

AMCP FOUNDATION SYMPOSIUM



*Transplanting European Health Technology Assessment
to America: What's Wrong with Our Version?*

OCTOBER 15, 2013 | SAN ANTONIO, TX | FINAL PROGRAM

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WELCOME

Dear Colleagues,

Welcome to the third annual AMCP Foundation Symposium! Our goal each year is to identify a topic that is timely yet provocative to managed care audiences. *Transplanting European Health Technology Assessment to America: What's Wrong with Our Version?* hits the mark in both respects. Not only is it timely, but it will also stimulate thought-provoking discussion among colleagues.

We are living in a period of rapid and transformational changes in our health care system. With the advent of innovative health care delivery models focused on quality, outcomes and risk-sharing, coupled with the escalating growth of specialty pharmaceuticals, health care providers are faced with new challenges in making informed formulary decisions. At the same time, the entire system, payers and policymakers especially, are under intense pressure to control costs, while improving outcomes. In this cutting edge session, we will explore the prospects, benefits and disadvantages of the United States looking across the pond and adopting the European model for formulary decision-making. We will discuss which elements are likely to be adopted in the next few years and which will have a longer development window.

We hope that you will enjoy today's presentations and find the discussions useful as you assess the most effective pharmaceuticals to enhance patient outcomes.

The AMCP Foundation will publish proceedings that will document the meeting's discussions and important findings. Attendees will receive a complimentary copy before they are published on the AMCP Foundation website.

Sincerely,

Edith A. Rosato, RPh, IOM
Chairman, Board of Trustees
Academy of Managed Care Pharmacy Foundation





PROGRAM OBJECTIVES

This program will help managed care pharmacists evaluate the factors that are important to their strategic resource development and decision structures.

The purpose of this program is to:

- Review current drug evaluation policies and processes in the U.S. and compare to those in Europe
- Define key changes in Comparative Effectiveness Research (CER), Health Technology Assessment (HTA) and risk-adjusted contracting and the challenges they create for more robust specialty decision-making
- Identify barriers to widespread adoption of CER, HTA and risk-adjusted pricing
- Present case studies for audience to consider roles of CER, HTA, risk and outcomes in formulary decision-making
- Solicit stakeholder recommendations on the quick hits needed to improve CER, HTA, research priorities, risk arrangements and formulary decision processes



AGENDA

- 11:00 am – 11:05 am **Welcome**
- Speaker:** Edith A. Rosato, RPh, IOM, Chairman, Board of Trustees, Academy of Managed Care Pharmacy Foundation
- Moderator:** Diana Brixner, RPh, PhD, Professor and Chair, University of Utah
- 11:05 am - 11:25 am **Keynote: US and International**
- Challenges in Making Informed Health Care Decisions: Promoting High Integrity, Evidence-Based Decisions that Improve Patient Outcome**
- Speaker:** Bryan Luce, PhD, MBA, Chief Science Officer, Patient-Centered Outcomes Research Institute (PCORI)
- 11:25 am – 11:45 am **HTA Outside the US: What, Why and How?**
- Speaker:** Chris Henshall, MD, PhD, Founding President, Health Technology Assessment International (HTAi), and Chair, HTAi Policy Forum
- 11:45 am – 12:25 pm **Are the Europeans Doing a Better Job Evaluating Drugs than U.S. P&T Committees? The Gap between CER and HTA**
- Speaker:** US - Lou Garrison, PhD, Professor, Pharmaceutical Outcomes Research & Policy Program, University of Washington
- Speaker:** EU - Peter Littlejohns, MD, PhD, Professor of Public Health at King's College London
- 12:25 pm – 1:00 pm **Panel discussion: How is Value Determined?**
- Attendees will be asked whether to approve the drug presented for addition to their formulary and whether there is enough evidence to recommend one drug over another.
- The panel will discuss the key attributes that the National Institute for Health and Care Excellence and Premera consider in their decision matrices and any construct differences that caused the decisions to diverge.



