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C O N T E N T S

VOLUME 46:2 • SUMMER 2018

Symposium Articles

SYMPOSIUM

Law and the
Opioid Crisis:
An Inter-
Disciplinary
Examination

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and Kate Stith

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the Editor

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Tousey Matthews

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Introduction

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Physician Autonomy and the Opioid Crisis

*Nathan Guevremont, Mark Barnes, and
Claudia E. Haupt*

The scope and severity of the opioid epidemic in the United States has prompted significant legislative intrusion into the patient-physician relationship. These prescriptive regulatory regimes mirror earlier legislation in other politically-charged domains like abortion and gun regulation. We draw on lessons from those contexts to argue that states should consider integrating their responses to the epidemic with existing medical regulatory structures, making physicians partners rather than adversaries in addressing this public health crisis.

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Pain and Addiction in Specialty and Primary Care: The Bookends of a Crisis

*Joseph R. Schottenfeld, Seth A. Waldman,
Abbe R. Gluck, and Daniel G. Tobin*

Specialists and primary care physicians play an integral role in treating the twin epidemics of pain and addiction. But inadequate access to specialists causes much of the treatment burden to fall on primary physicians. This article chronicles the differences between treatment contexts for both pain and addiction — in the specialty and primary care contexts — and derives a series of reforms that would empower primary care physicians and better leverage specialists.

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Treatment Innovation in Orthopedic Surgery: A Case Study from Hospital for Special Surgery

*Seth A. Waldman, Joseph R. Schottenfeld,
and Abbe R. Gluck*

Excessive prescribing of pain medications after surgery has contributed to the epidemic of opioid misuse and diversion in the United States. Pain specialists may be particularly well situated to address these issues. We describe an attempt to reverse the trend at an orthopedic surgical

hospital by implementing a peri-operative assessment and treatment service which minimizes preoperative opioid use, when necessary implements addiction treatment, and encourages early tapering from opioids.

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Debating Medical Utility, Not Futility: Ethical Dilemmas in Treating Critically Ill People Who Use Injection Drugs

*Stephen R. Baldassarri, Ike Lee, Stephen
R. Latham, and Gail D'Onofrio*

Physicians who care for critically ill people with opioid use disorder frequently face medical, legal, and ethical questions related to the provision of life-saving medical care. We examine a complex medical case that illustrates these challenges in a person with relapsing injection drug use. We focus on a specific question: Is futility an appropriate and useful standard by which to determine provision of life-saving care to such individuals? If so, how should such determinations be made? If not, what alternative decision-making framework exists? We determine that although futility has been historically utilized as a justification for withholding care in certain settings, it is not a useful standard to apply in cases involving people who use injection drugs for non-medical purposes. Instead, we are well-advised to explore each patient's situation in a holistic approach that includes the patient, family members, and care providers in the decision-making process. The scope of the problem illustrated demonstrates the urgent need to definitively improve outcomes in people who use injection drugs. Increasing access to high quality medication-assisted treatment and psychiatric care for individuals with opioid use disorder will help our patients achieve a sustained remission and allow us to reach this goal.

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Prisoners as Patients: The Opioid Epidemic, Medication-Assisted Treatment, and the Eighth Amendment

*Michael Linden, Sam Marullo,
Curtis Bone, Declan T. Barry,
and Kristen Bell*

This article argues that correctional institutions violate the Eighth Amendment when they refuse to establish MAT programs and prevent doctors from exercising medical judgment to properly treat incarcerated people with OUD.

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Our Ethical Obligation to Treat Opioid Use Disorder in Prisons:

A Patient and Physician's Perspective

Curtis Bone, Lindsay Eysenbach, Kristen Bell, and Declan T. Barry

The opioid epidemic has claimed the lives of more than 183,000 individuals since 1999 and is now the leading cause of accidental death in the United States. Meanwhile, rates of incarceration have quadrupled in recent decades, and drug use is the leading cause of incarceration. Medication-assisted treatment or MAT (i.e. methadone, buprenorphine) is the gold standard for treatment of opioid use disorder. Incarcerated individuals with opioid use disorder treated with methadone or buprenorphine have a lower risk of overdose, lower rates of hepatitis C transmission, and lower rates of re-incarceration. Despite evidence of improved outcomes, many jails and prisons do not offer MAT to individuals with opioid use disorder. This seems partly due to a scientifically unjustified preference for an abstinence-only treatment approach. The absence of MAT in prisons and jails results in poor outcomes for individuals and poses a public health threat to communities. Furthermore, it disproportionately harms poor communities and communities of color. Health care providers in prisons and jails have an ethical obligation to offer MAT to individuals with opioid use disorder to mitigate risk of infectious diseases, opioid overdose and health disparities associated with incarceration.

