

Incorporating Continuing Education into Single-Drug REMS: Exploring the Challenges and Opportunities

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Biographies



Gary J. Appio, PharmD, MBA, is the Head of US Safety Risk Management at Novartis Pharmaceuticals Corporation. He is responsible for strategic and tactical support of Novartis' risk management activities related to FDA required Risk Evaluation and Mitigation Strategies (REMS) and Global Risk Management Plan commitments. He provides expert opinion on risk management support for products in early development to assist in shaping risk management and risk communication strategies for patients and healthcare professionals. Before this role, Dr. Appio created the Medical Information and Communication contact center at Novartis, which provides medical information support to healthcare professionals on Novartis products across all therapeutic areas. Prior to Novartis, he worked 11 years at St. Francis Medical Center in Trenton, NJ in several clinical staff and leadership positions including Hospital Pharmacy Director. Dr. Appio earned his BS in Pharmacy from Rutgers University, PharmD from the University of Florida, and holds an MBA from the University of Massachusetts, Amherst.



Maureen Cahill, RN, has been an advanced practice nurse in adult and pediatric oncology for more than 35 years. In clinical roles as a nursing director and cancer center administrator, Maureen has had administrative accountability for other specialty APRNs. She joined NCSBN in the summer of 2011 to lead their Campaign for APRN Consensus, and assists Boards of Nursing in adoption of The Consensus Model. Maureen earned her Bachelor of Science in Nursing from the College of St. Teresa Winona and her Master's in Nursing from Boston University.



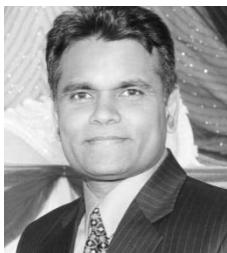
Kathy Chappell, PhD, has more than 25 years of experience including clinical practice as an emergency department and critical care nurse; hospital administration and system strategic planning; and quality management in support of professional nursing practice. She is responsible for accreditation of organizations providing continuing nursing and interprofessional education; and accreditation of programs including residencies and fellowships. Dr. Chappell also directs the Institute for Credentialing Research, analyzing outcomes related to credentialing. She holds a baccalaureate in nursing with distinction from the University of Virginia, a Master's of Science in advanced clinical nursing and a doctorate in nursing from George Mason University. Dr. Chappell is also a Distinguished Scholar & Fellow in the National Academies of Practice, recognized for her work in interprofessional education.



Paul Coplan, PhD, MBA, is Executive Director and head of the Risk Management and Epidemiology department at Purdue Pharma. In this role, he is responsible for therapeutic risk management activities at Purdue, implementing and evaluating Risk Management and Evaluation Systems (REMS) programs and Risk Management Plans, and for epidemiologic studies to assess safety and effectiveness of Purdue's products. He is also adjunct assistant professor in Epidemiology at the University of Pennsylvania School of Medicine. He has a Doctor of Science degree in Epidemiology from Harvard University, an MBA from Wharton Business School, a Master of Science in Public Health and Nutrition from the University of Massachusetts and a BS Honors in Biochemistry and Physiology from the University of Witwatersrand. He has worked on the successful approval of 8 pediatric and 1 adult vaccines and 9 drugs over the past 18 years in drug development research at Merck, Wyeth, Pfizer and a non-profit HIV prevention drug development organization. He has published over 60 peer-reviewed journal articles and has conducted studies in 15 countries. He is the co-chair of the Benefit-Risk Assessment Special Interest Group of the International Society of Pharmacoepidemiology, Chair of the 18-company collaborative Metrics Subteam for the Class REMS for Extended-Release and Long-Acting Opioid Analgesics, and chair of the 9-company Observational Studies Workgroup for studies of opioid analgesic safety required by the FDA.



Eric Davis, MD, is Director of Medical Services for Mylan Pharmaceuticals. He has been with Mylan for 13 years and during that time has worn many hats within company, providing medical expertise as requested. He is, or has been, involved with the Clinical Affairs, Medical Affairs, Medical Services, Product Development, and Product Safety and Risk Management Groups within the company. He has participated and overseen the development and operations of various RiskMAPS and currently oversees Mylan's participation in the development and operations of multiple shared REMS programs.



Kishore Gopu, MS, MBA, Director REMS Operations, is responsible for developing and managing both Risk Evaluation Mitigation Strategy (REMS) and Risk Management Programs for all US products for Teva Pharmaceuticals. He has over 8 years of experience with development, implementation and oversight of various single product and multi-sponsor risk management programs including observational studies, pregnancy registries, RiskMAPs and REMS programs. Currently, he is involved with industry's first single, shared REMS – iPLEDGE REMS since its inception along with other approved and pending, shared REMS programs including the class-wide Extended Release/Long Acting Opioid REMS. Kishore has been with Teva Pharmaceuticals since 2009 and with Barr pharmaceuticals prior to its acquisition by Teva Pharmaceuticals. Before joining Barr pharmaceuticals, he has had a long career in consulting for pharma and non-pharma companies, managing large programs.