1:00 pm – 2:00 pm	LUNCH
2:00 pm – 2:30 pm	ACO Staying Power: Will ACO and MCO Success Depend on New Risk Paradigms for Specialty Drugs? Speaker: Robert W. Dubois, MD, PhD, Chief Science Officer, National Pharmaceutical Council
2:30 pm – 3:10 pm	HTA's "Is it Worth it" and the Ethics of Oncology Decision-Making: European vs. US and Which Will Prevail? Speaker: US - Mirta Millares, PharmD, FCSHP, FASHP, Manager, Drug Information Services & Pharmacy Outcomes Research, Kaiser Permanente-CA Region Speaker: EU - Peter Littlejohns, MD, PhD, Professor of Public Health at King's College London
3:10 pm – 3:45 pm	Panel discussion: Making Decisions Based on Quality-Adjusted Life Year's (QALY) – Can it Work on Both Sides of the Atlantic? Attendees will be asked whether to approve the oncology specialty drug presented based on HTA's "is it worth it" attributes and to consider whether risk contracting might affect their decision. Also discussed by the panel: <ul style="list-style-type: none">○ Weighing and achieving balance: the perspectives of the payer and the patient in the value equation.○ How are patients kept whole in risk contracting?○ How much do risk contracts depend on rapidly growing our modeling research and our ability to dissect modeling studies?
3:45 pm – 4:00 pm	BREAK
4:00 pm – 4:25 pm	Panel Discussion: What Role Should AMCP Foundation Play in Spearheading Advances in CER, HTA, Research Methodologies, Transparent Risk Arrangements and Formulary Decision Processes?
4:25 pm – 4:30 pm	Closing Remarks



ABOUT THE ACADEMY OF MANAGED CARE PHARMACY FOUNDATION

The AMCP Foundation, a 501(c)3 nonprofit corporation, is a research, education and philanthropic organization supporting the Academy of Managed Care Pharmacy (AMCP). Established in 1990 as the Foundation for Managed Care Pharmacy, the AMCP Foundation was created to support the research and education agenda of AMCP. The Foundation exists to advance collective knowledge and insights on major issues associated with the practice of pharmacy in managed health care settings. More news and information about AMCP Foundation is available on the Foundation's Web site: www.AMCPFoundation.org.





FACULTY BIOS



Diana Brixner, RPh, PhD

**Professor and Chair
University of Utah**

Diana Brixner, RPh, PhD, is Professor and Chair of the Department of Pharmacotherapy, College of Pharmacy and Executive Director of the Pharmacotherapy Outcomes Research Center, and serves as the Director of Outcomes for the Program in Personalized Health Care at the University of Utah. Her research interests focus on applied outcomes research towards developing evidence for informed decision-making in healthcare, with a recent focus on personalized medicine in cancer.

During her career, Dr. Brixner published numerous articles in peer-reviewed journals, including the Journal of National Cancer Center Networks, Value in Health, Pharmacoepidemiology and Drug Safety, and the Journal of Managed Care Pharmacy, written five book chapters, has one issued patent and has been an invited as a speaker at a variety of professional meetings. She is Past-President of the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) and served on the Board of Directors for the Academy of Managed Care Pharmacy (AMCP). She is currently appointed as a Visiting Professor at the Institute of Public Health, Medical Decision Making and Health Technology Assessment in the Department of Public Health and Health Technology Assessment at UMIT - University for Health Sciences, Medical Informatics and Technology in Hall i.T., Austria.

Previously, Dr. Brixner was the Vice President of Health Care Management, Regional Sales Director and Executive Director of National Managed Care Accounts for Novartis Pharmaceuticals, based in East Hanover, New Jersey. She also held field-based liaison positions in managed care and outcomes for SmithKline Beecham and biotechnology marketing and bench research at NeoRx in Seattle, Washington.

