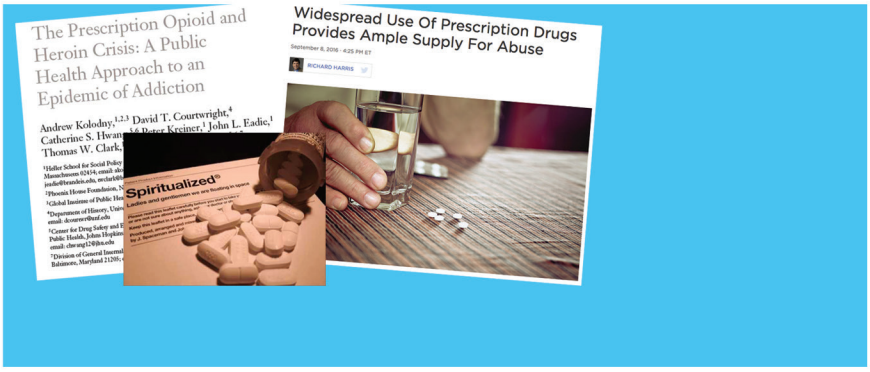
Balancing Access and Use of Opioid Therapy



Challenges Confronting Health Plans, Payers, Prescribers and Others

6th Annual Research Symposium
Monday, October 3, 2016 / 11:00 am - 5:00 pm
Gaylord National Hotel & Convention Center
National Harbor, Maryland

AMCP Academy of Managed Care Pharmacy
FOUNDATION
www.amcpfoundation.org

AGENDA AT-A-GLANCE

11:00	**Welcoming Remarks**
11:15	**Keynote Remarks**
	Overview on Opioid Pain Therapy Misuse and Abuse and Federal Initiatives
11:45	**Audience Discussion and Q&A**
Noon	**Luncheon**
12:45	**Managed Care Pharmacy's Leadership and Opportunities in CARA Implementation**
1:00	**Patient Perspectives & Access to Appropriate Therapy**
1:45	**Prescriber Perspectives, Challenges & Responsibilities**
2:45	**Break**
3:00	**Opioid Use Monitoring Measures**
3:45	**Managed Care and Health Plan Perspectives**
4:30	**Next Wave of Pain Treatment: What Does the Future Hold?**
4:50	**Closing Remarks**
5:00	**Reception** Maryland 4 & 5 Rooms

ABOUT AMCP FOUNDATION

The AMCP Foundation advances collective knowledge on major issues associated with the practice of pharmacy in managed health care, including its impact on patient outcomes. Other Foundation programs that facilitate the application of medication-related research include the *Emerging Trends in Health Care* reports and best poster competitions.

The Foundation cultivates future leaders in the field through immersive experiences for student pharmacists, like our National P&T Competition. The Foundation was established in 1990 as a 501(c)3 nonprofit organization, and is the research and education arm of the Academy of Managed Care Pharmacy (AMCP).

AMCP Academy of Managed Care Pharmacy
FOUNDATION

ABOUT AMCP

AMCP is a national professional association of pharmacists and other health care practitioners who develop and provide a diversified range of clinical, educational, business and medication management services and strategies on behalf of the 200 million Americans covered by a managed care pharmacy benefit. AMCP's more than 8,000 members serve society by the application of sound medication management principles and strategies to improve health care for all.

PROGRAM OVERVIEW

BALANCING ACCESS AND USE OF OPIOID THERAPY: CHALLENGES CONFRONTING HEALTH PLANS, PAYERS, PRESCRIBERS AND OTHERS

About 100 million Americans suffer from chronic pain – more than those living with diabetes, heart disease, and cancer combined, according to the Institute of Medicine. We live in an era where prescription painkillers are more widely used than tobacco, and deaths from opioid misuse and abuse annually exceed the number of individuals killed in traffic accidents. The Centers for Disease Control reports that there were nearly 30,000 deaths related to opioid overdose and abuse in 2014.

In addressing this issue, the AMCP Foundation developed our 6th Annual Research Symposium to provide a forum for representatives of key stakeholders to examine critical areas and strategies to combat and reduce opioid pain therapy misuse and abuse. In keeping with the Foundation's mission of supporting research and education to advance patient care, today's program seeks to share insights and best practices that can:

- Identify effective methods to decrease initiation of opioid pain therapy,
- Assess strategies to utilize appropriate alternative treatments to opioid therapy,
- Promote effective monitoring for potential abuse by patients and prescribers, and
- Assist in effective implementation of CDC Guidelines and CARA (Comprehensive Addiction and Recovery Act) provisions related to opioid medication pain therapy.

As American society and our health care system seek solutions to the challenges of opioid pain therapy misuse and abuse, questions of who is responsible to drive, measure and evaluate progress must be resolved.

The AMCP Foundation encourages active dialogue among presenters and attendees of today's symposium. To further promote awareness of viewpoints expressed today, the Foundation will issue a summary report that includes recommendations for consideration by stakeholders (including payers). This report will be issued in the next several weeks and should assist each stakeholder group in determining their roles and responsibilities.

Finally, with gratitude the AMCP Foundation acknowledges our partners. This program was made possible in part through support from Alkermes, Inc., Optum, Inc., Purdue Pharma L.P., and Teva Pharmaceuticals Industries Ltd.