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Buprenorphine Supply, Access, and Quality: Where We Have Come and the Path Forward

Christopher T. Breen and David A. Fiellin

Buprenorphine is a form of opioid agonist treatment that has been demonstrated to be an effective medication for opioid addiction. It is available in different formulations and marketed under various trade names, including commonly as a buprenorphine/naloxone combination. This paper provides an overview of existing literature on the supply of buprenorphine treatment, the ability of people to access treatment with buprenorphine, and the quality of treatment received. We argue that better data for each of these aspects of treatment could inform policy to expand effective treatment with buprenorphine, and we suggest steps to obtain and act on such data.

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Buprenorphine MAT as an Imperfect Fix

Brian Mund and Kate Stith

Expanding buprenorphine access in the United States requires evidence-based decision-making that considers both the drug's potential dangers and its potential benefits. Risks associated with buprenorphine misuse and diversion highlight the need for careful, ongoing evaluation during each stage of increased access.

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The Opioid Crisis and Federal Criminal Prosecution

Rachel L. Rothberg and Kate Stith

This article examines how federal law enforcement has responded to the opioid epidemic nationally and in a variety of locales. We focus in depth on two initiatives, including prosecution in opioid-death cases, undertaken by the U.S. Attorney's Office in Connecticut.

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Fentanyl: A Whole New World?

Rachel L. Rothberg and Kate Stith

This article seeks to document the latest danger in the opioid crisis: fentanyl and related synthetic opioids. Fifty times more potent than pure heroin, cheaper to manufacture in laboratories worldwide, and easily distributed by mail and couriers, fentanyl is flooding the illicit opioid markets throughout the country.

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We Can't Go Cold Turkey: Why Suppressing Drug Markets Endangers Society

Nick Werle and Ernesto Zedillo

This essay argues that policies aimed at suppressing drug use exacerbate the nation's opioid problem. It neither endorses drug use nor advocates legalizing the consumption and sale of all substances in all circumstances. Instead, it contends that trying to suppress drug markets is the wrong goal, and in the midst of an addiction crisis it can be deadly. There is no single, correct drug policy; the right approach depends crucially on the substance at issue, the patterns of use and supply, and the jurisdiction's culture, institutions, and material resources. Decriminalization is no panacea for a nation's drug problems. Nevertheless, either de jure or de facto decriminalization of personal drug possession is a necessary condition for mitigating this crisis.

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The Role of Civil Commitment in the Opioid Crisis

Ish P. Bhalla, Nina Cohen, Claudia E. Haupt, Kate Stith, and Rocksheng Zhong

This article seeks to shed light on civil commitment in the context of the opioid crisis, to sketch the existing legal landscape surrounding civil commitment, and to illustrate the relevant medical, ethical, and legal concerns that policymakers must take into account as they struggle to find appropriate responses to the crisis.

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**Civil Litigation and the Opioid Epidemic:
The Role of Courts in a National Health
Crisis**

*Abbe R. Gluck, Ashley Hall, and Gregory
Curfman*

The devastating impact of the national opioid epidemic has given rise to hundreds of lawsuits. This article details the extremely broad range of legal claims, compares the opioid cases to other public health litigation efforts, including tobacco, and describes the special mechanism — a multidistrict litigation — through which more than 700 opioid-related cases have been consolidated thus far, with settlement almost certain to follow.

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State Responses to the Opioid Crisis

*Andrew M. Parker, Daniel Strunk,
and David A. Fiellin*

This paper focuses on the most common state policy responses to the opioid crisis, dividing them into six broad categories. Within each category we highlight the rationale behind the group of policies within it, discuss the details and support for individual policies, and explore the research base behind them. The objective is to better understand the most prevalent state responses to the opioid crisis.

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**Case Study: County-Level Responses to
the Opioid Crisis in Northern Kentucky**

Quentin Johnson

This article highlights local government responses to the opioid crisis in Northern Kentucky through a series of interviews with county-level officials. The author's discussions with civic leaders reflect the challenges faced by local communities and the new approaches implemented to stem the epidemic.

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**The Impact of Prescription Drug
Monitoring Programs on U.S. Opioid
Prescriptions**

Ian Ayres and Amen Jalal

This paper seeks to understand the treatment effect of Prescription Drug Monitoring Programs (PDMPs) on opioid prescription rates. Using county-level panel data on all opioid prescriptions in the U.S. between 2006 and 2015, we investigate whether state interventions like PDMPs have heterogeneous treatment effects at the sub-state level, based on regional and temporal variations in policy design, extent of urbanization, race, and income. Our models comprehensively control for a set of county and time fixed effects, county-specific and time-varying demographic controls, potentially endogenous time-series trends in prescription rates, and other state-level opioid interventions such as Naloxone Access and Good Samaritan laws, Medicaid expansion, and the provision of Methadone Assistance Treatment. We find that PDMPs are only effective in reducing prescription rates if they obligate doctors to check for patients' history prior to

filling out a prescription, but the frequency at which a state requires its PDMP to be updated is irrelevant to its effectiveness. Moreover, the significant treatment effects of PDMPs are almost exclusively driven by urban and predominantly white counties, with the relatively more affluent regions showing greater responsiveness than their less affluent counterparts.

