



# Enabling the Exchange of Clinical and Economic Data Pre-FDA Approval

*An AMCP Partnership Forum*

September 13–14, 2016 | Tysons Corner, VA

## Program

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

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Understanding Comparative Effectiveness Research (CER) is the key to efficiently and effectively assessing the value of new treatments using multiple types of studies to inform medical policy and decision-making.

Online tools and training through the **CER Collaborative**, a joint program developed by the Academy of Managed Care Pharmacy, International Society for Pharmacoeconomics and Outcomes Research, and National Pharmaceutical Council, have been **updated and enhanced**. Enroll in the CER Certificate Program and gain:

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**Visit [www.amcp.org/CERCertificate](http://www.amcp.org/CERCertificate) today for more information.**

**About the Collaborative**—AMCP, ISPOR, and NPC formed the CER Collaborative to provide greater uniformity and transparency in the evaluation and use of evidence for coverage and health care decision-making with the ultimate goal of improving patient outcomes.

Developed by the **CER Collaborative**



# WELCOME



Welcome to the Academy of Managed Care Pharmacy's (AMCP's) partnership forum on developing recommendations that would allow biopharmaceutical companies to disseminate health care economic information (HCEI) on products still awaiting FDA approval.

This event follows on the heels of an AMCP forum in March 2016 that developed recommendations for new guidance on Section 114 of the FDA Modernization Act, which provides a safe harbor for the dissemination of HCEI on marketed products. At that forum, participants identified a need to disseminate HCEI to payers at least 12 to 18 months prior to approval. Early dissemination allows payers to build HCEI into forecasting and premiums, as waiting until product approval often is too late.

The goal of this event is to provide recommendations to Congress and the FDA on how current laws or regulations should be amended to allow for such pre-approval dissemination. Forum participants will:

- Create and define a new term to describe the ability of biopharmaceutical manufacturers to provide clinical and economic information at least 12-18 months prior to FDA approval (pre-approval).
- Create modernized definitions for existent terms in current laws, regulations or guidance to align with the identified new term.
- Articulate the standards that pre-approval clinical and economic information should meet.
- Determine the entities that should have access to pre-approval clinical and economic information and articulate the value to each.

- Articulate the type of information, format, and process by which eligible entities would like to receive pre-approval clinical and economic information.
- Consider necessary public health protections to prevent dissemination of pre-approval clinical and economic information to unintended entities.

Your voice on these matters will be very important, as we aim to achieve consensus among many stakeholders, including the biopharmaceutical industry, the managed care industry, pharmacoeconomic experts, academia, health care providers and patient advocacy groups. Guiding us through this process, I am delighted to say, will be health policy expert Susan Dentzer, President and CEO of the Network for Excellence in Health Innovation.

I would like to thank AbbVie, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Intarcia Therapeutics, Eli Lilly and Company, GlaxoSmithKline, Merck, National Pharmaceutical Council, Novo Nordisk, Pfizer, Pharmaceutical Research and Manufacturers of America, Precision for Value, Sanofi, Takeda, and Xcenda, whose generous support has made this event possible. And I would like to thank everyone here for being a part of this important discussion.

Sincerely,

A handwritten signature in blue ink that reads "Susan Cantrell". The signature is fluid and cursive.

**Susan A. Cantrell, RPh, CAE**

Chief Executive Officer  
Academy of Managed Care Pharmacy

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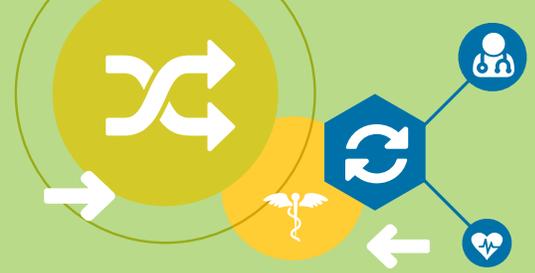
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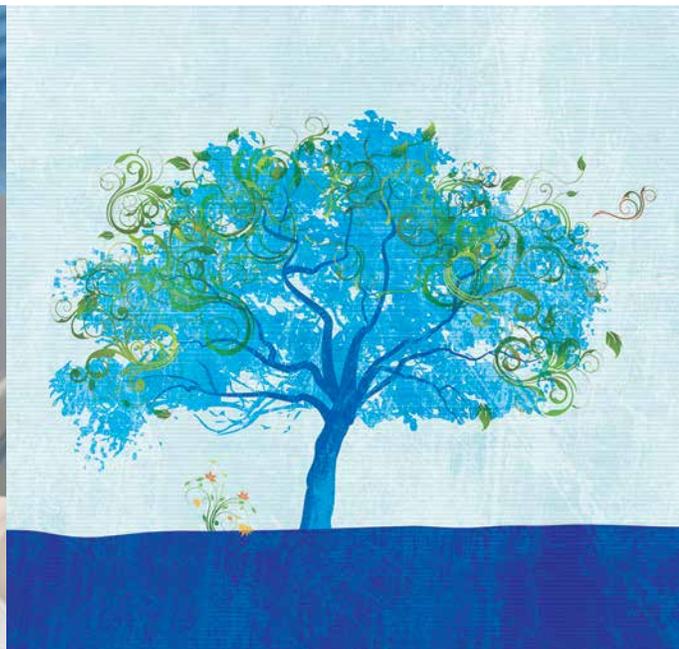
# AGENDA – DAY 1

All events are in Salons E-F on the Lobby Level unless otherwise noted.



