr. Behrman is a board-certified internist and infectious disease subspecialist. She received her MD from Mt. Sinai School of Medicine, her MPH from The Johns Hopkins School of Hygiene and Public Health, and her BA in mathematics from Washington University.

Kate Berry, MPP is the senior vice president of Surescripts. She works with a wide range of healthcare stakeholders at the national and state level to lead and coordinate electronic prescribing and electronic medical record deployment initiatives. Ms. Berry has 20 years of healthcare experience as an executive and consultant, is a nationally known expert on electronic prescribing and a sought after speaker on related topics. She is also executive director of the Center for Improving Medication Management. The Center was founded by the American Academy of Family Physicians, Blue Cross Blue Shield Association, Medical Group Management Association, Humana, Intel, and Surescripts. The mission of the Center is to improve outcomes of medication management through collaboration among physician practices, pharmacists, payers/employers, and patients. The Center is encouraging deployment of technology to enable electronic exchange of medication information and build knowledge on how to improve patient adherence with prescribed medications. Ms. Berry joined Surescripts after a career in healthcare management consulting and as a non-profit executive. As a consultant, she conducted a wide range of strategic planning and related engagements with healthcare organizations. At the American Red Cross, Ms. Berry served as executive vice president of external affairs and chief of staff.

Tom Bizzaro, RPh is vice president, health policy and industry relations for First DataBank, where he is responsible for proactively monitoring all healthcare policy issues and proposals emanating from both the federal and state governments as well as participating in health policy initiatives related to the use of electronic drug information. Mr. Bizarro is actively involved in various health informatics standards setting activities for interoperability, and participates in the development of common drug language standards. Mr. Bizzaro has more than 20 years of experience in retail pharmacy and retail pharmacy management. Prior to joining First DataBank, he was the regional pharmacy supervisor for HMO Health Ohio, Blue Cross Blue Shield of Ohio, where he was responsible for operations, pharmaceutical contracting, and formulary management for HMO Health Ohio's staff model pharmacies. Mr. Bizzaro has been a member of the National Council for Prescription Drug Programs (NCPDP) since 1996 and is past co-chair of Work Group 2 Product Identification (WG2). In February 2005 he was elected to the NCPDP Board of Trustees and in May 2007 was named the recipient of the NCPDP 2007 TIME (The Individual Member Excellence) Award. Mr. Bizzaro is also a member of the Academy of Managed Care Pharmacy, the American Society for Automation in Pharmacy, the Healthcare Information and Management Systems Society, Health Level Seven, and the Central Indiana Association of Pharmacists.

Pamela Budny, RPh, RAC is a manager in regulatory affairs - global scientific policy at Eli Lilly and Company. She has more than 30 years of experience in the pharmaceutical industry. She has made contributions in sales, marketing, human resources, and customer services. Most recently, she was engaged for more than 13 years in global labeling operations. She has actively participated in shaping and implementing significant changes in labeling such as the Physician's Labeling Rule (PLR) and Structured Product Labeling (SPL). She received the FDA Commissioner's Special Citation for her work on SPL. Currently, she is responsible for the labeling policy portfolio in Global Scientific Policy. She remains active on the SPL Leadership Team and the PhRMA Paperless Labeling Key Issue Team. Her training as a pharmacist has fueled her passion for clear and helpful patient communication. Ms. Budny holds a Regulatory Affairs Certification from the Regulatory Affairs Professional Society.

Baxter Byerly is the vice president of information technology at Catalina Health Resource. Mr. Byerly has more than 25 years of experience in information technology, and has worked at Catalina since 1990. Mr. Byerly led the original development of the Catalina Health Resource products and is the named inventor on numerous patents with regards to providing health information to consumers in the pharmacy. He has worked with all types of pharmacy systems, printers, technologies, retailers, and solution providers. Mr. Byerly also has served as information security officer for Catalina and is responsible for maintaining HIPAA standards to protect de-identified patient data. Additionally, he has held the position of vice president of research and development on projects related to customers in the pharmacy, physician's office, grocery, and mass merchandise environments.

