AMCP Academy of Managed Care Pharmacy®

FDAMA 114:

Improving the Exchange of Pharmacoeconomic Data

An AMCP Partnership Forum

March 1–2, 2016 | Washington, DC

Program

— Hosted by the Academy of Managed Care Pharmacy in partnership with —

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AMCP Academy of Managed Care Pharmacy®

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WELCOME

Welcome to the Academy of Managed Care Pharmacy (AMCP) Partnership Forum, *FDAMA 114: Improving the Exchange of Pharmacoeconomic Data.* We are delighted that you are here to share your ideas and expertise in addressing a major regulatory gap affecting the delivery of care.

This event is particularly timely as rising pharmaceutical costs come under intense scrutiny, and stakeholders across the health care spectrum seek new ways to ensure medications remain both accessible and affordable. It also comes as the Food and Drug Administration (FDA) recently announced its plans to issue guidance on FDAMA Section 114 later this calendar year.

FDAMA Section 114 established an evidentiary standard by which pharmaceutical companies may disseminate health care economic data on products to formulary committees or similar entities. The FDA, however, has never issued regulations or guidance on this provision, nor has it made any formal determinations on information disseminated under the standard. As a result, pharmaceutical companies have been hesitant to provide economic information due to compliance concerns, and formulary management teams have had to work with incomplete information.

Over the next two days, you will join representatives from a wide range of organizations, including the pharmaceutical industry, the managed care industry, academia, health care providers and pharmacoeconomic experts, to develop recommendations for FDA regulations or guidance that would clarify FDAMA 114. You also will consider whether FDAMA 114, or other areas of existing laws and regulations, should be expanded to provide pharmacoeconomic information to additional entities, including payers, health care providers, patient advocacy groups and organizations that develop value frameworks.

As a professional society of 8,000 pharmacists and other practitioners working in managed care settings, the Academy touches the lives of 200 million Americans. AMCP is a leader in developing principles and practices that improve access to affordable and effective medications. Through events such as this Forum, we are committed to tackling issues that will help all of us advance health care in America.

I would like to thank AbbVie, Amgen, Boehringer Ingelheim, Merck, National Pharmaceutical Council (NPC), Pfizer, Pharmaceutical Research and Manufacturers of America (PhRMA), Precision for Value, Takeda, and Xcenda, whose generous support has made this event possible.

Thank you for being a part of this important discussion.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer
Academy of Managed Care Pharmacy

AGENDA

All events are in the Shaw/LeDroit Park Room, Meeting Level 3 with the exception of the Networking Reception which will be in the Gallaudet University Room, Meeting Level 1.

TUESDAY, MARCH 1ST	
8:30am – 9:00am	**BREAKFAST**
9:00am – 9:30am	**WELCOME & INTRODUCTIONS**
	▶ **Susan A. Cantrell, RPh, CAE** *Chief Executive Officer* Academy of Managed Care Pharmacy ▶ **Mary Jo Carden, RPh, JD** *Vice President of Government & Pharmacy Affairs* Academy of Managed Care Pharmacy ▶ **Susan Dentzer** *Senior Policy Adviser* Robert Wood Johnson Foundation
9:30am – 10:15am	**PRESENTATION – Past, Present, and Future of FDAMA 114**
	▶ **Peter Neumann, ScD** *Director, Center for the Evaluation of Value and Risk in Health* Tufts Medical Center
10:15am – 10:30am	**BREAK**
10:30am – 11:15am	**PANEL DISCUSSION – Current Challenges & Barriers to FDAMA 114**
	▶ **Laurie Burke, RPh, MPH** *Founder* Lora Group LLC ▶ **Lisa Cashman, PharmD** *Director Clinical Formulary* MedImpact Healthcare Solutions ▶ **Gregory Daniel, MPH, PhD** *Deputy Director* Duke-Margolis Center for Health Policy ▶ **Dan Danielson, MS, RPh** *Pharmacy Manager, Clinical Services* Premera Blue Cross ▶ **Jeffrey K. Francer, JD, MPP** *Vice President and Senior Counsel* Pharmaceutical Research and Manufacturers of America ▶ **Jay McKnight PharmD, BCPS** *Director Clinical Strategies and Formulary Management* Humana
11:15am – 12:00pm	**PANEL DISCUSSION – What is Pharmacoeconomic Information Under FDAMA 114?**
	▶ **Christopher Michael Blanchette, PhD, MBA** *Vice President, Health Economics & Evidence Strategy* Precision for Value ▶ **Jennifer Graff, PharmD** *Vice President* National Pharmaceutical Council ▶ **Joel W. Hay, PhD, MS, MPhil** *Professor* University of Southern California ▶ **Daniel C. Malone, RPh, PhD, FAMCP** *Professor* University of Arizona
12:00pm – 1:00pm	**LUNCH**

