Dealing with Drugs: Ethical, Legal, and Policy Issues
From the Opioid Epidemic to Budget-Busting Blockbuster Drugs
Annual Medical Ethics Conference – 2018

Friday, March 23, 2018 | 8:30 am – 4:30 pm
Scaife Hall – 11th Floor Conference Center
University of Pittsburgh

Ira R. Messer Lecture:
Combatting the High Price of Drugs: What does patient empowerment have to do with it?
Peter A. Ubel, MD
Madge and Dennis T. McLawhorn University Professor
Duke University

Plenary Lecture:
The Role of Healthcare Financing in Causing (and Curbing) Opioid Abuse
Valarie Blake, JD, MA
Associate Professor of Law
West Virginia University

Keynote Lecture:
Pain Management and Subjectivity in a Climate of Distrust: The case of opioid contracts
Daniel Z. Buchman, MSW, PhD
Bioethicist, University Health Network
Assistant Professor, Dalla Lana School of Public Health
University of Toronto

Co-Sponsored by:
Ira R. Messer Fund of the Pittsburgh Foundation
Consortium Ethics Program, Center for Bioethics & Health Law, University of Pittsburgh
Master of Arts in Bioethics Program, University of Pittsburgh
Schools of Dental Medicine, Law, Medicine, and Social Work of the University of Pittsburgh
School of Medicine Center for Continuing Education in the Health Sciences, University of Pittsburgh
Year of the Healthy U of the University of Pittsburgh
Center for Ethics & Policy, Carnegie Mellon University
CONFERENCE ABSTRACT AND OBJECTIVES
This conference will explore the diverse roles drugs play in the health of individuals and the social and economic “health” of communities and American society. Speakers from the University of Pittsburgh and five other institutions will address ethical, legal, and policy issues associated with myriad uses and users of drugs.

Drug use, particularly the opioid epidemic, threatens the health and well-being of entire regions, communities, families, and individuals. Addressing the epidemic requires action at multiple levels from individual provider practices to state and national policies. At each level, ethical and legal issues arise. Two plenary lectures will address these issues, with Daniel Buchman (University of Toronto) focusing on the provider-patient relationship and Valarie Blake (West Virginia University) addressing systemic issues of healthcare financing and regulation. Issues regarding the opioid epidemic will be pursued in one “track” within the conference’s afternoon breakout sessions.

Simultaneously, blockbuster (and budget busting) new drugs promise life-saving and quality-of-life enhancing benefits to patients suffering from chronic and acute conditions, but threaten the fiscal viability of our healthcare system. Peter Ubel (Duke University) will give the annual Ira R. Messer Lecture and will explore the relevance of patient empowerment for combating high drug costs. The pharmaceutical industry’s social roles indeed raise ethical concerns about the health of our research and regulatory infrastructures and about transparency within the provider-patient relationship. A breakout session with George Loewenstein (Carnegie Mellon University) will discuss providers’ conflicts of interest and the effects of disclosing them on the provider-patient relationship.

Other breakout sessions will address issues associated with drugs for which scientific evidence and best practices are evolving. Pennsylvania has recently legalized the medical use of marijuana to improve patients’ quality of life. This legislative action raises legal and ethical questions for providers who, while waiting for the evidence to catch up to practice and for federal and state authorities to resolve policy differences, seek to provide compassionate care for severely ill patients who may benefit from medical marijuana. Pharmacogenomics (PGx) is at the forefront of precision medicine. While PGx is often considered to present far fewer ethical concerns than other aspects of genomic medicine, PGx offers an opportunity to consider at an early stage the ethical and policy questions that will be faced by patients, providers, and healthcare systems when precision medicine is more fully implemented. Ethical and policy issues associated with adherence to treatment regimens will be addressed in the contexts of both cancer and addiction treatment, while David Kappel and Valerie Satkoske (West Virginia State Trauma System and West Virginia University, respectively) will discuss development of ethical policy to guide valve replacement practices for patients with opioid use disorders who develop infected heart valves.