TUESDAY, SEPTEMBER 13 <sup>TH</sup>	
8:30am – 9:00am	<b>BREAKFAST</b>
9:00am – 10:00am	<b>WELCOME &amp; INTRODUCTIONS</b>
	<ul style="list-style-type: none"> <li>▶ <b>Susan A. Cantrell, RPh, CAE</b> <i>Chief Executive Officer</i> Academy of Managed Care Pharmacy</li> <li>▶ <b>Mary Jo Carden, RPh, JD</b> <i>Vice President of Government &amp; Pharmacy Affairs</i> Academy of Managed Care Pharmacy</li> <li>▶ <b>Susan Dentzer</b> <i>President and Chief Executive Officer</i> Network for Excellence in Health Innovation</li> </ul>
10:00am – 10:20am	<b>PRESENTATION – Overview of FDAMA 114 Partnership Forum</b>
	<ul style="list-style-type: none"> <li>▶ <b>Soumi Saha, PharmD, JD</b> <i>Assistant Director of Pharmacy &amp; Regulatory Affairs</i> Academy of Managed Care Pharmacy</li> </ul>
10:20am – 10:35am	<b>BREAK</b>
10:35am – 11:15am	<b>PRESENTATION – Off-Label Communications: Current Challenges &amp; Barriers</b>
	<ul style="list-style-type: none"> <li>▶ <b>Gregory Daniel, MPH, PhD</b> <i>Deputy Director</i> Duke-Margolis Center for Health Policy</li> </ul>
11:15am – 12:00pm	<b>DISCUSSION 1 – What term should be used to describe the ability of biopharmaceutical manufacturers to proactively share clinical and economic information about medications in the pipeline with payers and other entities prior to FDA approval?</b>
12:00pm – 1:00pm	<b>NETWORKING LUNCH – McLean Level Two</b>
1:00pm – 1:45pm	<b>DISCUSSION 1 – Report out and moderator lead discussion</b>
1:45pm – 2:15pm	<b>DISCUSSION 2 – What standards should clinical and economic information shared prior to FDA approval meet?</b>
2:15pm – 2:45pm	<b>DISCUSSION 2 – Report out and moderator lead discussion</b>
2:45pm – 3:00pm	<b>BREAK</b>
3:00pm – 3:30pm	<b>DISCUSSION 3 – What entities should have access to clinical and economic information prior to FDA approval? What is the value in each identified entity having access to this information?</b>
3:30pm – 4:00pm	<b>DISCUSSION 3 – Report Out and moderator lead discussion</b>
4:00pm – 4:30pm	<b>DISCUSSION 4 – What is the preferred format and process by which eligible entities should receive clinical and economic information prior to FDA approval from biopharmaceutical manufacturers?</b>
4:30pm – 5:00pm	<b>DISCUSSION 4 – Report Out and moderator lead discussion</b>
5:00pm – 5:30pm	<b>AGREEMENT ON CONSENSUS RECOMMENDATIONS FOR DAY 1 &amp; WRAP-UP</b>
5:30pm – 6:30pm	<b>NETWORKING RECEPTION – McLean Level Two</b>

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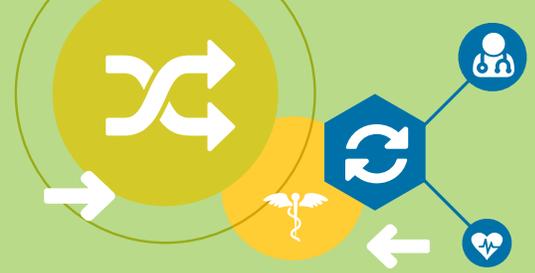
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# AGENDA – DAY 2

All events are in Salons E-F on the Lobby Level unless otherwise noted.



WEDNESDAY, SEPTEMBER 14 <sup>TH</sup>	
8:00am – 8:30am	<b>BREAKFAST</b>
8:30am – 8:45am	<b>WELCOME &amp; SUMMARY OF DAY 1</b>
8:45am – 9:30am	<b>DISCUSSION 5</b> – How should the definitions for existent terms referenced in current laws, regulations, or guidance documents (such as labeling, misbranded, intended use, etc) be modernized to align with the identified new term for the exchange of clinical and economic information prior to FDA approval?
9:30am – 10:00am	<b>DISCUSSION 5</b> – Report out and moderator lead discussion
10:00am – 10:30am	<b>DISCUSSION 6</b> – What public health protections should be considered to prevent the dissemination of clinical and economic information prior to FDA approval to unintended entities?
10:30am – 10:45am	<b>BREAK</b>
10:45am – 11:15am	<b>DISCUSSION 6</b> – Report out and moderator lead discussion
11:15am – 12:15pm	<b>AGREEMENT ON CONSENSUS RECOMMENDATIONS FOR DAY 2</b>
12:15pm – 12:30pm	<b>NEXT STEPS &amp; CLOSING REMARKS</b>
	<ul style="list-style-type: none"><li>▶ <b>Susan A. Cantrell, RPh, CAE</b> Chief Executive Officer Academy of Managed Care Pharmacy</li><li>▶ <b>Soumi Saha, PharmD, JD</b> Assistant Director of Pharmacy &amp; Regulatory Affairs Academy of Managed Care Pharmacy</li></ul>
12:30pm – 1:00pm	<b>NETWORKING LUNCH – McLean Level Two</b>

## THANK YOU

To our distinguished participants and guests.