1:00pm – 1:45pm	**DISCUSSION 1 – How should the terms "competent and reliable scientific evidence" and "formulary committee or other similar entity" be defined?**
1:45pm – 2:30pm	**DISCUSSION 1 – Report Out**
2:30pm – 3:15pm	**DISCUSSION 2 – How should the terms "health care economic information" and "directly relates to an indication approved" be defined?**
3:15pm – 3:30pm	**BREAK**
3:30pm – 4:15pm	**DISCUSSION 2 – Report Out**
4:15pm – 5:00pm	**DISCUSSION 3 – What is the preferred format and process by which managed care pharmacy should receive pharmacoeconomic information from pharmaceutical manufacturers?**
5:00pm – 5:45pm	**DISCUSSION 3 – Report Out**
5:45pm – 6:00pm	**AGREEMENT ON CONSENSUS RECOMMENDATIONS FOR DAY 1 & WRAP-UP**
6:00pm – 7:00pm	**NETWORKING RECEPTION**
WEDNESDAY, MARCH 2ND	
8:00am – 8:30am	**BREAKFAST**
8:30am – 9:00am	**WELCOME & SUMMARY OF DAY 1**
9:00am – 9:45am	**PANEL DISCUSSION – The Value of Expanding FDAMA 114**
	▶ **J. Russell Hoverman, MD, PhD** *Vice President of Quality Programs* Texas Oncology *Medical Director* The US Oncology Network ▶ **James K. Marttila, PharmD, MBA** *Director, Pharmaceutical Contracting and Formulary Management* Mayo Clinic ▶ **Joan McClure, MS** *Senior Vice President of Clinical Information and Publications* National Comprehensive Cancer Network ▶ **Eleanor M. Perfetto, PhD, MS** *Professor, Pharmaceutical Health Services Research* University of Maryland School of Pharmacy *Senior Vice President, Strategic Initiatives* National Health Council
9:45am – 10:00am	**BREAK**
10:00am – 10:45am	**DISCUSSION 4 – Should FDAMA 114, or other areas of existing laws and regulations, be expanded to provide pharmacoeconomic information to additional entities (such as payers, healthcare providers, patient advocacy groups, organizations that develop value frameworks, pharmacoeconomic organizations, and others) and what value would be gained by doing so?**
10:45am – 11:30am	**DISCUSSION 4 – Report Out**
11:30am – 12:00pm	**AGREEMENT ON CONSENSUS RECOMMENDATIONS FOR DAY 2**
12:00pm – 12:30pm	**NEXT STEPS & CLOSING REMARKS**
	▶ **Susan A. Cantrell, RPh, CAE** *Chief Executive Officer* Academy of Managed Care Pharmacy ▶ **Soumi Saha, PharmD, JD** *Assistant Director of Pharmacy & Regulatory Affairs* Academy of Managed Care Pharmacy
12:30pm – 1:00pm	**LUNCH**

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MODERATOR

Susan Dentzer

Senior Policy Adviser

Robert Wood Johnson Foundation

Susan Dentzer is Senior Policy Adviser at the Robert Wood Johnson Foundation, the nation's largest philanthropy focused on health and health care in the United States. In this role, she works closely with foundation leaders to carry out the organizational mission of improving the health and health care of all Americans. One of the nation's most respected health and health policy thought leaders and journalists, she is also an on-air analyst on health issues on the PBS NewsHour. From 2008 to April 2013, she was the editor-in-chief of *Health Affairs,* the nation's leading peer-reviewed journal of health policy, and led the transformation of that journal from a bimonthly academic publication into a highly topical publication and web site with more than 120 million page views annually. From 1998 to 2008, she led the PBS NewsHour's health unit as on-air health correspondent, and was the recipient of numerous honors and awards.

Dentzer is an elected member of the Institute of Medicine and the Council on Foreign Relations. Ms. Dentzer graduated from Dartmouth, is a trustee emerita of the college, and chaired the Dartmouth Board of Trustees from 2001 to 2004. She currently serves as a member of the Board of Overseers of Dartmouth Medical School and is an Overseer of the International Rescue Committee, a leading humanitarian organization. She is also on the board of directors of Research!America, an alliance working to make research to improve health a higher priority, and is a public member of the Board of Directors of the American Board of Medical Specialties. A widely admired communicator, Dentzer is a frequent speaker before a wide variety of health care and other groups, and a frequent commentator on such National Public Radio shows as the Diane Rehm Show and This American Life. She and her husband have three children and live in the Washington, DC area.