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The Opioid Crisis in Black Communities

Keturah James and Ayana Jordan

While much of the social and political attention surrounding the nationwide opioid epidemic has focused on the dramatic increase in overdose deaths among white, middle-class, suburban and rural users, the impact of the epidemic in Black communities has largely been unrecognized. Though rates of opioid use at the national scale are higher for whites than they are for Blacks, rates of increase in opioid deaths have been rising more steeply among Blacks (43%) than whites (22%) over the last five years. Moreover, the rate of opioid overdose deaths among Blacks already exceeds that of whites in several states. The lack of discussion of Black overdose deaths in the national opioid discourse further marginalizes Black people, and is highly consistent with a history of framing the addictions of people of color as deserving of criminal punishment, rather than worthy of medical treatment. This article argues that, because racial inequalities are embedded in American popular and political cultures as well as in medicine, the federal and state governments should develop more culturally targeted programs to benefit Black communities in the opioid crisis. Such programs include the use of faith-based organizations to deliver substance use prevention and treatment services, the inclusion of racial impact assessments in the implementation of drug policy proposals, and the formal consideration of Black people's interaction with the criminal justice system in designing treatment options.

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The Opioid Epidemic in Indian Country

*Robin T. Tipps, Gregory T. Buzzard,
and John A. McDougall*

The national opioid epidemic is severely impacting Indian Country. In this article, we draw upon data from the Centers for Disease Control and Prevention to describe the contours of this crisis among Native Americans. While these data are subject to significant limitations, we show that Native American opioid overdose mortality rates have grown substantially over the last seventeen years. We further find that this increase appears to at least parallel increases seen among non-Hispanic whites, who are often thought to be uniquely affected by this crisis. We then profile tribal medical and legal responses to the opioid epidemic, ranging from tribally-operated medication-assisted therapy to drug diversion courts rooted in traditional tribal cultures.

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Improving Rural Access to Opioid Treatment Programs

Quentin Johnson, Brian Mund, and Paul J. Joudrey

This article explores challenges to accessing opioid treatment programs in rural areas, and offers solutions that would ease these problems.

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Big Data and the Opioid Crisis: Balancing Patient Privacy with Public Health

John Matthew Butler, William C. Becker, and Keith Humphreys

Parts I through III of this paper will examine several, increasingly comprehensive forms of aggregation, ranging from insurance reimbursement “lock-in” programs to PDMPs to completely unified electronic medical records (EMRs). Each part will advocate for the adoption of these aggregation systems and provide suggestions for effective implementation in the fight against opioid misuse. All PDMPs are not made equal, however, and Part II will, therefore, focus on several elements — mandating prescriber usage, streamlining the user interface, ensuring timely data uploads, creating a national data repository, mitigating privacy concerns, and training doctors on how to respond to perceived doctor-shopping — that can make these systems more effective. In each part, we will also discuss the privacy concerns of aggregating data, ranging from minimal to significant, and highlight the unique role of stigma in motivating these concerns. In Part IV, we will conclude by suggesting remedial steps to offset this loss of privacy and to combat the stigma around SUDs and mental health disorders in general.

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Cracking the Code: Using Data to Combat the Opioid Crisis

Catherine Martinez

The goal of this article is to understand the value of data and to call for efforts to explore improved data sharing and collection among local, state, and federal agencies. It discusses the data available and existing barriers to sharing it. It also looks at examples of data sharing initiatives and analysis, such as mapping and visualization tools. The article then examines relevant regulations and calls for reforms. Finally, the article considers objections, including privacy interests, data security, and the costs and benefits of data sharing initiatives.

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Government Patent Use to Address the Rising Cost of Naloxone: 28 U.S.C. § 1498 and Evzio

Alex Wang and Aaron S. Kesselheim

The rising cost of the opioid antagonist and overdose reversal agent naloxone is an urgent public health problem. The recent and dramatic price increase of Evzio, a naloxone auto-injector produced by Kaléo, shows how pharmaceutical manufacturers entering the naloxone marketplace rely on market exclusivity guaranteed by the patent system to charge prices at what the market can bear, which can restrict access to life-saving medication. We argue that 28 U.S.C. § 1498, a section of the federal code that allows the government to use patent-protected products for its own purposes in exchange for reasonable compensation, could be used to procure generic naloxone auto-injectors, or at least bring Kaléo to the negotiating table. Precedent exists for the use of § 1498 to procure pharmaceuticals, and it could give meaning to the federal government’s recent declaration of a public health emergency around the opioid epidemic, discourage new market entrants from charging exorbitant prices, and yield important public health benefits.