*The Academy of Managed Care Pharmacy looks forward to holding more partnership forums focused on issues of greatest importance to our 8,000 members, the more than 200 million Americans covered by the pharmacy benefit, and other health care stakeholders.*





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# MODERATOR



## **Susan Dentzer**

*President and Chief Executive Officer*  
**Network for Excellence in Health Innovation**

Susan Dentzer is the President and Chief Executive Officer of the Network for Excellence in Health Innovation (NEHI), a not-for-profit organization that seeks intelligent ways to advance health and improve health care at sustainable costs. NEHI represents more than 120 organizations across the spectrum of health and health care.

A frequent speaker and commentator, Dentzer previously served as senior policy adviser to the Robert Wood Johnson Foundation. She also was formerly editor-in-chief of Health Affairs, and health correspondent for the PBS NewsHour. Dentzer wrote

and hosted the 2015 PBS documentary, *Reinventing American Healthcare*, focusing on the innovations pioneered by the Geisinger Health System.

Dentzer is an elected member of the National Academy of Medicine and also serves on the academy's Board on Population Health and Public Health Practice. She is also an elected member of the Council on Foreign Relations and a fellow of the National Academy of Social Insurance. Dentzer graduated from Dartmouth, is a trustee emerita of the college, and chaired the Dartmouth Board of Trustees from 2001 to 2004. She has served as a member of the Board of Overseers of Dartmouth Medical School for more than two decades.

# REALIZING THE VALUE OF INNOVATION

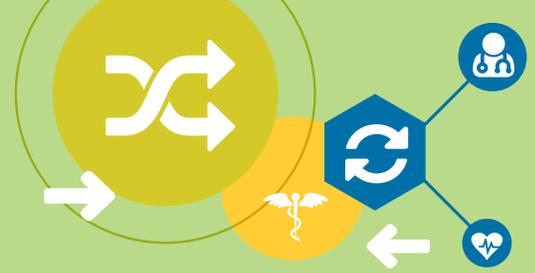


Patients, Science, and Innovation are the foundation of everything we do. At Celgene, we believe in an unwavering commitment to medical innovation, from discovery to development. Our passion is relentless—and we are just getting started.



# FORUM PARTICIPANTS

As of August 29, 2016



**Christopher Michael Blanchette, PhD, MBA**  
*Vice President, Evidence Strategy & Generation*  
Precision Health Economics  
*Associate Professor, Public Health Sciences*  
University of North Carolina at Charlotte

Christopher M. Blanchette, PhD, MBA is an epidemiologist and health services researcher with over a decade of experience in pharmacoconomics and pharmacoepidemiology in the pharmaceutical industry, consulting and academia. He is currently 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, Evidence Strategy & Generation with Precision Health Economics. He has authored over 70 papers in clinical and economic journals and presented over 100 studies at national conferences.



**Elizabeth L. Brusig, PharmD, MBA**  
*Clinical Pharmacy Specialist*  
Optima Health Plan

Elizabeth Brusig is a Clinical Pharmacy Specialist at Optima Health Plan in Virginia Beach, Virginia. In her role, Beth is responsible for the Plan's clinical pharmacy services including strategic formulary and utilization management programs. Beth received a Bachelor of Science degree in Biology from Mary Washington College, her Doctor of Pharmacy degree from Mercer University and a Masters of Business Administration degree from Liberty University. She completed a residency at Moses Cone Hospital in Greensboro, North Carolina. Beth is active in the Academy of Managed Care Pharmacy where she has served on the board and chaired several committees.



**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.



**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.

# TIME 2 DISRUPT™

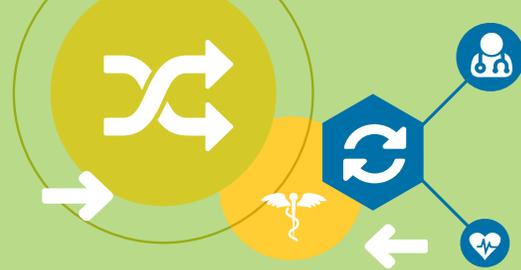
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# FORUM PARTICIPANTS

As of August 29, 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.