Cyndi Grimes is the Director for Continuing Medical Education for Medscape and is responsible for overseeing the development and implementation of activities and day-to-day operations of the Medscape CME program. Ms. Grimes works with the CME team and internal departments to ensure compliance with ACCME/ANCC/ACPE guidelines and adherence to policies and procedures of Medscape. Prior to joining Medscape, Cyndi was Managing Director of The Chatham Institute, an accredited provider of CME/CE activities for physicians, nurses and

pharmacists. Cyndi has over 17 years' experience working in independent medical education with expertise in management, educational/instructional design, content development, metrics and evaluation, and program delivery. She is a member of the Alliance for Continuing Education in the Health Professions, having presented many breakout sessions at their annual meetings. Cyndi is a CCMEP and received her BA from Catholic University of America.



Anne Grupe currently serves as Director of the American Society of Clinical Oncology (ASCO)'s Continuing Professional Development unit and has been with the Society since 2000. Educationally, her graduate work focused on adult education, with a Master of Science in Education from Virginia Tech, specializing in Vocational and Technical Education. Her research focused on perceptions of educational success, for which she received an Outstanding Masters Research Award from Omicron Tau Theta. In a volunteer capacity, Ms. Grupe is a current member and has served as Co-Chair for the IACE/Medical Specialty Society Working Group with ACEHP, which was honored with a President's Award at the 2013 ACEHP Annual Conference. Ms. Grupe is also a Distinguished Member with the ACEHP and received the Rising Star Award in 2013. Additionally, Ms. Grupe has served as the Chair of the CPD Directors Component Group for the Council of Medical Specialty Societies, after serving consecutive terms as Secretary.



Simone Karp is a Co-Founder of CECity.com, Inc. and serves in the role of Chief Business Officer. She has over 29 years of healthcare industry experience with the last 19 years at CECity focused on quality assessment, measurement, improvement, continuing professional development, and healthcare consulting services. During her career, Ms. Karp has pioneered efforts to improve the quality of patient care through the development of proprietary cloud based registries and technology solutions that enable the alignment of quality and performance improvement, professionalism and value based payment. She lectures regularly on the topics of quality improvement, pay for value and healthcare education. Prior to founding CECity, Ms. Karp provided consulting services to the pharmaceutical and biotechnology industries as a principal of Integrated Healthcare Associates, Inc., Amgen and Lederle Laboratories where she worked with some of the country's leading healthcare organizations in a variety of roles. Ms. Karp is a pharmacist by profession and holds a BS degree in Pharmacy from the University of Pittsburgh School of Pharmacy.



Ann Karty, MD, FAAFP, has been the Medical Director in the Continuing Medical Education (CME) Division at the American Academy of Family Physicians (AAFP) since 2009. Dr. Karty has been an active member of the AAFP since 1989 and has represented the AAFP at the Food and Drug Administration (FDA), the Institute of Medicine (IOM), the Federation of State Medical Boards (FSMB), and the Council of Medical Specialty Societies (CMSS). Dr. Karty currently is co-chair of the Inter-Society Coordinating Committee (ISCC) of the National Human Genome Research Institute (NHGRI) at the National Institutes of Health (NIH) and is active in the Conjoint Committee for Continuing Education (CCCE), concentrating on collaborative efforts of Risk Evaluation Mitigation Strategies (REMS) processes. Prior to the AAFP, Dr. Karty was Associate Professor in the Department of Family Medicine at Kansas City University of Medicine and Biosciences College of Osteopathic Medicine (KCUMB) where she also was Associate Program Director of the KCUMB Family Medicine Residency. Dr. Karty is Board Certified in Family Medicine, an AAFP Fellow, and holds four state medical licenses. She received her medical degree from

the University of Missouri – Kansas City School of Medicine and is pursuing an MBA from the University of Kansas.



Linda Kitlinski recently retired from her position as Senior Director, Clinical Affairs for Endo Pharmaceuticals, and has focused the past 29 years of her career in the areas of Scientific Affairs, Independent Medical Education and Risk Evaluation & Mitigation Strategies. Since 2009, Ms. Kitlinski has been involved in the development and implementation of the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS), the first REMS to utilize accredited continuing education (CE) to fulfill a REMS training requirement. In her capacity as Chair/Co-Chair of the REMS Program Companies' (RPC) CE Sub-team, Ms. Kitlinski worked with the CE Accreditors/Providers/the Conjoint Committee on CE, the FDA, and the RPC to operationalize REMS CE in a manner that was fully compliant with both the standards for industry-supported CE and the ER/LA Opioid Analgesics REMS requirements. Integral to that effort was facilitation of communications among diverse groups of REMS education stakeholders and working with the CE Community to establish the processes and infrastructure needed for REMS CE data collection and reporting. Since retiring from Endo, Ms. Kitlinski has continued to focus on REMS education as a consultant to the RPC CE Sub-team and liaison to the Conjoint Committee on Continuing Education's REMS Workgroups.