Dr. Brixner received her undergraduate degree in pharmacy from the University of Rhode Island and her doctorate in medicinal chemistry from the University of Utah. She previously held an adjunct faculty position at the College of Pharmacy at the University of the Sciences in Philadelphia, Pennsylvania.



Robert W. Dubois, MD, PhD

**Chief Science Officer
National Pharmaceutical Council**

Robert W. Dubois, MD, PhD, joined the National Pharmaceutical Council in October 2010 as its chief science officer. In this role, he oversees NPC's research on policy issues related to comparative effectiveness research, as well as on how health outcomes are valued.

Dr. Dubois, who is board certified in internal medicine, brings more than 25 years of experience in health services research and comparative clinical effectiveness. He has co-founded and led various health care research organizations in developing quality research with practical application. Most recently, he was the Chief Medical Officer at Cerner LifeSciences, where he focused on comparative effectiveness and the use of electronic health records infrastructure to implement clinical change.

Prior to joining Cerner in 2001, Dr. Dubois co-founded Protocare Sciences and was its executive vice president, chief medical officer, and later its CEO.

Throughout his career, Dr. Dubois' primary interest has centered on defining "what works" in health care and finding ways for that evidence to inform health care decision making. He is a recognized expert in the areas of defining best practice, disease management and appropriateness of care. He has authored more than 100 peer-reviewed articles on comparative effectiveness, evidence-based medicine, the development of practice guidelines and determining the optimal use of high-cost medical services.

Dr. Dubois received his AB from Harvard College, his MD from the Johns Hopkins School of Medicine and his PhD in Health Policy from the RAND Graduate School. He is a member of the Medicare Evidence Development and Coverage Advisory Committee and serves on several advisory boards, including the Center for Medicare and Medicaid Services (CMS) Multi-payer claims database project, the Center for Medical Technology Policy and the Institute for Clinical and Economic Review. Additionally, he is the associate editor of the Journal of Comparative Effectiveness Research and is on the editorial board for Health Affairs.



Lou Garrison, PhD

**Professor, Pharmaceutical Outcomes Research & Policy Program
University of Washington, School of Pharmacy**

Dr. Lou Garrison is Professor in the Pharmaceutical Outcomes Research & Policy Program in the Department of Pharmacy and Adjunct Professor in the Departments of Global Health and Health Services at the University of Washington, where he joined the faculty in 2004. During 2012-3, he is on sabbatical as Visiting Senior Research Fellow at the Office of Health Economics in London.

In the 12 years before joining UW, he worked as an economist in the pharmaceutical industry. In 2002-4, he was Vice President and Head of Health Economics & Strategic Pricing in Roche Pharmaceuticals, and was based in Basel, Switzerland. He oversaw the development of the economic and pricing strategies, and research plans for all Roche compounds. Prior to this, he was Director of the Project HOPE Center for Health Affairs. In eight years there, he worked on a wide variety of health policy issues, including studies of health care reform both in the U.S. and overseas. Before this, he worked at the Battelle Human Affairs Research Centers in Seattle, where he carried out studies of the adequacy of physician manpower supply and the cost-effectiveness of kidney and heart transplantation.

He received a B.A. in economics from Indiana University, and a Ph.D. in economics from Stanford University. Dr. Garrison's research interests include national and international health policy issues related to pharmacogenomics and personalized medicine, regulatory benefit-risk analysis, insurance, pricing, reimbursement, and risk-sharing agreements, as well as the economic evaluation of pharmaceuticals, diagnostics, devices, surgical procedures, and vaccines, particularly as related to organ transplantation, renal disease, influenza, measles, obesity, and cancer.

From 2007-9, he served on the Board of Directors of the International Society for Pharmacoeconomics and Outcomes Research. He currently chairs the ISPOR Health Science Policy Council. During 2012-3, he is on sabbatical as Visiting OHE Senior Research Fellow at the Office of Health Economics in London, UK.