Independent Articles

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The Proactive Patient: Long-Term Care Insurance Discrimination Risks of Alzheimer's Disease Biomarkers

Jalayne J. Arias, Ana M. Tyler, Benjamin J. Oster, and Jason Karlawish

Previously diagnosed by symptoms alone, Alzheimer's disease is now also defined by measures of amyloid and tau, referred to as "biomarkers." Biomarkers are detectable up to twenty years before symptoms present and open the door to predicting the risk of Alzheimer's disease. While these biomarkers provide information that can help individuals and families plan for long-term care services and supports, insurers could also use this information to discriminate against those who are more likely to need such services. In this article, we evaluate whether state laws prohibit long-term care insurers from making discriminatory or unfair underwriting and coverage decisions based on Alzheimer's disease biomarkers status. We report data demonstrating that current state laws do not provide meaningful protections from discrimination by long-term care insurers based on biomarker information.

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COMMENTARY Discrimination Risks of Alzheimer's as Support for Social Insurance for Long-Term Care

Allison K. Hoffman

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The Ethical Case for Mandating HPV Vaccination

Michelle J. Bayefsky

When the HPV vaccine was released over a decade ago, there was intense opposition to mandating the vaccine, including among bioethics and legal scholars. Some of the original concerns are now obsolete, while other objections continue to present an obstacle to mandating the vaccine. This essay responds to earlier critiques of mandatory HPV vaccination and offers a series of arguments in support of a vaccine mandate. The first section briefly addresses initial concerns that are no longer relevant. The second section makes the ethical case for mandating HPV vaccination, based on three principles: 1) the best interests of children, 2) solidarity, and 3) health equity. The final section addresses concerns related to implementation of the vaccine, including the validity of linking vaccination to school entry. The essay concludes that we have a moral imperative to protect children from the leading cause of cervical cancer, and that mandating HPV vaccination is the best way to ensure that children of all backgrounds receive the vaccine before they have been exposed to the virus.

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COMMENTARY HPV Vaccination: A Public Good and a Health Imperative

Lawrence O. Gostin

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The Boundaries of "Good Behavior" and Judicial Competence: Exploring Responsibilities and Authority Limitations of Cognitive Specialists in the Regulation of Incapacitated Judges

Brandon Hamm and Bryn S. Esplin

Both law and medicine rely on self-regulation and codes of professionalism to ensure duties are performed in a competent, ethical manner. Unlike physicians, however, judges are lawyers themselves, so judicial oversight is also self-regulation. As previous literature has highlighted, the hesitation to report a cognitively-compromised judge has resulted in an "open-secret" amongst lawyers who face numerous conflicts of interest.

Through a case study involving a senior judge with severe cognitive impairment, this article considers the unique ethical dilemmas that cognitive specialists may encounter when navigating duties to patient, society, and the medical profession, without clear legal guidance.

Systemic self-regulatory inadequacies in the legal profession are addressed, as well as challenges that arise when trying to preserve the trust and dignity of an incapacitated patient who must fulfill special duties to society.

Ultimately, because of their unique neurological expertise and impartial assessments, we submit that allowing cognitive specialists to submit their assessments to an internal judiciary board may act as an additional check and balance to ensure the fair and competent administration of justice.

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COMMENTARY The Boundaries of "Good Behavior" and Judicial Competence: Exploring Responsibilities and Authority Limitations of Cognitive Specialists in the Regulation of Incapacitated Judges

Rebecca Weintraub Brendel

Symposium

articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

Independent

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Wilson and
Lois Shepherd

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Imminent Death Donation: Ethical and Practical Policy Considerations

Jordan Potter

While the practice of organ donation after cardiac death has long been trending upwards in acceptance and use, it is still a highly controversial and practically inefficient method of organ procurement. One policy that has recently been proposed to try and alleviate some of the ethical and practical concerns with organ donation after cardiac death is the practice of imminent death organ donation. This type of live organ donation comes in patients at the end of their life who have decided to withdraw life-sustaining treatment, but still want to ensure that their organs are donated and not wasted, which isn't always the case with organ donation after cardiac death. This paper then gives some ethical and practical reflections and recommendations regarding the potential implementation of this controversial practice into regular transplant practice and policy.

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HEALTH POLICY PORTAL
Defining "True and Non-Misleading" for Pharmaceutical Promotion

Spencer Phillips Hey and Aaron S. Kesselheim