## **Amy Duhig, PhD**

*Senior Director, Outcomes Research  
Xcenda*

Amy M. Duhig, PhD, is Senior Director of the Outcomes Research Team at Xcenda. In this role, she leads research that helps manufacturers strategically develop evidence to communicate product value to internal and external stakeholders. Prior to joining Xcenda, Dr. Duhig held roles in global research departments in large pharmaceutical companies, providing strategic and tactical support within virology, endocrinology, and neuroscience therapeutic areas. She has her PhD in Clinical Psychology from the University of South Florida and completed her post-doctoral work at Yale University. She has been an invited speaker at national conferences and has authored numerous peer-reviewed articles.



## **Paul Eiting**

*Senior Manager, Value-Based Policy  
Blue Cross and Blue Shield Association*

Paul Eiting has over 10 years of experience in the health insurance field and on Capitol Hill. He is currently the Senior Manager of Value-Based Policy at BCBSA where he focuses on prescription drug and FDA-related issues. Previously, Paul served as the Policy Director at AHIP where he was the lead analyst during federal health care reform and managed AHIP's implementation of the Affordable Care Act. He also served as the Legislative Correspondent to Rep. Paul Ryan (R-WI), managing the member's constituent correspondence and researching policy and legislation for recommendations to the member. Paul received his undergraduate degree in political science and history from Carthage College and a master's degree in public policy from American University.



## **Elizabeth Engelhardt, RN, BSN**

*Head of Specialty Strategy & Clinical Management  
Aetna, Inc.*

Elizabeth Engelhardt is the Head of Specialty Strategy and Clinical Management Programs for Aetna Pharmacy Management. In this role Ms. Engelhardt is accountable for the development, design and execution of clinically sound, cost conscious Specialty medical and pharmacy pharmaceutical management for Aetna Commercial members. Prior to her current role, Ms. Engelhardt was the Director of Trade Relations for Aetna Pharmacy Management, accountable for setting strategic plans for Aetna's relationships with Pharmaceutical Manufacturers, managing a portfolio of rebate contracts and creating and maintaining valuable partnerships within the manufacturer community. She joined Aetna in 2011. She holds a Bachelor of Science degree in Nursing from Molloy College, Rockville Center, NY.

A woman with dark hair, wearing safety glasses and a white lab coat with a red 'Lilly' logo on the pocket, is focused on her work in a laboratory. The background is blurred, showing laboratory equipment. The image is framed by a large red graphic element that curves around the top and right sides.

*Hong Hu, Research Advisor,  
Lilly Research Laboratories*

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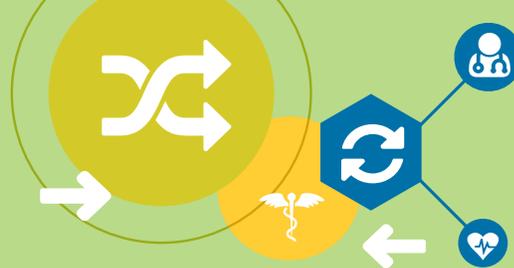
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# FORUM PARTICIPANTS