Following the conference, participants will be able to:

• outline ethical, legal, and policy-related factors associated with the opioid epidemic’s development and interventions proposed to address it
• explain ethical and policy issues associated with drugs/drug-related interventions for which scientific evidence and best practices are evolving
• articulate ethical and policy challenges associated with the high cost and other burdens of drugs and other therapeutic interventions, including issues of adherence, access, and affordability

The 27th Annual Medical Ethics Conference
Providing attendees with an opportunity to learn from national and local experts about pressing medical ethics issues, the Center’s annual Medical Ethics Conference features morning plenary lectures with ample time for discussion and afternoon breakout sessions. This course is designed for clinicians and investigators, lawyers, clergy, community members, and students of the humanities and health and social sciences.
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<th>Time</th>
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<td>8:00 – 8:30 am</td>
<td>Registration and Continental Breakfast</td>
<td>Scaife Hall – 11th Floor</td>
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<td>Conference Center – Foyer</td>
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<td>8:30 – 8:35 am</td>
<td>Welcome</td>
<td>Room 1105 A/B/C</td>
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<td>Lisa S. Parker, PhD*</td>
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<td>8:35 – 9:50 am</td>
<td>Combatting the High Price of Drugs: What does patient empowerment have to do with it?</td>
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<td><strong>Abstract:</strong> Free market enthusiasts think that empowering patients to act as healthcare consumers will lower the cost, and raise the quality, of healthcare. But how does such “empowerment” play out at the bedside, and what are the ethical implications of asking patients to tackle healthcare costs?</td>
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<td>9:50 – 10:00 am</td>
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<td>10:00 – 11:00 am</td>
<td>The Role of Healthcare Financing in Causing (and Curbing) Opioid Abuse</td>
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<td><strong>Abstract:</strong> The 2016 Comprehensive Addiction and Recovery Act failed to address an important feature of the American sociocultural context of the opioid epidemic: health insurers. Insurers play critical gateway roles in enabling both addiction and its treatment, and they bear many of the economic costs of the epidemic. The public and policy makers should be interested in how insurers undertake to address opioid addiction and should employ regulatory measures to maximize social and health benefits while avoiding unintended, but foreseeable negative consequences.</td>
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<td>11:00 am – 12:10 pm</td>
<td>Pain Management and Subjectivity in a Climate of Distrust: The case of opioid contracts</td>
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<td><strong>Abstract:</strong> North America is in the grips of an epidemic of opioid-related morbidity and mortality. Opioids are frequently prescribed for chronic pain, and both pain and opioid use are highly stigmatized. One clinical strategy to reduce the various harms associated with prescribed opioids is the use of opioid</td>
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contracts. Opioid contracts are widely implemented and outline the conditions patients must agree to in order to receive controlled opioids. In this presentation, I review the empirical research on opioid contracts and describe the moral arguments in favor of and against their use. I argue that opioid contracts reflect tensions surrounding the role of subjective knowledge in pain management, uncertainties about addiction, and the trustworthiness of people in pain. I argue that the use of opioid contracts may not only intensify stigma but also facilitate what Miranda Fricker calls epistemic injustice. I discuss a potential role for epistemic humility, as a form of epistemic justice, which may help promote more responsive and collaborative care plans and help all parties place trust wisely in pain management encounters.

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<th>12:10 – 1:00 pm</th>
<th>Lunch on your own</th>
<th>PUH Cafeteria is adjacent to the Conference Center</th>
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1:00 – 2:00 pm  | Concurrent break-out sessions #1 – 3 |

**Session #1**  
Policy Challenges in Expanding Access to Opioid Addiction Treatment  
*Julie M. Donohue*, PhD**  
Professor and Vice Chair for Research Department of Health Policy and Management, Co-Director of the Center for Pharmaceutical Policy and Prescribing (CP3)  
University of Pittsburgh  
Room on 11th floor TBD

**Abstract:** The US opioid epidemic has focused attention on the inadequate supply of high-quality addiction treatment providers. Policy levers aimed at expanding access can sometimes exacerbate underlying quality problems. This session will review the current landscape of addiction treatment financing and delivery systems. The discussion will focus on ethical and clinical challenges facing policy makers and regulators seeking to expand treatment access.