Paula J. Eichenbrenner, CAE, Executive Director
Ebony S. Clay, Program Manager
Phillip L. Schneider, MA, MS, Senior Consultant, Strategic Initiatives

Alkermes® OPTUM® PURDUE Teva Pharmaceuticals Industries Ltd.

AGENDA

11:00

Welcoming Remarks

Paula J. Eichenbrenner, CAE, AMCP Foundation Executive Director

Brett Norman, Symposium Moderator and POLITICO Health Policy Editor

Brett Norman is a staff writer at POLITICO, covering health care and pharma politics. He has worked as a science writer at Rockefeller University in New York and started his career covering cops, courts and government for the Pensacola News Journal, where he was on a team of reporters twice nominated for the Pulitzer Prize in Public Service. He graduated from the University of Chicago and Columbia University Graduate School of Journalism and lives in Washington with his wife and two sons. Brett is a 2015-2016 Rosalynn Carter Mental Health Journalism fellow.

11:15

Keynote Remarks

OVERVIEW ON OPIOID PAIN THERAPY MISUSE AND ABUSE AND FEDERAL INITIATIVES

Christopher M. Jones, PharmD, MPH, Director, Division of Science Policy, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services (HHS)

Christopher M. Jones currently serves as the Director of the Division of Science Policy in the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services (HHS). The Division serves as the ASPE lead on public health and biomedical science issues and initiatives, including programmatic and policy areas that involve complex or rapidly evolving science and technology. The Division is responsible for policy coordination; long-range planning; legislative development; economic, program, and regulatory analysis; and research and evaluation focused on the HHS science agencies CDC, FDA, NIH, and Office of the Assistant Secretary for Preparedness and Response (ASPR). Dr. Jones has previously served as senior advisor in the Office of Public Health Strategy and Analysis in the Office of the Commissioner at the FDA, led CDC's drug abuse and overdose activities, and served as Senior Public Health Advisor to the White House Office of National Drug Control Policy (ONDCP). Dr. Jones is a nationally recognized expert on drug abuse and overdose and has authored more than 50 peer-reviewed publications on the topic.

11:45

Audience Discussion and Q&A

NOON-12:45

Luncheon

12:45-1:00

MANAGED CARE PHARMACY'S LEADERSHIP AND OPPORTUNITIES IN CARA IMPLEMENTATION

Susan A. Cantrell, RPh, CAE, AMCP CEO and AMCP Foundation Chair

1:00-1:45

PATIENT PERSPECTIVES AND ACCESS TO APPROPRIATE THERAPY

Glenna Crooks, CEO, Strategic Health Policy International, Inc.

Glenna Crooks, Ph.D., is an entrepreneur and innovator. As Founder of Strategic Health Policy International, Inc. she solves tough health care problems for business and government clients globally. Known as a 'one-woman think tank,' she brought significant innovations to the field, earning her recognition as a Disruptive Woman in Healthcare. As founder of BestEdge™ she developed personal strategic plans for C-Suite executives to optimize their personal performance and leadership. Her latest venture is as Founder of SageLife, LLC, a new way to understand, visualize and transform personal, family, career and business networks to achieve greater health, happiness and success. It creates a new approach to understanding burden-of-illness, managing chronic disease and addressing the challenges that lie ahead as an increasingly larger, older population prepares to age-in-place.

She is in demand as a keynote speaker and as confidential counsel to senior government and business leaders, who respect her for the wisdom and candor she offers about the dilemmas they face.

She served as a senior policy advisory in government, appointed by President Ronald Reagan. Later, she was Director of Policy for the American Pharmaceutical Association. During Merck&Co., Inc.'s Most Admired Corporation years, her policy group was recognized as the best in the Fortune 500. She served as Global Vice President of the Merck Vaccine Business. She was Chair of the National Commission on Rare Diseases and received the Congressional Exemplary Service Award for Orphan Products Development. She was the first civilian to receive the highest award for contributions to public health, the Surgeon General's Medallion from C. Everett Koop.

She is a Fellow of the University of Pennsylvania Center for Neuroscience and Society, Fellow of the Drexel University Center for Population Health and Community Impact, Adjunct Professor at the University of the Sciences of Philadelphia, serves on corporate and non-profit Boards and is the author of several books, among them Covenants: Inspiring the Soul of Healing and The Network Sage: Unleashing Your Pit Crew Network Superpower, which will be published later this year.

The Path of Pain: Labyrinth or Maze? There is a difference between a labyrinth and a maze that most people don't appreciate. A maze has dead-ends and blind alleys. As a result, it is possible to get lost in a maze and even, to die. Many people would say that "fits" their experience of pain. Serious acute pain can rob people of any instinct beyond immediate relief. Enduring chronic pain can dead-end in addiction. Intractable pain can test the capacity of patients to endure and their families to witness. Any of those experiences can trigger anger, anxiety, helplessness, grief, fear, disillusionment, social isolation, unemployment, addiction and early death. Once someone is lost in the maze, it is hard to find a way out. It is easy to get stuck.