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FORUM PARTICIPANTS

As of February 10, 2016

Yanjun (Carol) Bao, PhD

Senior Director, HCV, Health Economics and Outcomes Research

AbbVie

Yanjun (Carol) Bao joined Abbott/AbbVie in 2008 as Manager, Health Economics and Outcomes Research (HEOR). She has since led HEOR global support for HUMIRA across various indications in immunology before assuming her current role as Senior Director for HEOR HCV global lead in July 2015. Prior to joining AbbVie, she was Senior Pharmacoeconomist at Abt Associates Inc in Boston, MA. Carol attended University of Illinois at Chicago and received a Ph.D. in Economics. She has a Bachelor's degree in Economics from Fudan University, China.

Christopher Michael Blanchette, PhD, MBA

Vice President, Health Economics & Evidence Strategy

Precision for Value

Christopher M. Blanchette, PhD, MBA, is an epidemiologist and health services researcher with more than a decade of experience in pharmacoeconomics and pharmacoepidemiology in the pharmaceutical industry, consulting and academia. He currently is the Director of the Data Science Initiative and an Associate Professor of Public Health Sciences with the College of Health & Human Services at the University of North Carolina at Charlotte, as well as Vice President, Health Economics and Evidence Strategy with Precision for Value. He has authored more than 60 papers in clinical and economic journals and presented over 100 studies at national conferences.

Laurie Burke, RPh, MPH

Founder

Lora Group LLC

Laurie Burke, RPh, MPH, is Founder of LORA Group, LLC, an advisor of global medical product development organizations regarding best practices in outcomes research, regulatory strategy, product labeling and advertising. Ms. Burke is a retired 29-year career U.S. Public Health Service officer assigned to the FDA's Center for Drug Evaluation and Research. Ms. Burke led the FDA response to FDAMA section 114 at the time of its original implementation in 1997. She was lead author of the FDA Patient-Reported Outcomes Guidance published as draft in 2006 and final in 2009. She received a Master of Public Health in Epidemiology from the Uniformed Services University of the Health Sciences, and a bachelor of science in pharmacy from the University of Kansas.

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Lisa Cashman, PharmD

Director Clinical Formulary

MedImpact Healthcare Solutions

Lisa Cashman received her B.A. from the University of California, San Diego, and a PharmD degree from the University of California, San Francisco. Dr. Cashman serves as Director of Clinical Services at MedImpact Healthcare Systems, where she has responsibility for formulary management, strategy and execution (Medicare Part D, Commercial, Medicaid, Health Insurance Exchange), Co-Chairman of the MedImpact National Pharmacy and Therapeutics Committee, Specialty Drug management, Drug Information and Drug Data. In addition to pharmacy, she co-founded a non-profit biomedical research institute specializing in pre-clinical drug development addressing diseases of the central nervous system. She served as CEO at the Human BioMolecular Research Institute for six years.

Elizabeth J. Cobbs, PhD

Executive Director, Center for Observational & Real World Evidence

Merck & Co., Inc.

Elizabeth J. Cobbs currently serves as Head, Medical Policy & Quality Research, within Merck's Center for Observational and Real World Evidence (CORE). In this capacity, Liz is responsible for the strategic development, translation and dissemination of data that will enhance decision-making in public policy arenas. Liz has been working for Merck for 15 years in global positions in both Policy and Access. She led MSD's Health Policy & Access efforts in Japan from 2005-2011 where she managed the Company's relationships with the Ministry of Health, Labour & Welfare. In 2011, Elizabeth took up a role in Europe as MSD's Regional Market Access Lead. In 2014, Liz returned to the U.S., working from Merck's Washington, D.C., office.

Gregory Daniel, MPH, PhD

Deputy Director

Duke-Margolis Center for Health Policy

Dr. Gregory Daniel is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio. Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution, and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc). Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes from the University of Arizona, as well as an MPH, MS, and BS in Pharmacy, all from The Ohio State University.

FORUM PARTICIPANTS

As of February 10, 2016

Dan Danielson, MS, RPh

Pharmacy Manager, Clinical Services

Premera Blue Cross

Dan Danielson received his Bachelors of Pharmacy degree from Oregon State University in 1994 and a Masters in Pharmacoeconomics and Health Policy Analysis from the University of North Carolina-Chapel Hill in 2002. Dan is a member of the pharmacy management team at Premera Blue Cross, a large Blues plan in Washington State, Oregon and Alaska with over 2 million members. He's held administrative positions for Kaiser Permanente-Colorado and the former Medco Health Solutions. At Premera, his primary responsibilities are the development and expansion of the Premera's Value-Based Benefits, support for the Value Assessment Committee, and management of Premera's Pharmacy MarketWatch Program, a strategic drug management and business competitive intelligence program.