Claudia Manzo, PharmD, serves as the Acting Director of the Office of Medication Error Prevention and Risk Management, Office of Surveillance and Epidemiology (OSE), FDA. Dr. Manzo has over 15 years of drug safety experience and in her current role she directs review staffs that advise and review Risk Evaluation and Mitigation Strategies (REMS), Proprietary Names, Human Factors Studies, and Medication Errors for drugs and biologic products regulated by CDER. She received her Doctor of Pharmacy degree from the University of Tennessee, after which she completed a residency in clinical pharmacy practice at the Regional Medical Center in Memphis and a fellowship in Nutrition Support at the Philadelphia College of Pharmacy and Science. Prior to joining FDA she was a clinical pharmacist at Walter Reed Army Medical Center and a pharmacy officer in the US Army.



Mark McClellan, MD, PhD, is a senior fellow and director of the Initiative on Value and Innovation in Health Care at the Brookings Institution. Within Brookings, his work focuses on promoting quality and value in patient centered health care. A doctor and economist by training, he also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan chairs the FDA's Reagan-Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and was an associate professor of economics and medicine at Stanford University.



Eric D. Peterson, EdM, FACEHP, CHCP, is Senior Director of Performance Improvement CME at the American Academy of Physician Assistants. Over a period of nearly 25 years he has had responsibility for interdisciplinary continuing education units accredited for a range of health-care professions including physicians, physician assistants, nurses, nurse practitioners, pharmacists, dietitians, laboratory medicine professionals, and dentists. He is a volunteer ACCME accreditation surveyor, a Fellow of the Alliance for Continuing Education in the Health Professions, and a Certified Healthcare CDP Professional. He serves on a the

Test Development Committee for the Commission on Certification of Healthcare CPD Professionals and was recently appointed to the Advisory Board for Interprofessional Continuing Education facilitated through the National Center for Interprofessional Practice at the University of Minnesota. He has published his work related to education assessment and practice-based learning and improvement in the peer-reviewed literature.



Kate Regnier, MA, MBA, is Executive Vice President of the Accreditation Council for Continuing Medical Education (ACCME) and has been with the ACCME since 1995. Ms. Regnier oversees the processes of Accreditation and Reaccreditation for national and international providers of continuing medical education (CME), the Recognition of the US-based State/Territory Medical Societies as accreditors within their states according to the Markers of Equivalency, and the Joint Accreditation of Providers of Interprofessional Continuing Medical Education with colleague accreditors, the Accreditation Council for Pharmacy Accreditation and the American Nurses Credentialing Center. Ms. Regnier is also responsible for the review of non-US accreditors for their Substantial Equivalency with the ACCME's system. As Chief

Operating Officer, Ms. Regnier oversees the education, communications, monitoring, and business functions of the ACCME. Ms. Regnier is also the primary staff liaison to the ACCME Board of Directors. Kate received a Bachelor of Arts Degree in English from the College of the Holy Cross (1986), a Master's Degree in English from Northwestern University (1990), and a Master's Degree in Business Administration from Loyola University of Chicago (1995). Kate is married to John Regnier, a stay-at-home dad and cartoonist, and they are the proud, but often tired, parents of four children – Emma, Noah, Brennan, and Roan.

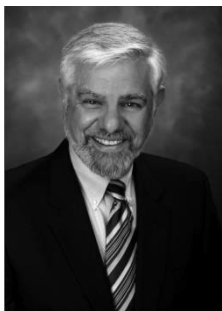


Rachel Sobel, DrPH, is a Senior Director and the Global Innovative Pharmaceuticals (GIP - Inflammation/Immunology and Rare Diseases/Women's Health/Other) Group Lead for Epidemiology at Pfizer, Inc. in New York, NY. Since joining Pfizer in 2001, Dr Sobel's responsibilities have included general epidemiology support and contributing to the design and implementation of risk management strategies for medicines in several therapeutic areas. She negotiated, designed, and led the implementation of

various epidemiologic commitments with the US FDA and EMA, and oversees a team of epidemiologists. Before coming to industry, Dr. Sobel was an Autoimmune Disease Registry and Repository Coordinator at the Hospital for Special Surgery/Weill Cornell Medical Center in New York. She has published and presented numerous articles and abstracts on epidemiology and risk management, and co-authored a chapter in Strom's Textbook of Pharmacoepidemiology. Rachel holds her degrees from Columbia University: a DrPH and MPH from the Mailman School of Public Health and a BA from Barnard College.