A labyrinth, on the other hand, is path without dead-ends. Though a traveler in a labyrinth can lose sight of what lies beyond the next turn, those who keep going always arrive at their destination. There is no way to get lost in a labyrinth. The only way to get stuck is to stop. What if pain was a labyrinth rather than a maze? Is there a different way for patients – and those who support their care – to view pain? One that might be more fruitful for everyone?

This session explores the experience of one patient with two types of pain: acute surgical pain and long-term, traumatic-injury chronic pain. It will summarize encounters with both traditional and alternative providers and treatments. It will also explore pain through lessons-learned building three labyrinths, believing the knowledge gained can contribute to an understanding of pain management.

PATIENT PERSPECTIVES AND ACCESS TO APPROPRIATE THERAPY

Cindy Reilly, MS, BS Pharm, Director, PEW Charitable Trusts' Substance Use Prevention and Treatment Initiative

As director of The Pew Charitable Trusts' substance use prevention and treatment initiative, Ms. Reilly works on federal and state initiatives to reduce the inappropriate use of prescription opioids while ensuring patients have access to effective pain management. She also focuses on expanding access to effective treatment for substance use disorders through increased use of medication-assisted treatment.

Prior to joining Pew, Ms. Reilly worked on issues related to the safety and quality of medication use for the American Society of Health-System Pharmacists in Bethesda, Maryland. Areas of focus included the development of clinical policy, dissemination of best practices to improve patient outcomes, and coordination of initiatives aimed at ensuring the availability and integrity of drug products. In this role, she coordinated the society's work in support of rescheduling hydrocodone combination products from Schedule III to Schedule II to improve the safe and appropriate use of those therapies. In addition, she led development of policy that called on clinicians to increase efforts to combat prescription drug abuse while also ensuring patient access to needed pain therapies.

Reilly received her bachelor's degree in pharmacy from Temple University, and her master's degree in global health and medical policy from George Mason University.

Balancing Harm Reduction with Patient Access to Pain Management Therapies: Prescription opioid misuse has had a devastating impact on communities across this country. In 2014, approximately 19,000 people in the United States died from overdoses involving prescription opioids–the highest number of these deaths ever recorded. This alarming statistic has prompted stakeholders from across the medical and policy community to call for immediate action to reduce harms associated with the misuse of these drugs while ensuring that patients still have access to effective pain management. Prescription drug monitoring programs (PDMPs) and patient review and restriction programs (PRRs) are two tools that can help clinicians and drug benefit managers achieve these dual aims. PDMPs are state-run electronic databases that collect information on controlled substances dispensed to patients, and PRRs are insurer-based programs that assign patients who are at risk for drug misuse to predesignated prescribers and pharmacies for their controlled substance needs. PDMPs and PRRs are sometimes mischaracterized as mechanisms that restrict medication access. In fact, these programs provide essential tools to help ensure that patients receive safe and effective pain management therapy. This session will describe current use of these tools to inform prescribing decisions and improve care coordination and identify opportunities to optimize use of these strategies.

1:45-2:45

PRESCRIBER PERSPECTIVES, CHALLENGES & RESPONSIBILITIES

Caleb Alexander, MD, MS, Co-Director of the Center for Drug Safety at Johns Hopkins University

G. Caleb Alexander, MD, MS is an Associate Professor of Epidemiology and Medicine at Johns Hopkins Bloomberg School of Public Health, where he serves as founding Co-Director of the Center for Drug Safety and Effectiveness and Principal Investigator of the Johns Hopkins-FDA Center of Excellence in Regulatory Science and Innovation (CERSI).

The Center for Drug Safety and Effectiveness seeks to improve the safe and effective use of medications by bringing together researchers at Johns Hopkins to accomplish a fourfold mission – training, research, patient care and public service – towards best

medication practices. The CERSI program was created to provide institutions with a valued opportunity to work directly with regulators while simultaneously providing the FDA opportunities for access and exposure to advanced scientific exchange and training focused on the FDA's priority areas.

Alexander is a practicing internist and pharmacoepidemiologist and is internationally recognized for his research examining prescription drug utilization, safety and effectiveness. Dr. Alexander received his B.A. cum laude from the University of Pennsylvania, an MD from Case Western Reserve University, and a Master of Science from the University of Chicago.

Prescription opioids are essential medicines for relieving suffering at the end of life as well as for the treatment of acute pain and pain associated with active cancer. However, a sharp increase in opioid prescribing for chronic, non-cancer pain during the past two decades has been associated with large increases in opioid addiction and overdose deaths in the United States. In many clinical settings, clinicians and patients have overestimated the effectiveness of opioids and underestimated their risks. The two most important things that clinicians can do to reduce opioid-related injuries and death are to prescribe opioids more judiciously and to improve the identification and treatment of the millions of Americans with opioid addiction. Fortunately, an increasing number of evidence-based guidelines are available to help clinicians and patients reduce our historic overreliance on prescription opioids. While risk mitigation measures, such as urine toxicology screening, patient contracts, and risk assessment tools, are also increasingly popular, they remain a limited means to improve the risk-benefit balance of these products for many patients. Abuse deterrent formulations are also promising yet problematic, since they are no less addictive, patients and providers may have may have misconceptions regarding their safety, and most non-medical use occurs orally. Efforts to improve the risk-benefit balance of opioids have raised concern on the part of some that there will be untoward effects on those with pain. These are understandable concerns, however, there is no conflict between reducing the overuse of opioids in clinical practice and improving the quality of care for those in pain.