As of August 29, 2016



## **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.

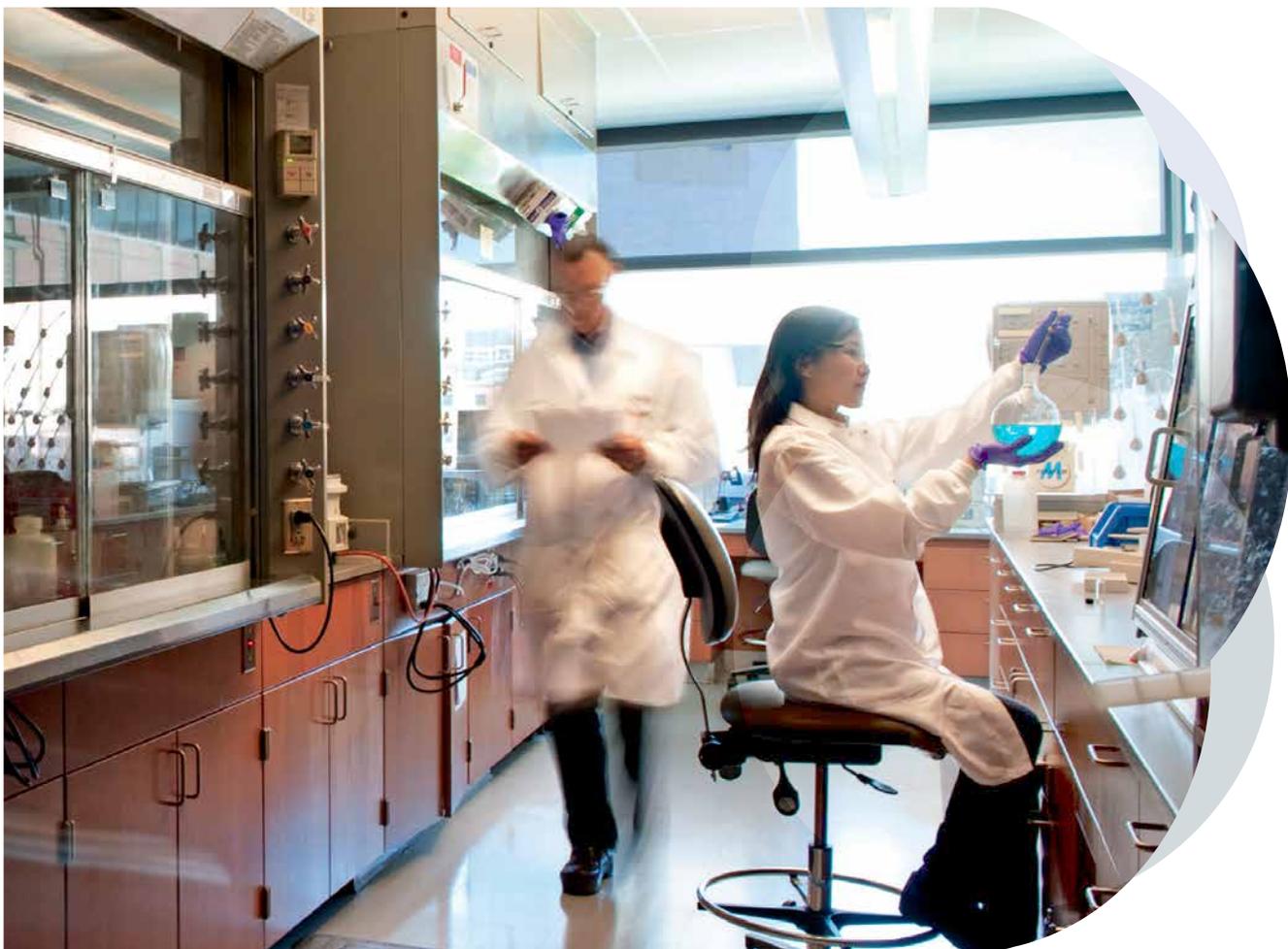


## **Dorothy Hoffman, MPP**

*Director, Global Public Policy/Head,  
U.S. Health Policy*  
Eli Lilly and Company

Dorothy Hoffman, M.P.P., is the head of U.S. Health Policy at Eli Lilly and Company. In this role, Dorothy provides advice to business and scientific executives on how legislative and regulatory changes will impact the development and commercialization of Lilly's innovative medicines portfolio.

Dorothy began her career at Lilly in 2004 and has held positions in Corporate Affairs of increasing responsibility at the Company Headquarters in Indianapolis, Indiana and in affiliate offices in Belgium and the United Kingdom.



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# FORUM PARTICIPANTS

As of August 29, 2016



## **Crystal Kuntz, MPA**

*Vice President, Policy and Regulatory Affairs  
America's Health Insurance Plans (AHIP)*

Crystal Kuntz is the Vice President for Policy and Regulatory Affairs at America's Health Insurance Plans where she focuses on a range of policy and regulatory issues, including affordability of prescription drugs. Crystal has nearly 20 years of experience in healthcare policy. Before moving to the private sector, Crystal led legislative and policy efforts related to the Medicare Advantage program and Part D within the Office of Legislation at the Centers for Medicare & Medicaid Services (CMS). She was part of the CMS team that worked on the passage of the Medicare prescription drug benefit in 2003 and its early implementation. She received her undergraduate degree in government and international affairs from Augustana College and has a master's degree in public administration from Syracuse.



## **Jeff Lee, PharmD, FCCP**

*Associate Professor, Pharmacy Practice  
Lipscomb University College of Pharmacy*

Jeff Lee has been involved in generating and communicating value evidence in healthcare for 25 years. Prior to joining Lipscomb University College of Pharmacy in Nashville in 2013, Dr. Lee held a number of senior level positions in the pharmaceutical industry, notably Vice President of Global Health Outcomes at Allergan. In addition to his ongoing teaching and research activities, Jeff is currently Chair of the AMCP Format Executive Committee, and led the committee's development of the recently launched AMCP Format for Formulary Submissions, Version 4.0.



## **Erin Lopata, PharmD**

*UPMC Health Plan  
Manager of Clinical Pharmacy*

Erin Lopata is manager of clinical pharmacy at UPMC Health Plan in Pittsburgh, PA. During her time at UPMC Health Plan, Dr. Lopata has focused on specialty pharmacy initiatives, including formulary management and the development and implementation of care management programs for specialty populations. She is an adjunct faculty member at the University of Pittsburgh School of Pharmacy and serves as the Residency Program Director for the UPMC Health Plan PGY1 Managed Care Residency Program. She received her PharmD from the University of Pittsburgh in 2008 and completed a PGY1 Managed Care Residency at UPMC Health Plan in 2009. Dr. Lopata is currently pursuing a Master of Public Health (MPH) degree at the University of Pittsburgh Graduate School of Public Health.



## **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.

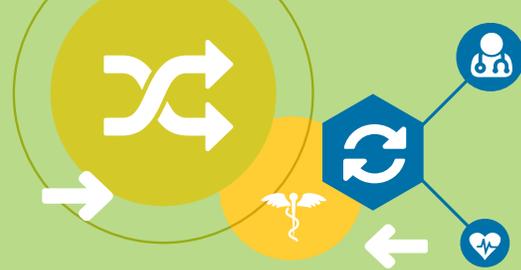
# Who Can Share What, and When?