Jeffrey K. Francer, JD, MPP

Vice President and Senior Counsel

Pharmaceutical Research and Manufacturers of America

Jeff Francer is Vice President and Senior Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA) and serves as principal counsel to the association on issues relating to the research, development, and regulation of medicines. Mr. Francer manages PhRMA's legal advocacy before the FDA and other global regulators. He served as Associate Chief Counsel of the FDA from 2003-2005. Immediately prior to joining PhRMA, Mr. Francer served as Associate General Counsel, U.S. Compliance Officer, and Chief Privacy Officer of Biogen Idec, Inc. Mr. Francer received his A.B. in Public Policy and Economics from Brown University, his M.P.P. from Harvard University, and his J.D. from the University of Virginia.

Jennifer Graff, PharmD

Vice President

National Pharmaceutical Council

Jennifer Graff, PharmD, is the National Pharmaceutical Council's (NPC) vice president of comparative effectiveness research (CER). Dr. Graff works to advance evidence-based medicine through policy research initiatives assessing the methods, application, and communication of CER. Prior to joining NPC, Dr. Graff led strategic health economic and outcomes research activities at MedImmune and Pfizer Pharmaceuticals. She has authored over 15 peer-reviewed articles and presents frequently on policy issues affecting the biopharmaceutical industry. Dr. Graff holds a Doctorate of Pharmacy from the University of Nebraska Medical Center, and completed a Health Outcomes and Pharmacoeconomics fellowship at the University of Michigan.

Joel W. Hay, PhD, MS, MPhil

Professor

University of Southern California

Joel Hay is Professor and Founding Chair in the Department of Pharmaceutical and Health Economics and a Professor in the Leonard Schaeffer Center for Health Policy and Economics, with a joint appointment in the Department of Economics at the University of Southern California. He is a Health Economics Research Scholar at the UCLA Center for Vaccine Research. He is a founding member and Executive Board member of the American Society for Health Economics (ASHEcon) and of the International Society for Pharmaceutical Economics and Outcomes Research (ISPOR), and founding Editor-in-Chief of ISPOR's journal Value in Health.

J. Russell Hoverman, MD, PhD

Vice President Quality Programs

Texas Oncology

Medical Director

The US Oncology Network

J. Russell Hoverman, MD, PhD, earned a medical degree at Duke University. His postdoctoral training included a residency (including service as Chief Resident) in internal medicine at Baylor Affiliated hospitals in Houston, Texas, and a fellowship in hematology and oncology at Duke and Baylor. Dr. Hoverman also received a PhD in Philosophy from the University of Texas in Austin. Dr. Hoverman is currently Vice President for Quality Programs for Texas Oncology and Medical Director of Innovent Oncology in The US Oncology Network. Much of his activity now involves development of delivery models for value-based oncology care with recent publications on pathways, palliative care, medical oncology management and the Choosing Wisely campaign.