PRESCRIBER PERSPECTIVES, CHALLENGES & RESPONSIBILITIES

Kathryn Cates-Wessel, Executive Director, American Academy of Addiction Psychiatry & Principal Investigator and Project Director, Providers Clinical Support System for Medication Assisted Treatment and Providers Clinical Support System for Opioid Therapies

Kathryn Cates-Wessel has more than 30 years background in the substance use disorder field in administration, medical education, and policy. She is Executive Director of the American Academy of Addiction Psychiatry and Principal Investigator and Project Director for PCSSMAT and PCSSO grants. Prior to her work at AAAP, she was Associate Director of Brown University's Center for Alcohol and Addiction Studies for over 19 years and Executive Director of Physicians and Lawyers for National Drug Policy a think tank of leaders from law and medicine advocating for prevention/treatment over incarceration and earlier Director of Administration for Five Oaks Residential Treatment Center for adolescents with substance use and mental disorders.

This workshop will provide an overview of two SAMHSA-funded projects that provide education/training and mentoring resources for all health professionals on the evidence-based clinical practices in the prevention, identification, and treatment of substance use disorders with a primary focus on opioid use disorders. Providers' Clinical Support Systems for Medication Assisted Treatment (www.pcssmat.org) focuses on the FDA-approved medications used to treat opioid use disorder. Providers' Clinical Support System for Opioid Therapies (www.pcss-o.org) focuses on the interface of chronic pain and opioid use disorders.

American Academy of Addiction Psychiatry is the lead organization in collaboration with American Medical Association (AMA), American Dental Association (ADA), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Psychiatric Association (APA), American Osteopathic Academy of Addiction Medicine (AOAAM) and other key national professional organizations. Collectively these organizations represent more than one million health professionals, provide online modules, webinars, and other educational resources on evidenced based approaches to prevention, identification and treatment of substance use disorders with an emphasis on opioid use disorders. This workshop will provide an overview of the vision of the project, lessons learned and future plans for the project. The presenter will provide information about key components of both projects, showcasing the educational resources available to the general public via website portals and detailing the free mentoring/coaching program that allows primary care providers direct access to clinical experts in addiction psychiatry and addiction medicine. Presenter will highlight key educational activities developed through the grant and share outcomes data with workshop attendees.

PRESCRIBER PERSPECTIVES, CHALLENGES & RESPONSIBILITIES

Corey Waller, MD, MS, FACEP, DFASAM, American Society of Addiction Medicine

R. Corey Waller is an addiction, pain, and emergency medicine specialist and the Senior Medical Director for Education and Policy at the Camden Coalition of Healthcare Providers (CCHP). Before joining CCHP he worked for the Spectrum Health System in Grand Rapids, Michigan, which is a fully integrated health system with 11 hospitals and over 1000 employed physicians. He was the Medical Director of the Spectrum Health Medical Group Center for Integrative Medicine, the Medical Staff Chief of Pain Medicine to the Spectrum Health Hospital System, the President of the Michigan Society of Addiction Medicine, as well as SUD Medical Director at Lakeshore Regional Partners (Community Mental Health-Region 3).

Dr. Waller earned a Master's of Science in neuromolecular biology at Southwest Texas State University and earned his Medical Degree at the University of Texas Medical School in San Antonio. Dr. Waller completed his Emergency Medicine residency at Thomas Jefferson University in Philadelphia and is board Certified in Emergency Medicine and Addiction Medicine.

In the current environment, of opioid overdose being the leading cause of injury related deaths in the US, there can be a lot of preconceived notions about the utilization of opioids for the treatment of both acute and chronic pain. Along with this the prescribing habits of providers differ widely and in many ways are not connected to patient improvement or outcomes. He will discuss ways that changes in formulary, improvement in pharmacy based screening and closer collaboration with providers can improve patient safety and decrease diversion. His presentation will address his special interests, such as creating a comprehensive workforce development suite for the care of complex high cost patients, understanding the biopsychosocial and financial impact of high cost complex patients as well as the unique interaction of pain and addiction.

2:45-3:00

Break

3:00-3:45

OPIOID USE MONITORING MEASURES

Philip Burgess, RPh, National Association of Boards of Pharmacy

Phil Burgess currently holds numerous leadership positions within the pharmacy community. He has been the President of the Community Pharmacy Foundation since its inception in 2002, on the Executive Committee of the National Association of Boards of Pharmacy, and serving his 15th year on the Illinois State Board of Pharmacy (5 terms as Chairman). After 40 years at Walgreens holding numerous corporate management positions including National Director of Pharmacy Operations and National Director of Pharmacy Affairs, he founded Philip Burgess Consulting in 2009. His company is primarily focused on assisting in regulatory changes that maximize the use of technology to improve patient care.

His various honors include receiving the NACDS Harold Pratt Lifetime Achievement Award, the Operation PUSH Unity Partner Award and being selected as APhA's Honorary President for 2017.