**Session #2**  
Medication Adherence in the Era of Expensive Oral Cancer Therapy  
*Walid Gellad*, MD, MPH  
Associate Professor of Medicine and Health Policy  
Director, Center for Pharmaceutical Policy and Prescribing (CP3)  
University of Pittsburgh  
Room on 11th floor TBD

**Abstract:** As therapy for cancer increasingly transitions from hospital- or clinic-administered chemotherapy to oral therapy administered at home, the problem of medication non-adherence becomes more challenging. This challenge is accentuated as the costs of these therapies have increased. Ethical and policy issues around medication adherence to expensive oral therapies will be discussed.

**Session #3**  
Smoke Signals: Navigating medical marijuana, compassionate care, and evidence based practice in a conflicted landscape  
*Jack Rozel*, MD, MSL**  
Room on 11th floor TBD
### Abstract:
Medical marijuana is imminently available in Pennsylvania as it already is in most states. At the same time, the US Attorney General is authorizing US Attorneys to pursue criminal investigations and charges against medical marijuana programs. Against this backdrop, while waiting for the evidence to catch up to practice, front line providers are faced with the challenges of providing compassionate care for severely ill patients who may benefit from medical marijuana. Potential adverse effects of medical marijuana in psychiatric patients and developing adolescents remain an open question. This session will explore some of these conflicts and the legal and ethical challenges that providers and health care systems are currently navigating.

#### Session #4
**How to Save a Life: The ethical and practical considerations of access and interventions addressing the opioid epidemic**
John A. Libonati
Mercer County Coroner

* Alyson D. Stover, MOT, JD, OTR/L, BCP
  Assistant Professor
  University of Pittsburgh

**Room on 11th floor TBD**

#### Abstract:
As we identify new and emergent ways to work with individuals with opioid use disorder, many novel issues arise related to the administration of and access to these interventions. This panel will address the issues surrounding the use of naloxone by the public and emergency medical professionals, as well as non-pharmacological follow-up care options. Additionally, it will discuss the implications of policy for the delivery of these treatments and the disparity of distribution based on geographical location.
Herbert A. Simon University Professor of Economics and Psychology
Carnegie Mellon University

Abstract: This talk will discuss diverse research showing that disclosing conflicts of interest can have perverse effects, decreasing trust in advice but increasing pressure to comply with it. However, disclosure can also have beneficial effects when providers can eschew conflicts and, with the option of disclosure, reveal that they have “nothing to disclose.”

Session #6
Ethical and Policy Challenges for Pharmacogenomics, Lessons for Precision Medicine
Lisa S. Parker, PhD*
Professor of Human Genetics
Director, Center for Bioethics & Health Law
University of Pittsburgh

Abstract: While pharmacogenomics is often considered to present far fewer ethical concerns than other aspects of genomic medicine, pharmacogenomics offers an opportunity to consider at an early stage the ethical and policy questions that will be faced by patients, providers, pharmaceutical researchers, and healthcare systems as precision medicine is more fully implemented. These questions will be explored with particular attention to who stands to benefit and who may be less well-served as populations are stratified with regard to genotypes associated with differential drug response.

3:10 – 3:20 pm
Break
Foyer

3:20 – 4:20 pm
Concurrent break-out sessions #7 & 8

Session #7
New Issues for New Moms: Challenges in managing perinatal substance use in the midst of the opioid crisis
Jody B. Glance, MD
Assistant Professor of Psychiatry
University of Pittsburgh
Medical Director, Addiction Medicine Services, Western Psychiatric Institute and Clinic of UPMC

Priya R. Gopalan, MD
Assistant Professor of Psychiatry
University of Pittsburgh
Medical Director, Psychiatry Consultation-Liaison Service, UPMC
Chief of Psychiatry, Magee Women’s Hospital

Julie Kmiec, DO
Assistant Professor of Psychiatry

Room on 11th floor TBD
Abstract: The number of infants born physiologically dependent on heroin and other opioids has increased five-fold in the past 15 years. While just one of many manifestations of the opioid emergency impacting the US, perinatal addiction creates a unique set of clinical, legal, and ethical challenges for health care professionals and social services. This session will feature a panel of addiction and perinatal psychiatry experts exploring some of these issues in an interactive discussion exploring the science and ethics of this challenge.