Vanessa Cajina is the statewide policy analyst for the California Immigrant Policy Center (CIPC), a statewide organization that seeks to inform public debate and policy decisions on issues affecting the state's immigrants and their families in order to improve the quality of life for all Californians. She develops strategies to protect state budget and policy matters affecting access to health and social services for immigrants in California, and works with elected and appointed officials to educate them on the needs of some of the state's most vulnerable residents. Prior to joining CIPC, Ms. Cajina served as the regional networks director for the Latino Coalition for a Healthy California, where she authored and carried legislation to standardize prescription drug labels throughout California and make them patient-friendly. She has also worked as a certified application assistant for Medicaid and SCHIP and has connected more than 700 families to affordable, comprehensive health insurance.

Marissa Craddock is the manager of labeling, advertising, and promotional materials for Roxane Laboratories, Inc. She has been with Roxane since 1998. She has 12 years of generic industry experience. Her responsibilities include oversight of all multisource labeling, both pre-approval submissions and lifecycle maintenance, drug listing activities, Structured Product Labeling (SPL), National Drug Code assignments, and review of all advertising and promotional materials. Prior to joining Roxane, Ms. Craddock graduated from Marietta College with a degree in advertising, public relations, and marketing. She has worked with the Generic Pharmaceutical Association for more than three years on issues such as the use of medication guides to distribute drug risk information, risk communication information, and the use of labeling to minimize medication errors.

John M. Coster, PhD, RPh is senior vice president of government affairs for the National Community Pharmacists Association. From 2007 to 2009, he served as vice president, federal affairs and public policy, at Rite Aid Corporation, the nation's third largest drug chain with 5,100 pharmacies in 37 states and the District of Columbia. He was responsible for maintaining and developing relationships with policymakers, members of Congress, and regulatory agencies, and identifying and impacting federal health program legislation and trends that impacted Rite Aid's business objectives and operations. He was also responsible for developing and executing policy and strategy relating to federal and state health care issues. From January 2000 until July 2007, Dr. Coster served as vice president, policy & programs, with the National Association of Chain Drug Stores (NACDS) in Alexandria, VA. At NACDS, he was responsible for policy issues relating to federal health care programs, such as Medicare

and Medicaid, and federal regulatory issues, such as FDA and CMS. From April 1990 through April 1994, he served as a professional staff member of the United States Senate Special Committee on Aging. In this capacity, he was responsible for all issues relating to pharmaceutical coverage and cost containment. Dr. Coster was involved in the drafting of the Medicaid pharmaceutical rebate provisions of the Omnibus Budget Reconciliation Act (OBRA) of 1990, the Veterans Health Care Act of 1992, and the Medicaid pharmaceutical and vaccine-related provision of OBRA 93. He served as a member of the President's Task Force on Health Care Reform, and helped to draft the pharmaceutical-related provisions of the President's Health Security Act, including the Medicare outpatient prescription drug benefit. Prior to joining the staff of the Senate Aging Committee, he was a health analyst at the United States Congress Office of Technology Assessment, a Policy Fellow at the Center Drugs and Public Policy at the University of Maryland Graduate School in Baltimore, and a staff member of the American Society of Hospital Pharmacists.

James Allen Heywood is the co-founder and chairman of PatientsLikeMe and the d'Arbeloff Founding Director of the ALS Therapy Development Institute. A Massachusetts Institute of Technology engineer, Mr. Heywood entered the field of translational research and medicine when his brother Stephen was diagnosed with ALS in 1998 at the age of 29. His scientific and business innovations are transforming the intersection of biotechnology and pharmaceutical development, personalized medicine, and patient care. As chairman and co-founder of PatientsLikeMe, Mr. Heywood provides the scientific vision and architecture for its patient-centered medical platform. Launched in 2005 and named one of "15 companies that will change the world" by CNNMoney, PatientsLikeMe is a personalized research and peer care platform that allows patients to share in-depth information on treatments, symptoms, and outcomes. In 1999, Mr. Heywood founded the ALS Therapy Development Institute (ALS TDI), the world's first non-profit biotechnology company, where he served as chief executive officer until 2007. Pioneering an open research model and an industrialized therapeutic validation process, he led ALS TDI to become the largest and most comprehensive ALS research program. A published author, frequent speaker and active investment advisor, Mr. Heywood's work has been profiled by the *New Yorker, New York Times Magazine, BusinessWeek*, 60 Minutes, CBS Evening News, NPR, *Science*, and *Nature*. Mr. Heywood and his brother were the subjects of Pulitzer Prize winner Jonathan Wiener's biography, *His Brothers Keeper* and the Sundance award-winning documentary, "So Much So Fast."