Jay Jackson, PharmD, MPH

Vice President, Global Health Economics & Outcomes Research

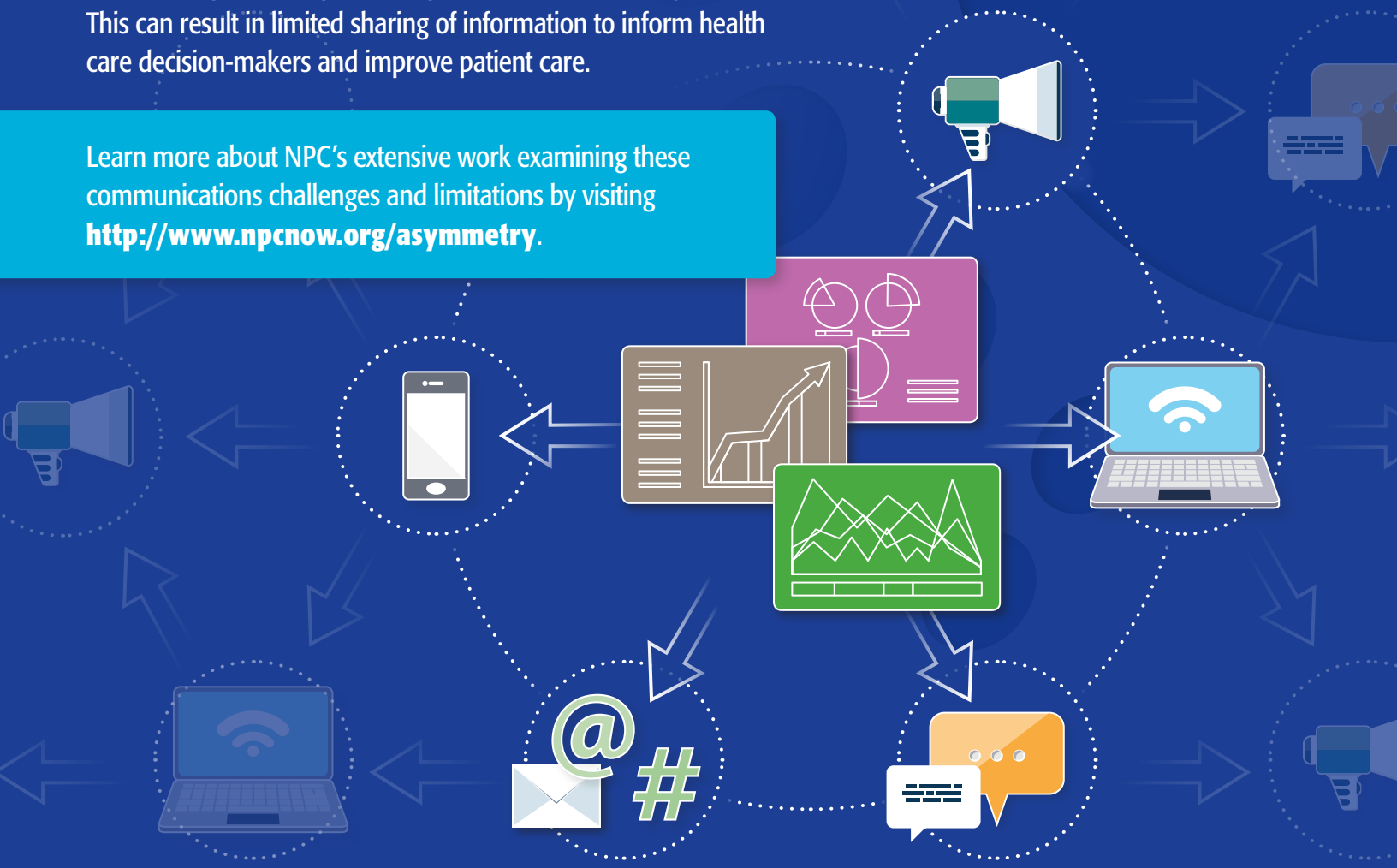
Xcenda

Jay Jackson, PharmD, MPH, is a Vice President at Xcenda and leads the Global Health Economics & Outcomes Research consulting practice. During his tenure at Xcenda, Dr. Jackson has partnered with manufacturers to design, develop and implement well over 300 health economic and outcomes research studies. His contributions also have been instrumental to the development of numerous interactive customer tools and market access strategies. Dr. Jackson received his PharmD from the Mercer University Southern School of Pharmacy. He received a Masters of Public Health in Epidemiology from the University of South Florida College of Public Health. Dr. Jackson currently serves as adjunct faculty for University of South Florida College of Public Health.

Who Can Say What, and When?

The National Pharmaceutical Council believes that the use of high-quality, real-world evidence can provide meaningful information for health care decision-making and should be broadly communicated by all stakeholders. However, lack of clarity in current laws and regulations makes sharing information with health plans and providers problematic for industry. This can result in limited sharing of information to inform health care decision-makers and improve patient care.

Learn more about NPC's extensive work examining these communications challenges and limitations by visiting **http://www.npcnow.org/asymmetry**.



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FORUM PARTICIPANTS

As of February 10, 2016

Sean Karbowicz, PharmD

Director Policy and Clinical Business Development

OmedaRx

Sean Karbowicz is Director of Innovation and Policy for OmedaRx. In this role, Sean develops projects and programs to promote safe, cost-effective use of medications. He is a member of AMCP and serves on the public policy committee. Sean is one of the original architects of the OmedaRx medication-technology assessment process. He is passionate about advancing best practices in evidence-based medicine, technology, and public policy to facilitate economically sustainable medication utilization. Sean earned a Bachelor of Pharmacy degree from the University of Connecticut, and a Doctor of Pharmacy degree from Oregon Health Sciences University. He lives in Portland, Oregon.

Jeffrey Larson, RPh, MS, MBA

Clinical Director

CVSHealth

As Clinical Director at CVS Caremark, Jeff Larson supervises a team responsible for the clinical programs and clinical management services provided to CVS Caremark clients in the Health Plan market segment. He supports internal departmental interfaces with the Drug List Review Committee, Formulary Review Committee and the National P&T Committee process. Mr. Larson has clinical management experience with multiple managed care organizations of all sizes including managed Medicaid, private label and commercial health plans. Mr. Larson earned his Bachelor of Science degree in Pharmacy from North Dakota State University, his Master of Science degree in Hospital Pharmacy from the University of Minnesota, and an MBA from the University of St. Thomas.