Payers and other entities need clinical and economic information about medications before FDA approval so that they can make business forecasting and benefit decisions. However, lack of clarity in current laws and regulations makes sharing information about products prior to FDA approval with health plans problematic for the biopharmaceutical industry. This can result in limited sharing of scientific data to inform health care decision-makers and can slow the availability of innovative medications for patients.

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

# FORUM PARTICIPANTS

As of August 29, 2016



## **Joan S. 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. She earned a MS degree from the University of Maryland, College Park.



## **Newell McElwee, PharmD, MSPH**

*Associate Vice President, Center for Observational and Real World Evidence*

*Merck & Co., Inc.*

Newell McElwee, PharmD, MSPH is Associate Vice President in the Center for Observational and Real- World Evidence (CORE) at Merck Research Laboratories. His team at CORE focuses on ensuring payer / HTA agency informed research plans, conducting collaborative research with academic institutions and health plans, developing strategic partnerships with international research institutions, and conducting research in medication adherence and health policy. Newell received his PharmD degree from Mercer University, his MSPH (epidemiology) at the University of Utah and completed a clinical pharmacy residency at Osteopathic Medical Center of Texas and a McNeil Clinical Pharmacology and Toxicology Fellowship at the University of Utah.



## **Corey Pelletier, PhD**

*Director, US Health Economics and Outcomes Research*

*Celgene*

Corey Pelletier is currently Director US HEOR leading up the Solid Tumor team at Celgene. She has worked previously at Eisai Inc and Novartis Oncology in various Global Health Economics and Market Access roles.



## **Eleanor M. Perfetto, PhD, MS**

*Professor, Pharmaceutical Health Services Research School of Pharmacy, University of Maryland*

*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. 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.

ALEJANDRO KULICK  
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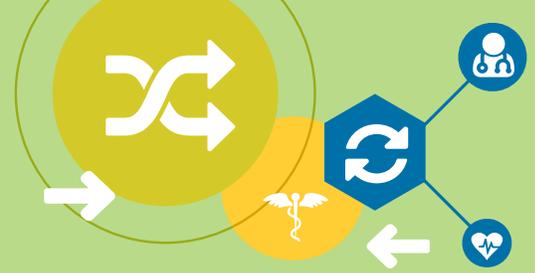
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# FORUM PARTICIPANTS

As of August 29, 2016



## **Michael Ryan, PharmD**

*Senior Vice President, Value Access & Payment  
Bristol-Myers Squibb*

Dr. Ryan is the Senior Vice President for US Value, Access and Policy for Bristol-Myers Squibb. In this role, Dr. Ryan is responsible for all pricing, contracting, payer strategy, Value and Access Marketing, and Policy across the \$8B US BMS portfolio, as well as all field reimbursement strategy and execution across all US payers. Dr. Ryan is a graduate of the University of California at Los Angeles (1976) and the University of California at San Francisco (1980), and completed his residency program at the University of Michigan Hospitals and College of Pharmacy in 1981. After completing his residency, Dr. Ryan continued to work with the University of Michigan College of Pharmacy and the University of Michigan Medical Center for 15 years.



## **Elizabeth Seifert**

*Senior Director, US Public Policy & Executive Branch  
GlaxoSmithKline Public Policy*

Elizabeth Seifert is Senior Director of US Public Policy and Executive Branch at GlaxoSmithKline (GSK). In this role, she oversees the analysis of state and federal legislation and regulation and the development of proactive strategies on issues affecting GSK and patients. She was formerly legislative counsel to the American Medical Association in Washington, DC where she analyzed federal legislation for its impact on physicians. Prior to joining the AMA, Elizabeth worked as Legislative Counsel on health care issues for US Senator Jesse Helms. Elizabeth holds a law degree from Wake Forest University and a BA in English from Sweet Briar College.



## **Sheila M. Thomas, PharmD**

*Sr. Director, Evidence Based Medicine  
Sanofi, Inc.*

Sheila Thomas serves as the Senior Director, Evidence Based Medicine at Sanofi, Inc. As head of the National Outcomes Liaison Directors, she is responsible for developing and executing the scientific data communication and dissemination strategy in support of demonstrating the value of Sanofi's products and services to US population-based healthcare decision makers. In addition, she is instrumental in formulating and implementing HEOR strategies and plans for pipeline and marketed products across multiple therapeutic areas. Dr. Thomas received her BS in Pharmacy and PharmD degrees from The Ohio State University, Columbus, Ohio.



## **Robin S. Turpin, PhD**

*Lead Director, HEOR  
Takeda Pharmaceuticals, USA*

Robin Turpin is Lead Director, U.S. HEOR, Takeda. She received her Ph.D. in Applied Social Psychology from Loyola University Chicago and was a Distinguished Fellow with the National Institute of Disability and Rehabilitation Research. With 30 years of experience in healthcare evaluation and outcomes research, she has co-authored more than 100 books, book chapters, and journal articles on health economics, health behavior, and population health management. Robin's research has won awards from the AMCP, ASHP, ISPOR, the Joint Commission, and the Disease Management Association of America. She has held previous academic appointments with Loyola University Chicago and Northwestern University Medical School, and serves on the editorial board of Population Health Management.