Session #8
Futility, Fairness, or Frustration: Considering multiple heart valve replacements for patients with substance use disorders
Valerie Satkoske, PhD**
Director of Ethics, Wheeling Hospital
Associate Director, Center for Health Ethics and Law
West Virginia University

David E. Kappel, MD, FACS
Deputy Medical Director
West Virginia State Trauma System

Room on 11th floor TBD

Abstract: As IV drug use escalates in the US, so does the number of patients with opioid use disorders who develop infected heart valves. Many of these patients continue to use opioids after an initial valve replacement, which has spawned conversation among healthcare professionals about the fairness of spending healthcare resources for “non-compliant” patients who may be less likely to benefit from the intervention. This presentation will consider the justice concerns that have been raised regarding the fairness of providing multiple heart valve replacements for patients who have not successfully abstained from drug use. The presenters will argue that many of such concerns appear to stem from the stigma attached to having a substance use disorder rather than legitimate justice claims and/or claims of futility.

4:20 pm Adjournment

CONFERENCE PLANNING COMMITTEE
Ronald L “Ron” Carico Jr, PharmD, MPH, Pharmacy Fellow in Medication Safety and Outcomes
Center for Health Equity Research and Promotion/VA Center for Medication Safety

* Lisa S. Parker, PhD, Professor of Human Genetics and Director of the Center for Bioethics & Health Law
** Jack Rozel, MD, MSL, Professor of Psychiatry and Medical Director, re:solve Crisis Network
* Mark Wicclair, PhD, PhD, Adjunct Professor of Medicine, University of Pittsburgh
* Center for Bioethics & Health Law faculty member
** Center for Bioethics & Health Law affiliated faculty member
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The University of Pittsburgh School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Pittsburgh School of Medicine designates this live activity for a maximum of 6.0 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Other health care professionals are awarded 0.6 continuing education units (CEU’s) which are equal to 6.0 contact hours.

The University of Pittsburgh, School of Dental Medicine, Center for Continuing Education will recognize this properly sponsored program for a maximum of 6 credit hours for the maintenance and improvement of professional competence. Continuing Education credits awarded for participation in the Continuing Education activity may not apply toward license renewal in all states. It is the responsibility of each participant to verify the requirements of his/her State Licensing Board. The University of Pittsburgh is an ADA CERP Recognized Provider. ADA CERP is a service of the American Dental Association to assist dental professionals in identifying quality providers of continuing dental education. ADA CERP does not approve or endorse individual courses or instructors, nor does it imply acceptance of credit hours by boards of dentistry. Concerns or complaints about CE provider may be directed to the provider or to ADA CERP at www.ada.org/goto/cerp.

This program is offered for 6.0 hours of social work continuing education through co-sponsorship of the University of Pittsburgh’s School of Social Work, a Council of Social Work Education-accredited school, and therefore, a PA pre-approved provider of social work continuing education. These credit hours satisfy the requirements for LSW/LCSW, LPC and LMFT biennial license renewal. For more information on social work continuing education credit call 412-624-3711.

This program has been approved by the Pennsylvania Continuing Legal Education Board for (6) hours of substantive credit, available to those who have registered and paid the $120 fee for processing CLE credit for this event.

The University of Pittsburgh is an affirmative action, equal opportunity institution.

Participation by all individuals is encouraged. Advance notification of any special needs will help us provide better service; please contact bioethics@pitt.edu by March 9.