Past activities include serving on the Presidential Advisory Council on HIV/AIDS during the Clinton and Bush Administrations, the National Board of Directors of the Human Rights Campaign, APhA's representative on the HIT Advisory Board, and the Pharmacy e-Health Information Technology Collaborative. His pharmacy degree is from the University of Tennessee and received his MBA from the University of Chicago.

Prescription drug abuse is a serious, complex problem in America. To help address the issue, 49 states and the District of Columbia have enacted prescription monitoring programs (PMPs). These programs collect prescription data for controlled substances and provide that information to both prescribers and pharmacists. By providing this data in a readily available format, it assists these health care professionals in treating their patients as well as attempt to curb potential prescription drug abuse, misuse, and diversion.

Although each program is created by specific state legislation and rules/regulations, the programs are very much alike. All collect the same core information: date of dispensing, dispenser identity, drug identity and quantity, patient identity, and prescriber identity. And, all states utilize a similar format for pharmacies to report the data. More than half of the states require (or will soon require) data to be reported daily.

Thirty-three (33) states now have mandatory access provisions – a statute, rule, or board policy that requires a prescriber or dispenser to query the PMP for information regarding their patient in certain circumstances. The circumstances vary from state to state according to different state challenges, programs, and resources.

As states continue to develop resources to address prescription drug abuse, PMPs provide essential drug history information to prescribers and pharmacists to support their evaluation and treatment decisions for their patients. Practitioners are encouraged to intervene with patients under their care to avoid or abate future drug misuse, abuse, or potential addiction. Pro-active action by prescribers can play a critical role in preventing this path to addiction.

OPIOID USE MONITORING MEASURES

Daniel Raymond, VP Policy, Harm Reduction Coalition

Daniel Raymond is the Policy Director of the Harm Reduction Coalition, a national advocacy and capacity-building organization that promotes the health and dignity of people who use drugs and their communities. Harm Reduction Coalition focuses on policies, practices and programs that address the health effects of drug use, including overdose, HIV/AIDS and hepatitis C, and substance use disorders.

Daniel has worked in the field of harm reduction for over two decades. His extensive experience spans direct service in syringe access to advocacy for drug user health, overdose prevention and hepatitis C treatment access. In his capacity as Harm Reduction Coalition's Policy Director, Daniel works with federal and state officials, advocates, and providers to expand critical drug user health interventions, including overdose education and naloxone distribution, syringe access programs, medication-assisted treatment, HIV and hepatitis C care and treatment, and quality health care for people who use drugs. He is based in New York City.

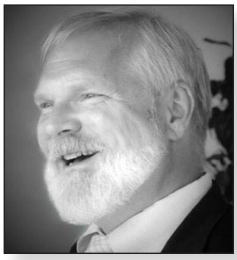
Opioid safety and the role of naloxone: Prescription opioids have inherent risks and have been implicated in a dramatic increase in drug poisonings and overdose deaths. A number of predictors of opioid overdose risk have been identified, including higher doses and concomitant use of benzodiazepines. In the context of this greater recognition and policy focus on opioid overdose risk, the co-prescription of the opioid antagonist naloxone has received increasing attention as a risk mitigation strategy. New guidelines for use of opioids for chronic pain from the Centers for Disease Control and Prevention have endorsed consideration of naloxone co-prescribing for opioid patients at elevated risk, and professional groups including the American Medical Association have also promoted expanded access to naloxone.

This presentation will provide a review of the role of naloxone in reducing opioid overdose mortality, including the context and history for growing interest in naloxone co-prescribing. The discussion will review the role of initiatives to train and equip laypersons – including friends and family – with naloxone, recent developments to increase pharmacy access to naloxone, and interest from manufacturers and regulators in the development of new devices and strategies to expand access. Insights and examples for incorporating naloxone co-prescribing into clinical practice to increase opioid safety will also be shared.

3:45-4:30

MANAGED CARE AND HEALTH PLAN PERSPECTIVES

Tracy Mayne, PhD, Executive Medical Director, Purdue Pharma



Tracy J. Mayne, PhD received his doctorate in clinical health psychology from Rutgers University and completed his clinical training in the Psychiatry Residency Program at the University of California – San Francisco.

He went on to a research fellowship at the Institut National de la Santé et de le Recherché Medical where he designed and executed the first national study of HIV among injection drug users in France. Upon return to the US, Dr. Mayne served as the Director of HIV Epidemiology and Surveillance at the New York City Department of Health.

Dr. Mayne joined the pharmaceutical industry at Pfizer, where he launched Bextra, served as economic lead for the Celebrex/Bextra portfolio, then become the economic lead for Lipitor. He next joined Amgen and became the Global Renal Anemia Lead for Epogen/Aranesp, also supporting the launches of Kepivance and Vectibix. Dr. Mayne spent the following decade in pharmaceutical consulting, ending as the

vice president of Covance Market Access. He returned to the industry as Head of Medical Affairs Strategic Research at Purdue Pharma.