Daniel C. Malone, RPh, PhD, FAMCP

Professor

University of Arizona

Daniel C. Malone, RPh, PhD, FAMCP, is a Professor of Pharmacy at the University of Arizona College of Pharmacy, with cross appointment in the Mel and Enid Zuckerman College of Public Health at the University of Arizona. Dr. Malone leads the Comparative Effectiveness Research Group at the University of Arizona. He was the Director of the Pharmaceutical Outcomes research core of the Arizona Center for Education and Research on Therapeutics (AzCERT) and is on the Board of Directors for Credible Meds. He is currently President of the International Society for Pharmacoeconomics and Outcomes Research. Dr. Malone has over 120 peer-review research publications and has obtained over $15 million in extramural funds for his research programs.

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As of February 10, 2016

James K. Marttila, PharmD, MBA

Director, Pharmaceutical Contracting and Formulary Management

Mayo Clinic

Dr. James Marttila serves as the pharmacy director for formulary and contract management for Mayo Clinic, a position he has held for 11 years. In the previous 29 years at Mayo Clinic, he has served in a number of roles including outpatient pharmacy director. He received his bachelor's degree and PharmD. from the University of Minnesota, College of Pharmacy. Dr. Marttila taught for 15 years at the University before taking a job to start up all outpatient pharmacies at Mayo Clinic. He also was a co-owner of a small pharmacy startup that landed a contract to fill managed care prescriptions for a clinic site owned by a predecessor corporation to what is now known as HealthPartners.

Craig Mattson, MS, MBA, RPh

Senior Director, Formulary Development

Prime Therapeutics

Craig Mattson, MS, MBA, RPh, serves as Senior Director of Formulary Development at Prime Therapeutics. He leads the clinical evaluation of all new drugs, including specialty drugs and medications covered under the medical benefit, and oversees the critical positioning of all drugs within each therapeutic class. Craig's leadership provides the clinical vision, strategy, and oversight for Prime's clinical management of drug therapy and utilization. His responsibilities include overseeing the Prime National P&T Committee and the drug pipeline reporting. Craig holds a BS in pharmacy from the University of Minnesota, a MS in hospital/clinical pharmacy from the University of Iowa, and a MBA from the University of St. Thomas in St. Paul, Minnesota.

Joan McClure, MS

Senior Vice President of Clinical Information and Publications

National Comprehensive Cancer Network

Joan S. McClure, MS, is Senior Vice President of Clinical Information and Publications for the National Comprehensive Cancer Network (NCCN). Ms. McClure's group develops the NCCN Clinical Practice Guidelines in Oncology, associated NCCN Guidelines for Patients®, the NCCN Drugs & Biologics Compendium(NCCN Compendium®), NCCN Chemotherapy Orders Templates (NCCN Templates®), the NCCN Biomarkers Compendium™, and the Journal of the National Comprehensive Cancer Network. Ms. McClure previously managed national oncology information programs on contracts with the U.S. National Cancer Institute, and supported the FDA in identifying and developing standards for medical and toxicology data used for regulatory submissions in the U.S., Europe, and Japan. She earned a MS degree from the University of Maryland, College Park.

Jay McKnight, PharmD, BCPS

Director Clinical Strategies and Formulary Management

Humana

Jay McKnight, PharmD, BCPS, is Director, Pharmacy Clinical Strategies at Humana Pharmacy Solutions. In this position, Jay leads Humana's Pharmacy Clinical Strategy and Formulary/Policy Management teams. His responsibilities include improving member outcomes and quality of life, while reducing the cost of health care. In addition he leads Humana's: pharmacy & therapeutics processes; formulary strategy and management processes; drug policies and management processes; pharmacy clinical trend management strategies; and pharmacy clinical and quality programs. A Board Certified Pharmacotherapy Specialist, Jay received both his PharmD from University of Kentucky and a Bachelors of Business Administration from the University of Kentucky, with honors in finance and management.

David S. Memel, MD, MS, MBA

Vice President, Health Economics & Outcomes Research

Boehringer Ingelheim Pharmaceuticals, Inc.

Dr. David Memel, MD, MS, MBA, is the Vice-President of U.S. Health Economics and Outcomes Research (HEOR) and a key member of the U.S. Market Access Leadership Team for Boehringer Ingelheim Pharmaceuticals (BI). Leading the evolution and expansion of HEOR's capabilities, services and customer engagement model, Dr. Memel has enhanced BI's ability to demonstrate the value of, increase patient access to and drive appropriate use of BI's medicines. Dr. Memel was the architect of BI's strategy for innovative payer and healthcare delivery system and serves as a leader in BI's global integration of real world evidence into development and commercialization.