Chris Henshall, MA, PhD

**Doctor
Consultant**

Chris Henshall works as an independent consultant, advising governments, public and private sector organisations on health, research and innovation policy. He was the Founding President of Health Technology Assessment International (HTAi) and is currently Chair of the HTAi Policy Forum and a Board member of the Alberta Research and Innovation Authority, an Associate Professor in the Health Economics Research Group at Brunel University, and an honorary Fellow in the Centre for Health Economics at the University of York.

Chris has worked previously for the Health Promotion Research Trust, the UK Medical Research Council, the Department of Health and NHS in England (where he was involved in establishing the NHS R&D Budget, the NHS HTA Programme and the National Institute for Health and Clinical Excellence), the Department of Trade and Industry (where he was responsible for UK science and innovation policy and funding), and the University of York (where he was responsible for promoting enterprise and innovation and links with the economy, government and businesses at home and overseas).



Peter Littlejohns, MD, PhD

**Professor of Public Health
King's College London**

Peter is Professor of Public Health at King's College London and Deputy Director of the National Institute for Health Research's South London Collaboration for Leadership in Applied Health Research and Care. During his career he has held a range of service and academic posts including Director of the NHS Research and Development funded Healthcare Evaluation Unit at St Georges, University of London and Chief Scientist on a European Union BIOMED II project, which developed a critical appraisal instrument for clinical guidelines (AGREE).

In 1998 he spent a year in South Africa undertaking research into health policy funded by the Health Systems Research Trust. Between 1999 and 2012 he was the founding Clinical and Public Health Director of the National Institute for Health and Care Excellence (NICE) in the UK. He is a Fellow of the Royal College of Physicians, Fellow of the Faculty of Public Health and Fellow of the Royal College of General Practitioners. His research interests are aimed at improving the cost-effectiveness of health care and he is currently leading an international research programme addressing how to balance efficiency with equity in order to allocate health care resources fairly.



Bryan Luce, PhD, MBA

**Chief Science Officer
PCORI**

Bryan R. Luce, PhD, MBA, is PCORI's Chief Science Officer (CSO). In this position, Luce will be responsible for leading the development and implementation of PCORI's patient-centered comparative clinical effectiveness research (CER) agenda.

Luce joins PCORI from United BioSource Corporation (UBC), where he served as Senior Vice President for Science and Policy and focused on CER and the development of novel research methods to support a more patient-centered approach. Luce joined UBC in 2004 with the organization's acquisition of MEDTAP International, a company he founded to provide health economics and outcomes research services for the pharmaceutical and biotechnology industry.

Luce has devoted his career to developing research methods, policies, and applications to help improve evidence-based information to support health care decision-making. In 2008, he founded the Pragmatic Approaches to Comparative Effectiveness (PACE) Initiative, a collaborative effort to improve the practicality and efficiency of comparative clinical studies to meet demands by payers, clinicians, and policy makers for more "real-world" evidence. Luce has also served in leadership positions at Battelle, Centers for Medicare and Medicaid Services, and Office of Technology Assessment of the United States Congress. He has been an advisor to numerous government and nonprofit agencies as well as pharmaceutical and device firms worldwide.

Luce holds adjunct faculty positions at the Department of Health Policy, Jefferson Medical College, the Leonard D. Schaeffer Center for Health Policy and Economics, University of Southern California, and the Department of Pharmacy, University of Washington. A former Special Forces Officer, Luce is a Lieutenant Colonel (Retired), Medical Service Corps, US Army Reserves. Luce served as the 5th President of the International Society for Health Economics and Outcomes Research (ISPOR) and in 2008 received the society's highest recognition, the Avedis Donabedian Outcomes Research Lifetime Achievement Award. He received his bachelor's and master's degrees from the University Massachusetts at Amherst and his doctorate from the School of Public Health at the University of California at Los Angeles.