Dr. Mayne has over 40 peer-reviewed publications and has authored books on clinical psychology, health and emotion. Dr. Mayne has received several awards for his work, including:

- Hyacinth Foundation President's award for outstanding service to people with AIDS
- Society for Behavioral Medicine award for outstanding research
- New York City Department of Health award for community and collaborative research
- Amgen "Fulcrum" award for successfully defending quality of life claims in the EPOGEN label
- DaVita "It takes a Village" award for top sales
- Association for the Advancement of the Study of Liver Disease President's Award for innovative research

Healthcare in the US is evolving rapidly. The role between payer and provider are blurring or disappearing. Pharma's role as a drug developer, manufacturer and distributer is changing into one of partner in advancing disease management. This talk will highlight 3 initiatives demonstrating ways in which Purdue Pharma is partnering with payers and physicians to advance pain treatment and fight opioid abuse.
The first study involves the creation of an atlas of treatment patterns, characterizing the prescribing of extended release opioids in the U.S. These data allow payers to better understand normative treatment patterns, with a goal of eventually identifying potentially aberrant prescribing and utilization patterns as early warning signs of abuse.

The second study characterizes healthcare resource utilization leading up to and following an initial opioid abuse diagnosis. While intended as an economic study, feedback from payers provided insight that the data might be used as a way to predict and prevent an opioid abuse episode. The third study is a collaboration between Pharma and an integrated delivery network to develop and test wearable technology as a way to improve pain treatment and outcomes. If successful, this work has the potential to change the paradigm of chronic pain treatment.

MANAGED CARE AND HEALTH PLAN PERSPECTIVES

David Calabrese, RPh, MHP, OptumRx, VP & Chief Pharmacy Officer

David Calabrese is Vice President and Chief Pharmacy Officer for OptumRx, the nation's 3rd largest Pharmacy Benefit Manager (PBM), serving over 66 million lives across multiple lines of business. At OptumRx, David maintains executive level oversight and strategic accountability for several of the organization's clinical programs and services, including but not limited to Clinical Account Management; Pharmacy & Therapeutics Committee activity; and overall Clinical Strategy. Calabrese comes to OptumRx through its acquisition of Catamaran, a large national PBM based in Chicago, where he also served as Chief Pharmacy Officer since 2011. Prior to that, he served as Chief Clinical Officer at MedMetrics Health Partners, a small regionally-based PBM in Massachusetts.

Calabrese's career spans over 28 years in managed care clinical pharmacy leadership including roles at Harvard Pilgrim Health Care, a large, regionally-based non-profit health plan, and with CareGroup, an integrated healthcare system, both in Boston, MA.

Calabrese holds both a Bachelor's degree in Pharmacy and a Master's degree in Health Professions from Northeastern University, where he currently maintains academic appointment as Assistant Clinical Professor in NU's Bouvé College of Pharmacy and Allied Health Sciences.

He is an active member of several professional organizations including AMCP where he has served in various leadership positions. He also maintains a role as Clinical Editor of the healthcare industry journals,

FormularyWatch and Managed Healthcare Executive and serves as an editorial advisory board member for various other key industry publications. Calabrese speaks at numerous forums and is published on a variety of topics pertaining to pharmacy management in managed health care.

The prescription opioid abuse epidemic today represents one of the most significant and most challenging health care crises in our nation's history. So dramatic is this problem that in 2014, drug overdose overtook automobile accidents as the leading cause of accidental death in the U.S, according to the CDC. The death toll however tells only half the story. According to the national data, an additional 4.5 million Americans are estimated as being addicted to opioid prescription pain relievers.

Unlike previous healthcare emergencies which have impacted the US, the prescription opioid addiction issue is unique for several reasons. Foremost, it does not discriminate by race, ethnicity, gender, age or socioeconomic status. Secondly, its death toll is amongst the highest of any nation in the world and the trend rate continues to get worse each year. Lastly, and most disturbingly, it is an epidemic that has been brought about by the primarily well-intentioned, yet tragically misguided efforts of our own healthcare system.

With this crisis being of a highly multidimensional nature, most would agree that is also requires a well-coordinated, multi-stakeholder solution. As accountable parties in this crisis, our nation's health plans and pharmacy benefit managers are at the same time in a very unique position to help develop and lead with much needed, market-disruptive strategies that will drive positive change in this area and ultimately save lives.

During this session, we will share at, a high-level, our "Five for Life" approach in which we break down effective, end-to-end opiate abuse management into five primary domains. These include:

1. Upfront education and prevention
2. Minimizing early exposure
3. Vigilant prescriber and pharmacy surveillance
4. 'High-risk' patient identification and intervention
5. Appropriate support and management of the afflicted

MANAGED CARE AND HEALTH PLAN PERSPECTIVES

Penny Mohr, MA, Senior Program Officer, Improving Healthcare Systems Patient Centered Outcomes Research Institute (PCORI)

Penny Mohr, MA is Senior Program Officer for the Improving Healthcare Systems (IHS) group, at PCORI, where she provides scientific leadership and oversight for the IHS portfolio. While at PCORI, she has played an active leadership role in developing a research agenda addressing improved strategies to manage chronic pain and prevent unsafe opioid prescribing.

Before joining PCORI, she was the Senior Vice President for Program Development at the Center for Medical Technology Policy (CMTP), where she led initiatives to expand the use of pragmatic clinical trial designs, merge approaches to adaptive licensing with coverage with evidence development, and refine approaches to match appropriate research methods for specific comparative effectiveness research questions. Mohr also was Director of the Division of Research on Health Plans and Drugs at the Centers for Medicare and Medicaid Services (CMS) with responsibility for the oversight of demonstration evaluations pertaining to Medicare Part C and Medicare Part D. Before working at CMS, she was a Senior Research Director at Project HOPE's Center for Health Affairs, where she pursued longstanding interests in medical technology policy.