Philip Naughten, PharmD

Sr. Director U.S. Research

Takeda Pharmaceuticals U.S.A.

Phil Naughten, Pharm D, is Senior Director of Field Medical in the medical affairs department of Takeda Pharmaceuticals USA. Currently his responsibilities include the oversight of field medical teams, including their contribution to the therapeutic strategies across Takeda's portfolio. Prior to his current role he was responsible for Takeda's Research functions with the US Medical Affairs department, which included the Health Economic and Outcomes, phase IV, and granted research programs. Along with his research responsibilities he contributed to Takeda's movement towards performance based contracting. Prior to these roles he was responsible for oversight of the US medical affairs operations. Prior to Takeda Phil worked at AstraZeneca and as a Pharmacist.

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Peter Neumann, ScD

Director, Center for the Evaluation of Value and Risk in Health

Tufts Medical Center

Peter J. Neumann, Sc.D., is Director of the Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, and Professor of Medicine at Tufts University School of Medicine. Prior to joining Tufts, he was on the faculty of the Harvard School of Public Health. He is the founder and director of the Cost-Effectiveness Registry, a comprehensive database of cost-effectiveness analyses in health care. He is the author or co-author of over 200 papers in the medical literature, and the author of Using Cost-Effectiveness Analysis to Improve Health Care (Oxford University Press, 2005). He has served on many advisory boards, including for the Congressional Budget Office and Robert Wood Johnson Foundation.

Eleanor M. Perfetto, PhD, MS

Professor, Pharmaceutical Health Services Research

University of Maryland School of Pharmacy

Senior Vice President, Strategic Initiatives

National Health Council

Dr. Eleanor M. Perfetto was named Senior Vice President of Strategic Initiatives for the National Health Council (NHC) in July of 2015, and holds a part-time faculty appointment at the University of Maryland, Baltimore School of Pharmacy where she is Professor of Pharmaceutical Health Service Research. Her research and policy work primarily focus on patient engagement in comparative effectiveness and patient centered-outcomes research, medical product development; patient-reported outcome selection and development; and health care quality. Dr. Perfetto holds BS and MS degrees in pharmacy from the University of Rhode Island, and a PhD from the University of North Carolina School of Public Health with concentrations in health policy and epidemiology.

Laurie Wesolowicz, PharmD

Director II, Pharmacy Services Clinical

Blue Cross Blue Shield of Michigan

Laurie Wesolowicz is Director II of Pharmacy Services Clinical at Blue Cross Blue Shield of Michigan. She's been an adjunct clinical assistant professor at the University of Michigan since 1995. Her clinical expertise includes formulary development, specialty pharmacy initiatives, physician and pharmacist pay-for-performance incentives, medication safety and clinical utilization management operations, including pharmacy-related fraud and abuse. Laurie also serves as chair on the Blue Cross P&T, Specialty Drug and Controlled Substances committees. She received her Doctor of Pharmacy degree from the University of Michigan and completed an accredited residency program at Hamot Medical Center in Erie, Pa.

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As of February 10, 2016

Rhys Williams, MSc, DSc

Executive Director, Global Health Economics
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As Chief Risk Management Officer of Leavitt Partners, Susan Winckler, R.Ph., Esq., advises corporate executives on policy and business matters, such as Medicare/Medicaid and FDA practices. As CEO of the Food & Drug Law Institute from 2009 to 2014, she provided stakeholders with a neutral forum for addressing domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad stakeholders. As APhA Vice President Policy/Communications and Staff Counsel, Ms. Winckler served as the association's lead spokesperson. She earned a B.S. from the University of Iowa College of Pharmacy and her J.D. magna cum laude from Georgetown University Law Center.