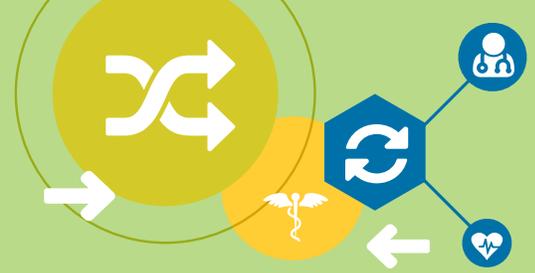


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# FORUM PARTICIPANTS

As of August 29, 2016



## **Anthony Wang, PhD, MPH**

*Senior Manager  
AbbVie*

Anthony Wang, PhD, MPH, is an epidemiologist and health economist with over 10 years of real-world research experience. He is currently the US HEOR Gastroenterology lead at AbbVie and is responsible for the development and execution of strategic research plans, as well as the dissemination of research findings. Anthony received his PhD in Epidemiology and MPH in Community Health Sciences from the UCLA Fielding School of Public Health.



## **Melea Ward, PhD, PharmD**

*Director, Global Outcomes and Evidence  
Pfizer*

Melea Ward, PhD, PharmD has several years of experience in health economics and outcomes research within managed care, consulting, and pharmaceutical industry settings. After completing a managed care pharmacy residency at Humana, she joined their CRO, Comprehensive Health Insights, supporting evidence generation for pharmaceutical companies and government agencies. In 2014, Melea joined GSK and is currently the US Outcomes and Evidence lead for Ibrance within Pfizer Oncology. Melea received her Doctor of Pharmacy degree from The Ohio State University, PhD in Pharmaceutical Outcomes and Policy from University of North Carolina (UNC), and is an active diplomat for UNC's AMCP student chapter.



## **James Weatherall, BBA, MA, PhD**

*Director, Health Economics & Outcomes Research  
Novo Nordisk Inc.*

James Weatherall, PhD, is a Director in Health Economics and Outcomes Research who has a wealth of education and experience in hemophilia and diabetes. He joined Novo Nordisk in Global Development in 2006 as a Health Economist supporting hemophilia products. In 2012, James transitioned to support development activities in the diabetes franchise and since then has spent time working on GLP-1 antagonists, rapid, and long acting insulins. James has leveraged his strong experience to support the value story of pipeline and launched products through the development of health economic and outcomes research evidence which has led to multiple scientific articles and posters presented at economic and disease specific conferences.



## **Susan C. Winckler, RPh, Esq**

*Chief Risk Management Officer  
Leavitt Partners, LLC*

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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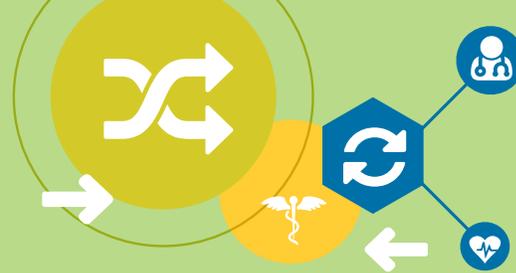
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As of August 29, 2016



## **Kat Wolf Khachatourian, PharmD**

*VP-Pharmacy Services & Strategy  
Qualchoice Health Plan Services*

Dr. Kat Wolf Khachatourian, PharmD is Vice President, Pharmacy Services & Strategy for Qualchoice Health Plan Services, overseeing the management of multiple regional Medicare Advantage plans. Dr. Wolf worked 11 years in retail pharmacy as a technician and intern. After receiving her Doctorate of Pharmacy from Mercer University, Dr. Wolf completed Group Health Cooperative's Managed Care PGY-1 residency. Since completing residency, Dr. Wolf has held accountabilities for pharmacy services and strategy for her organization. Dr. Wolf's current role involves clinical, cost, and utilization evaluations, benefit planning and development, PBM oversight, formulary management, provider education, compliance, staff management, and cross-functional initiatives.



## **Kristina Yu-Isenberg, PhD, MPH, RPh**

*VP & Head, Evidence Generation and Analytics  
Intarcia Therapeutics*

Kristina Yu-Isenberg, PhD, MPH, RPh, joined Intarcia Therapeutics in July 2016 as Vice President and Head of Evidence Generation & Analytics. Dr. Yu-Isenberg has more than 15 years of HEOR and Medical Affairs experience in both US and Global leadership roles at pharmaceutical, biotechnology and managed care companies. She has extensive expertise across multiple therapeutic areas as well as all aspects of outcomes research and "real-world" evidence, including effectiveness, patient-reported outcomes, economic evaluations and quality improvement. Dr. Yu-Isenberg received her PhD in Health Services Research from the Johns Hopkins Bloomberg School of Public Health; MPH from the University of Massachusetts; and BS in pharmacy from the University of North Carolina at Chapel Hill.