Mohr has over 30 years experience in health services research using diverse qualitative and quantitative methods. She has published widely on a variety of health services research topics. Mohr received a Master's

degree at the University of Sussex, England where she studied economics. She serves on the editorial board of the Journal of Comparative Effectiveness Research and the American Journal of Managed Care, and is a former board member of the International Society for Pharmacoeconomics and Outcomes Research.

The Patient-Centered Outcomes Research Institute is an independent, non-profit organization created by the Affordable Care Act to fund comparative clinical effectiveness research.

One of our mandates is to work with stakeholders to identify national priorities for research and establish a research agenda in those areas. Members of our governing board and payers, as well as friends and family members who lost someone to prescription opioid abuse, patients with chronic pain, and state and federal policymakers, identified clinical strategies to better manage opioid use for treatment of pain as an important area that warranted further research. Health systems have been experimenting with a wide variety of strategies to prevent opioid-related harms. However, robust evaluation is often lacking, as well as understanding the impact of these programs on patient pain management as well as other patient outcomes.

To fill these gaps in evidence, PCORI has dedicated nearly $70 million over the last two years to fund multiple large, pragmatic studies that address two major areas of interest: the initial prevention of unsafe prescribing for potential users of opioids and the clinical management of chronic pain patients on long-term opioid use. Research funded under both initiatives must strike a balance between minimizing opioid dependence, risk and harm, and helping patients effectively manage their pain. I provide an overview of PCORI-funded work in this area, our ongoing initiatives, and some of the challenges faced in implementing and sustaining health systems changes to address this issue.

4:30-4:50

NEXT WAVE OF PAIN TREATMENT: WHAT DOES THE FUTURE HOLD?

Peggy Compton, RN, PhD, FAAN, Professor, Associate Dean for Research, Evaluation and Graduate Programs and Interim Chair, Department of Advanced Nursing Practice, Georgetown University School of Nursing & Health Studies

Dr. Compton is Professor and Associate Dean of Research, Evaluation and Graduate Studies at the Georgetown University School of Nursing and Health Studies, and a Fellow of the American Academy of Nursing. Her areas of clinical expertise are opioids, addiction and pain. She has published extensively in the scientific literature on addiction in chronic pain patients on opioid therapy, and the pain responses of opioid addicts with and without chronic pain. Having worked in several public treatment settings, she is especially expert in the use of methadone, buprenorphine and naltrexone in the treatment of addiction. She has served on FDA, SAMHSA and NIH expert panels on prescription opioid abuse, and contributed to position statements from the American Pain Society, College on Problems of Drug Dependence, and the American Society of Pain Management Nurses on pain management for patients with addictive disease. She currently serves as principal investigator on an NIDA-supported grant exploring hyperalgesic responses in individuals undergoing opioid taper.

Treating Chronic Pain with Opioids: Where Are We? Chronic nonmalignant pain is highly prevalent in the US, and rates are only expected to increase as the population ages. It is estimated that up to 8 million individuals are taking opioid analgesics on a regular basis for the treatment of chronic pain. Chronic pain engages different brain systems than acute pain, and affective and cognitive components predominate over tissue injury, thus medications are less likely to be effective.

The CDC has recently released Guidelines for Prescribing Opioids for Chronic Pain which build upon recommendations from previous guidelines by the American Pain Society, the American Academy of

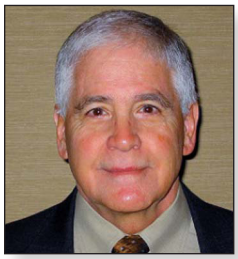
Pain Medicine, DOD/VA and the American Society of Pain Management Nurses. Consistent across all guidelines is the recommendation to assess pain to determine if opioids are indicated. In the assessment process, clinicians are encouraged to utilize published risk assessment tools to determine the likelihood for a poor treatment response (including misuse, abuse, overdose), and consider using published adherence monitoring tools, urine toxicology and prescription monitoring programs to mitigate risk. In preparing their recommendations, the CDC posed the following questions: what is the accuracy of instruments for predicting risk for opioid overdose, addiction, abuse or misuse; the effectiveness of risk mitigation strategies; the effectiveness of risk management strategies; and comparative effectiveness of treatment strategies for managing patients with addiction.

A detailed meta-analysis of the literature reveals insufficient evidence to provide answers to these questions or to support the recommendations; in fact, data suggest that all cited risk assessment tools have low validity. The CDC Guidelines have raised discussions about "responsible opioid prescribing" and "opioid-sparing strategies," bringing the concomitant benefit of refocusing treatment on non-opioid and non-medication interventions for chronic pain.