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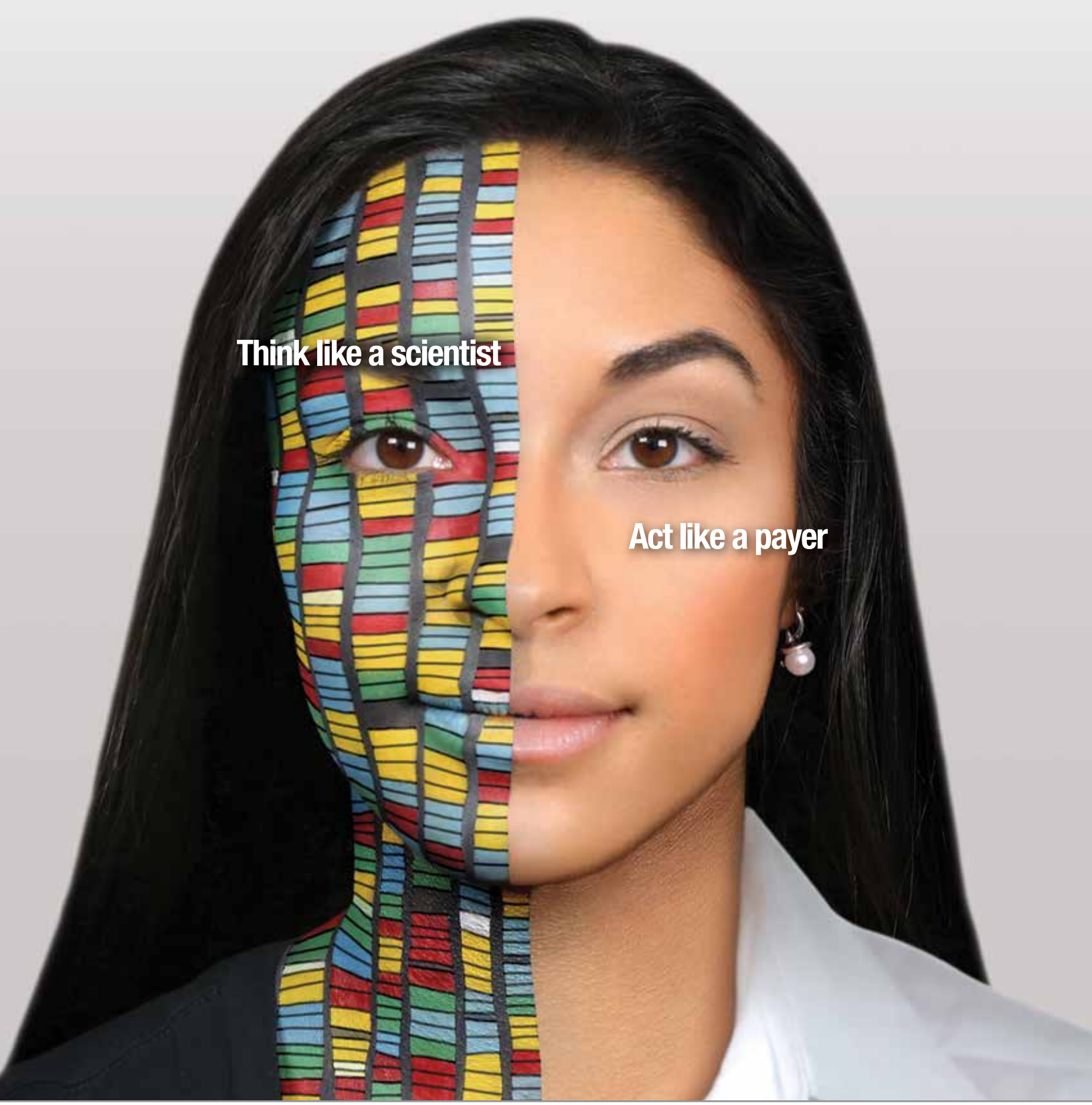

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To our distinguished participants and guests.

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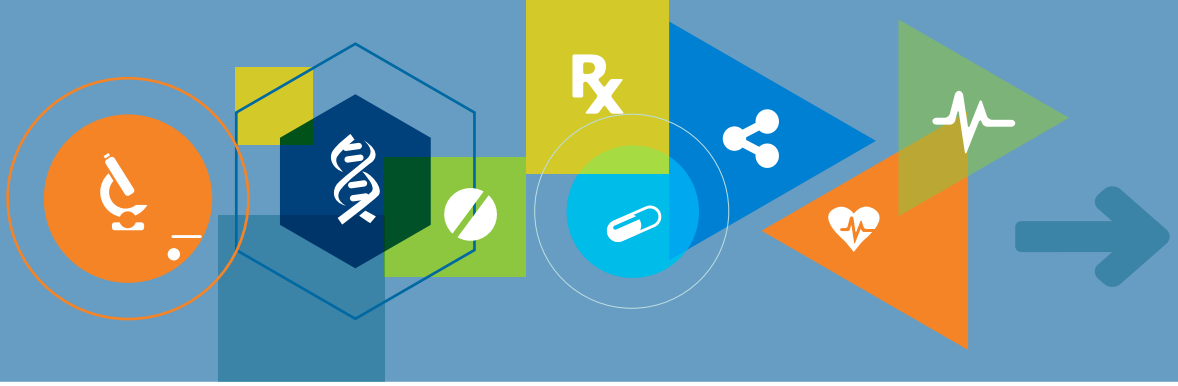

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