Theresa (Terry) Toigo, RPh, MBA, Associate Director for Drug Safety Operations, Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). She is responsible for the creation and oversight of CDER processes for management of cross-Office and cross-Center safety projects, including REMS. Immediately prior to returning to CDER in October 2010, Ms. Toigo served as Director, Office of Special Health Issues (OSHI) for 15 years, working with patients, their advocates, and health professionals to encourage and support their active participation in FDA regulatory decision-making. Ms. Toigo joined FDA in 1984, working as a Consumer Safety Officer in the Division of Surgical Dental Drug Products. She held various FDA positions in CDER, the Center for Biologics Evaluation and Research, and the Commissioner's office. Ms. Toigo received her pharmacy (BS) and business (MBA) degrees from Rutgers University. She completed a pharmacy residency at the USPHS Hospital in Staten Island, NY.



Peter H. Vlases, PharmD, DSc (Hon.), BCPS, FCCP, is the Executive Director of the Accreditation Council for Pharmacy Education. Dr. Vlases received his Bachelor of Science and Doctor of Pharmacy degrees from the Philadelphia College of Pharmacy and Science (PCPS) and served a residency in hospital pharmacy at Thomas Jefferson University Hospital in Philadelphia, PA. His professional experience includes service as a clinical faculty member at The Ohio State University College of Pharmacy and PCPS. He served as Head of the Clinical Research Unit and Research Associate Professor of Medicine and Pharmacology, Jefferson Medical College, in Philadelphia, and then as Director, Clinical Research & Investigator Services, University HealthSystem Consortium, Oak Brook, IL. Dr. Vlases is a Founding Member, Fellow and Past-President of the American College of Clinical Pharmacy (ACCP). His awards include the Russell R. Miller Award from ACCP in recognition of his sustained and outstanding contributions to the biomedical literature, the ACCP Service Award, the PCPS Alumnus of the Year Award, and an Honorary Doctor of Science degree from Mercer University, Atlanta, GA. He serves on the National Advisory Council for the National Center for Interprofessional Practice and Education. ACPE is the U.S. agency for the accreditation of both professional degree programs in pharmacy and providers of continuing pharmacy education. ACPE, the Accreditation Council for Continuing Medical Education (ACCME) and the American Nurses Credentialing Center (ANCC) jointly accredit CE providers committed to interprofessional team CE.



Julie Webb, RPh, has extensive experience in pharmacy practice, association management, and educational meeting planning. As Vice President of the Office of Professional Development at the American Society of Health-System Pharmacists (ASHP), she oversees ASHP educational enterprise including the ASHP Midyear Clinical Meeting and ASHP's Summer Meetings. In addition she is responsible for the exploration and implementation of products and services to support ASHP's overall mission as a membership association. She oversees ASHP Advantage branded educational offerings, ASHP's Certification product line development, and ASHP's eLearning platform. Prior to assuming the role of Vice President, Julie served as the Senior Managing Director for Resources Development and Senior Director of Business Development for ASHP Advantage where she was responsible for program development, promotion, and marketing activities. Julie has also served as the Director of the ASHP Section of Home Care Practitioners, a membership component group of the American Society of Health-System Pharmacists. Julie's pharmacy practice experience includes home, acute care, and veterinary medicine. She has also served as a consultant to the home infusion industry. An alumnus of the School of Pharmacy at the University of North Carolina at

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Chapel Hill, Julie completed an ASHP-accredited residency in hospital pharmacy at the Medical University of South Carolina in Charleston.



Julie L. White, MS, CHCP, is the Administrative Director, Continuing Medical Education at Boston University School of Medicine, serving in this capacity since 1995. Julie received her B.A. from Bennington College in French Literature and her M.S. in Management from Antioch New England Graduate School. Boston University School of Medicine Continuing Medical Education/Continuing Nursing Education earned and has maintained

Accreditation with Commendation from the ACCME since 2006 and received accreditation with Distinction from the ANCC in 2012. The BUSM CME/CNE team was awarded the first grant by the REMS Program Companies to provide the FDA mandated education which includes comprehensive prescriber education in safe use of opioid medications. Julie's team was recognized in 2008 and again in 2011 with the Alliance for Continuing Education in the Health Professions' Award for Outstanding Industry-Supported Certified CME Activity. BUSM CME/CNE has a national reputation for producing high quality performance improvement activities. Julie has given numerous presentations at the Alliance and other venues including talks on small group learning, the interface of quality improvement and continuing medical education, and facilitating the patient voice in CE. Julie writes for and currently serves on the Alliance's Almanac Editorial Board.