4:50-5:00

Closing Remarks

Allan J. Chernov, M.D., Medical Director, Medical Policy and Quality, Blue Cross and Blue Shield of Texas, and President, AMCP Foundation



Dr. Allan Chernov, an internal medicine specialist, is Medical Director, Medical Policy and Quality, for Blue Cross and Blue Shield of Texas (BCBSTX). Dr. Chernov is responsible for medical policy. In this role he works with medical directors from the Blue Cross and Blue Shield plans of Illinois, New Mexico and Oklahoma on development and maintenance of medical policies for Health Care Service Corporation (HCSC). He also supports BCBSTX quality improvement initiatives, peer review for provider credentialing and recredentialing, and pharmacy programs.

Born and educated in Vancouver, British Columbia, Canada, Dr. Chernov received his doctor of medicine degree there in 1964 at the University of British Columbia. He completed a rotating internship and three-year internal medicine residency at the University of Michigan in Ann Arbor. He served in the U.S. Navy from 1966 to 1968 as a general medical officer attached to the Marine Corps Base at Camp Pendleton, California.

Dr. Chernov was in private general internal medicine practice in San Francisco for 13 years. In 1985, he left direct clinical practice to become Vice President Medical Affairs/Medical Director for Bay Pacific Health plan, an IPA-model HMO based in San Bruno, California. He has worked as a physician for health plans since that time, and joined BCBSTX in November 2001. Prior to that, following his stint at Bay Pacific Health Plan, he was Vice President Medical Affairs at PHP Minnesota (then Medica, then Allina) in Minnetonka, Regional Medical Director for Prudential Healthcare's Southwest Group Operations in Houston and Southwest Regional Medical Director for Aetna U.S. Healthcare in Dallas. He has an active medical license in Texas. He is certified and re-certified by the American Board of Internal Medicine.

5:00-6:00

Reception

AMCP FOUNDATION SPEAKERS

Susan A. Cantrell, RPh, CAE, AMCP CEO and AMCP Foundation Chair

Susan Cantrell became CEO of the Academy of Managed Care Pharmacy (AMCP) in February 2016. Previously in her career, Susan was Senior Vice President and Managing Director, Americas for the Drug Information Association (DIA), an 18,000-member global society of professionals involved in the development and life-cycle management of pharmaceuticals and other medical products. She was responsible for the development and implementation of DIA's strategy in North, Central, and South America.

Before joining DIA, Susan was Vice President of Resources Development at the American Society of Health-System Pharmacists (ASHP), where she worked for 19 years in a series of progressively responsible positions. While at ASHP, she helped launch ASHP Advantage and build ASHP's online learning enterprise. Under her leadership, ASHP became the only pharmacy association accredited by the Accreditation Council for Continuing Medical Education as a provider of continuing medical education for physicians.

Susan is a graduate of the University of Mississippi College of Pharmacy and she completed an ASHP-accredited hospital pharmacy residency program at University of Mississippi Medical Center, as well as a Certificate in Public Health from the University of North Carolina. A registered pharmacist and former hospital and home care pharmacy administrator, she has extensive experience in pharmacy leadership, medical education, health policy and regulation, and nonprofit association management. She is a Certified Association Executive (CAE) and an active member who has served in a number of volunteer leadership positions in AMCP, ASHP, the American Society of Association Executives, and the International Pharmaceutical Federation.

Paula J. Eichenbrenner, CAE, Executive Director, AMCP Foundation

Paula J. Eichenbrenner was appointed Executive Director of the Academy of Managed Care Pharmacy (AMCP) Foundation in November 2015. In this capacity, she partners with the Board of Trustees to provide strategic leadership for the AMCP Foundation, the Academy's philanthropic and educational arm. Prior to joining the AMCP Foundation, Ms. Eichenbrenner held leadership roles at the American Society for Nutrition/ASN Foundation and the Council for Affordable and Rural Housing. She has been recognized with numerous industry distinctions, including the Association Forum/USAE 40 Under 40 in Non-Profit Management Award.

Eichenbrenner is a Certified Association Executive (CAE) with fundraising and public affairs experience in diverse non-profit settings including trade associations, professional societies and foundations. An honors graduate of Tulane University, she is currently pursuing a Master's in Business Administration from Virginia Tech. She is a member of the American Society of Association Executives (where she serves on the Ethics Committee), the Association of Fundraising Professionals and the Association Foundation Group. Additionally, Paula serves on the Newcomb College Institute Director's Advisory Council.

ADDITIONAL MATERIALS PROVIDED TO SYMPOSIUM ATTENDEES WILL INCLUDE READING LIST, PROGRAM RESOURCES, PARTICIPANT ROSTER, EXECUTIVE SUMMARY AND SYMPOSIUM REPORT. VISIT WWW.AMCPFOUNDATION.ORG

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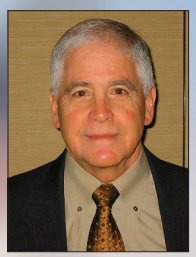

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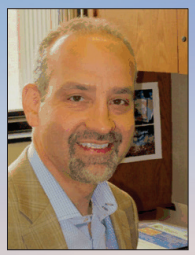

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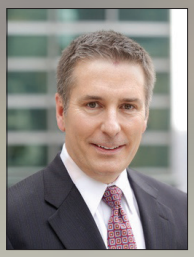

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Start training now for the AMCP Foundation's next race during the AMCP Managed Care & Specialty Pharmacy Annual Meeting in Denver, March 27–30, 2017!

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