Mirta Millares, PharmD, FCSHP, FASHP

**Manager, Drug Information Services and Outcomes Research Manager
Kaiser Permanente – CA Regions**

Dr. Mirta Millares is Manager of Kaiser Permanente's Drug Information Services and Pharmacy Outcomes Research in the California Regions and has been actively engaged in all aspects of drug information practice and education for over 25 years. She oversees a department of over 35 staff responsible for providing evidence analysis, drug forecasting, and drug utilization strategy to support formulary decision-making by the Northern and Southern CA Pharmacy & Therapeutics Committees for the Commercial Formulary; the Interregional Medicare Part D Pharmacy & Therapeutics Committee for KP's National Medicare Part D Formulary; and for the new California Marketplace Formulary. The department's outcomes research group conducts retrospective database studies providing program-specific insight into comparative effectiveness and outcomes achieved.

Dr. Millares is an Adjunct Assistant Professor of Pharmacy Practice at the University of Southern California, School of Pharmacy and has provided APPE and training opportunities for pharmacy students and PGY1 residents from across the state. She is Program Director for KP CA's ASHP-accredited Post-Graduate Year 2 Residency program in Drug Information Practice. She is editor of the textbook, Applied Drug Information: Strategies for Information Management and was appointed to the ASHP (American Society of Health-System Pharmacy) Expert Panel which developed the organization's "Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System" in 2008.

Dr. Millares received her Doctor of Pharmacy degree from the University of California, San Francisco School of Pharmacy, and completed a 12-month residency in clinical pharmacy followed by a specialty residency in drug information practice also at UCSF.



Edith A. Rosato, RPh, IOM

**Chairman, Board of Trustees
Academy of Managed Care Pharmacy Foundation**

Edith A. Rosato R.Ph., IOM, became Chairman of the Board of Trustees of the AMCP Foundation and Chief Executive Officer of the Academy in October 2011. Rosato brings nearly 30 years of pharmacy and non-profit management experience to AMCP. As a registered pharmacist, she has a deep commitment to the advancement of managed care pharmacy principles of expanding a patient's access to health care, enhancing the quality of health care delivery and finding ways to manage the escalating costs of health care in the United States. Ms. Rosato is an advocate for the expanding role for pharmacists in new care delivery models where a patient's care is coordinated across the health care system by many health care providers.

For the past 11 years she has held leadership positions at the National Association of Chain Drug Stores (NACDS), a \$30 million national trade association representing over 1,000 member companies in an \$800 billion industry. Most recently, she served as President of the NACDS Foundation and as Senior Vice President, Pharmacy Affairs. During her tenure at NACDS she also served as Senior Vice President of Strategic Alliances and Development, Executive Director, Leadership Council and Vice President, Pharmacy Affairs.

Prior to her time at the NACDS, she was Director of Customer Development, Healthcare Systems, and National Accounts Manager for Wyeth-Ayerst Laboratories and Corporate Pharmaceutical Buyer for CVS, which is now CVS Caremark.

Rosato has served on the Boards of eight separate nationally recognized organizations, including the American Foundation for Pharmaceutical Education. She received an Executive Healthcare Leadership Certification from Thunderbird Graduate School of International Management as well as her Institute for Organizational Management certification from the U.S. Chamber of Commerce.

Rosato also holds a bachelor's degree from Temple University School of Pharmacy. She remains actively involved at Temple University School of Pharmacy and is a member of their Russell H. Conwell Society.



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LIST OF ATTENDEES (as of 10.01.13)

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AstraZeneca, L.P.
Wilmington, DE

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Excelsior, MN

Jenny Blackham

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Donna Booth

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Research Triangle Park, NC

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CECity.com, Inc.
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Teri Breidenbach

Montpelier, VA

Diana Brixner

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Catamaran
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Kim Caldwell

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McKinney, TX

H. Eric Cannon

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NOTES



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