Nancy Hughes is the assistant vice president of communications and marketing for the National Health Council (NHC), the only organization of its kind that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic conditions and their family caregivers. Made up of more than 100 national health-related organizations and businesses, the NHC's core membership includes 50 of the nation's leading patient advocacy groups, which control the NHC's governance. Prior to her work at the NHC, Ms. Hughes served as the vice president of communications and information services at the American Academy of Physician Assistants in Alexandria, Va. She is a former radio and television reporter from Colorado and former deputy press secretary for Gov. Dick Lamm. Ms. Hughes also served as press secretary for Colorado Congressman David Skaggs, vice president of communications for the Denver Chamber of Commerce, and public affairs manager for MCI-West Division. She is a former chair of the American Society of Association Executives Communication Section Council and currently serves as chair-elect of the Public Relations Society of America Health Academy Executive Committee.

Freda C. Lewis-Hall, MD, FAPA is chief medical officer and senior vice president of Pfizer Inc, the world's largest biopharmaceutical company. She leads Pfizer Medical, the division devoted to the safe, effective and appropriate use of Pfizer's medicines, vaccines and consumer products, from the first time they are used by patients in clinical trials until their last day of sale anywhere in the world. She is a member of Pfizer's Executive Leadership Team and reports to Pfizer's chairman and chief executive officer, Jeff Kindler. Dr. Lewis-Hall joined Pfizer in 2009 and immediately launched an initiative to reshape Pfizer's regulatory and medical policies during a time of fast-changing expectations for health care companies and a wave of new therapies in development at Pfizer, particularly in vaccines

and biologics. Prior to Pfizer, she was a leader in medical affairs and biomedical product development with Vertex, Pharmacia, Bristol-Myers Squibb and Eli Lilly. She also held leadership, medical and research positions at the National Institute of Mental Health and at the Howard University Hospital and College of Medicine. In September 2010, Dr. Lewis-Hall was appointed by the Comptroller General of the United States to the inaugural Board of Governors for the new Patient-Centered Outcomes Research Institute, which will prioritize and direct a range of research programs to improve the nation's quality of health care. She also serves on the boards of the New York Academy of Medicine; The Institute of Medicine; The Foundation for the National Institutes of Health; Harvard Medical School; Society for Women's Health Research; and the American Heart Association, Power to End Stroke. Dr. Lewis-Hall is a well-known speaker on health care disparities, mental illness and women's issues, and was cited by *Forbes* magazine in their September 2010 article, "Mythbusters – Who says women can't do math and science?" She was recently named among the nation's 75 Most Powerful Women in Business by *Black Enterprise* magazine and among the 25 Most Influential African-Americans in health care by *Black Health* magazine.

Will Lockwood, MA, MPhil is assistant to the executive director for the American Society for Automation in Pharmacy (ASAP). ASAP's mission is to foster understanding of the role that technology plays in assisting pharmacists to promote patient safety and the proper use of medications, comply with laws and regulations, and operate their practices more efficiently. Mr. Lockwood is also director of editorial content for ComputerTalk Associates, Inc., publisher of *ComputerTalk for the Pharmacist*, a magazine that covers the role of technology in pharmacy clinical and business management. He participates in the National Community Pharmacists Association's technology committee and recently authored a chapter titled "Automation of Ambulatory Care Pharmacy Operations" in *Building Core Competencies in Pharmacy Informatics* (Fox, Thrower, Felkey; American Pharmacists Association, 2010). Mr. Lockwood holds degrees from Dartmouth College, the University of California, Santa Barbara, and the University of Cambridge.

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.

Amie C. O'Donoghue, PhD is a social science analyst in the Division of Drug Marketing, Advertising, and Communications (DDMAC) in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA), where she conducts research on direct-to-consumer advertising and the communication of information to physicians and consumers. She also provides technical assistance on research and communication issues to DDMAC staff, CDER staff, and external groups and organizations. Before joining DDMAC, Dr. O'Donoghue taught psychology at St. Mary's College of Maryland. She received her doctorate in psychology from Washington University in St. Louis and her undergraduate degrees in psychology and studio art from Lafayette College.