## **Lori Zablow-Salles, Esq.**

*Executive Director, Executive Counsel  
Boehringer Ingelheim Pharmaceuticals, Inc.*

Lori Zablow-Salles is a pharmaceutical lawyer with broad and deep experience in regulatory, compliance and transactional matters, and all aspects of drug development, production and commercialization. She currently serves as Executive Director, Executive Counsel at Boehringer Ingelheim Pharmaceuticals, Inc., where she leads a team that provides strategic advice on market access and numerous "go to market" initiatives, managed care sales and marketing, health economic research and information, government pricing and contracting, cross functional legal matters and the development and commercialization of specialty products. She serves as lead attorney on a variety of projects and teams dedicated to maintaining the company's relevance and compliance in an evolving market landscape.

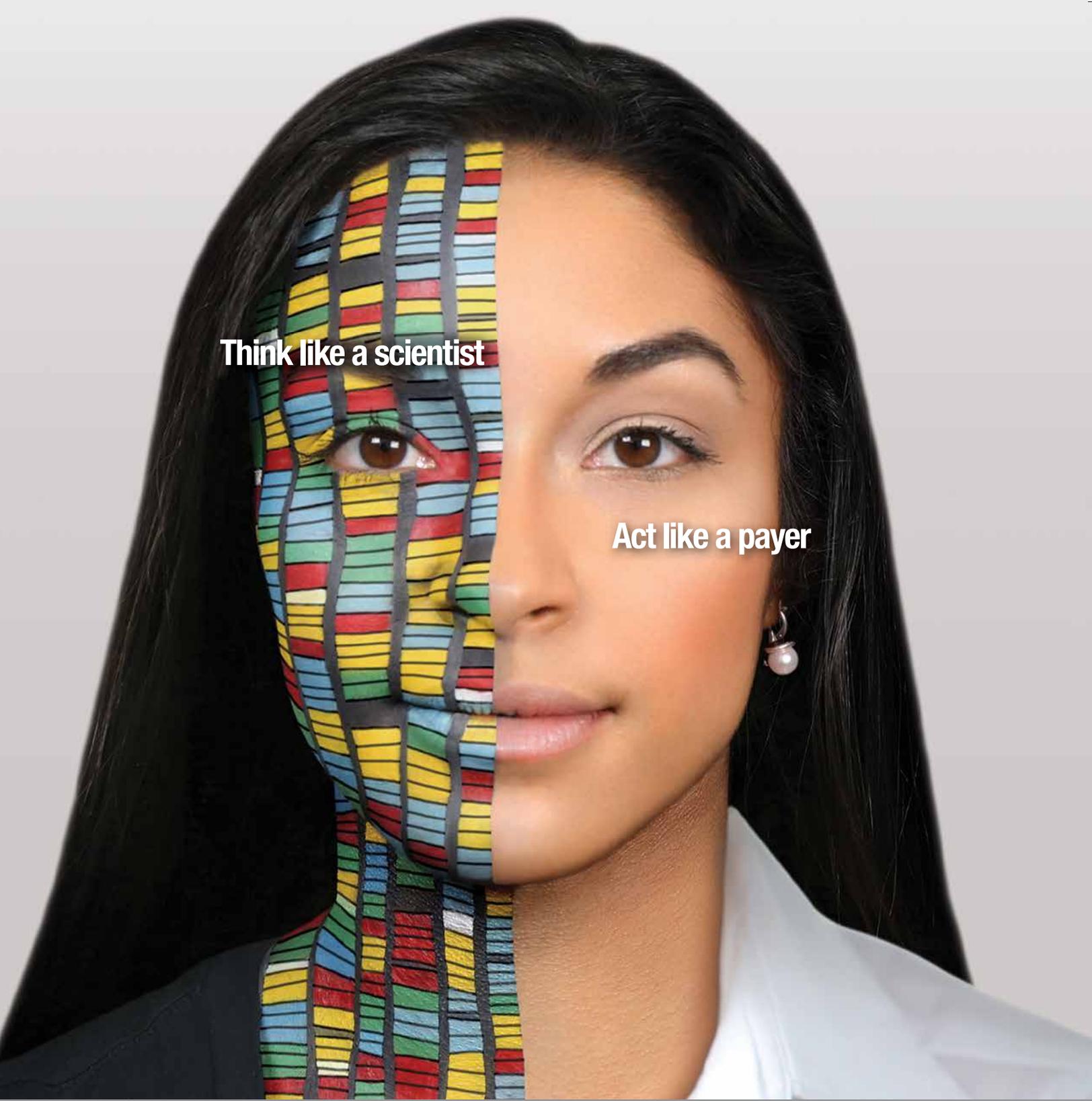


## **FORUM WRITER**

### **Emily Zacherle**

*Analyst, Evidence Strategy and Generation  
Precision Health Economics*

Emily Zacherle, MS is an analyst, Evidence Strategy and Generation for Precision Health Economics, where she supports the execution of real-world evidence studies, literature review analyses and manuscript development. Prior to joining Precision For Value, Emily was a Research Associate at the University of North Carolina at Charlotte. Emily held key responsibilities in project management and assisted in the development of proposals, protocols, analysis plans, reports and manuscripts for the health economics and outcomes research group. Emily received her MS in Kinesiology with a concentration in Applied Physiology where she conducted research on the physiology and mechanical properties of cardiovascular tissue.



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