Doris Peter, PhD is manager of the Consumer Reports Health Ratings Center. She has spent the past 10 years in medical publishing, translating complex medical and scientific evidence for both professionals and consumers. She currently serves as the principal investigator for Consumers Union's grant under the Consumer and Prescriber Education Grant Project (Consumer Reports Health Best Buy Drugs) that involves translating and disseminating comparative effectiveness research into actionable advice for consumers. Dr Peter has also lead projects that translate information about the safety, effectiveness and strength of evidence behind treatments for more than 180 conditions as well as in translating and presenting hospital quality data for consumers. Prior to joining Consumers Union, she was an editor and publisher at *The Medical Letter* and then North American editor for an international evidence-based medicine journal. Dr Peter is a neurobiologist by training, earning her PhD at UCLA, and she completed a postdoctoral fellowship in cellular biophysics at Rockefeller University. She was awarded individual NIH grants for both her PhD work and her postdoctoral fellowship.

N. Lee Rucker, MSPH has pharmaceutical policy expertise that spans several decades, across a variety of stakeholders. Ms. Rucker has served in public policy or senior advocacy roles for: physicians in multispecialty group practices (American Medical Group Association), the pharmaceutical industry (the former Ciba-Geigy Pharmaceuticals), pharmacists (American Pharmacists Association), and a medicine communication coalition (National Council on Patient Information and Education). Since 2004, this multidisciplinary perspective has hallmarked her role as senior strategic policy advisor at the AARP Public Policy Institute. Ms. Rucker's research focus includes drug safety, drug therapy management, benefit design in Medicare Part D, and ensuring value across the pharmaceutical marketplace. She is a member of the Medicare Model Guidelines Expert Panel (2010-2011), U.S. Pharmacopeia (USP), a role she first served in 2004 in preparation for implementing Medicare Part D. She also served on USP's inaugural Safe Medication Use Expert Committee (2000-2005). She is a board member of the Pharmacy Quality Alliance; and serves as vice chair, National Council on Patient Information and Education. Ms. Rucker is a graduate of The University of Michigan, Ann Arbor; and earned her MSPH at the School of Public Health, University of North Carolina, Chapel Hill.

William Shrank, MD, MSHS is an assistant professor of medicine at Harvard Medical School and an associate physician in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. His research is focused on understanding how cost-sharing requirements and formulary design impact communication about costs and adherence to chronic medications. His research interests also include evaluating quality in pharmacologic care, enhancing adherence to chronic medications, and improving prescription drug labels. He is the principal investigator of the CVS Caremark Harvard Partnership for Improving Medication Adherence, a multi-disciplinary research initiative to improve how patients take medication. He is also supported by a K-23 career development award from the National Heart, Lung, and Blood Institute of the National Institutes of Health to evaluate interventions to improve rational prescribing in cardiovascular disease, and is evaluating several randomized interventions to improve adherence to chronic medications. Dr. Shrank is a voting member on the FDA's Non-prescription Drug Advisory Committee. He serves on Committees on Prescription Drug Labeling for the American College of Physicians Foundation and for the USP. He attended Brown University, received his MD from Cornell University, and did his residency training in internal medicine at Georgetown University. He served on the clinical faculty in General Internal Medicine at University of Colorado Health Sciences Center before finishing a health services research fellowship at UCLA, Rand, and the West Los Angeles VA Hospital where he earned an MS in health services. He also practices general internal medicine at the Brigham and Women's Hospital.

J. Russell Teagarden, MA, DMH currently serves as vice president of clinical practices & therapeutics at Medco Health Solutions, Inc., where he is responsible for managing a group involved in various clinical development functions of the company. Prior to joining Medco in 1993, he worked for nearly a decade and a half as a clinical pharmacist in critical care and drug information. Dr. Teagarden currently serves as a member of the Board of Trustees of the Institute of Safe Medication Practices and on the Oversight Body of the American Medical Association Ethical Force Program, and he holds faculty appointments at several colleges of pharmacy. Dr. Teagarden received a Bachelor of Science degree in pharmacy from the University of Illinois College of Pharmacy, a Master of Arts degree in research methodology from Loyola University of Chicago, and a Doctor of Medical Humanities degree from Drew University. He completed a residency in hospital pharmacy at Northwestern University Medical Center in Chicago and received formal training in bioethics in residence at the Department of Bioethics of the National Institutes of Health.

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