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Trust, Conflicts of Interest, and Concussion Reporting in College Football Players Christine M. Baugh, Emily Kroshus, William P. Meehan, and Eric G. Campbell

A Matter of Intent: A Social Obligation to Improve Criminal Procedures for Individuals with Dementia Jalayne J. Arias and Lauren S. Flicker

The Legal Consequences of Research Misconduct: False Investigators and Grant Proposals Eric A. Fong, Allen W. Wilhite, Charles Hickman, and Yeolan Lee A Journal of the American Society of Law, Medicine & Ethics • www.aslme.org

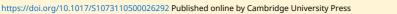
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SYMPOSIUM

Opioid Controversies: The Crisis — Causes and Solutions

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Cover image ©Getty Images

238 Introduction

Robert M. Sade

241 Opioids May be Appropriate for Chronic Pain Paul J. Christo

Patients living with chronic pain require appropriate access to opioid therapy along with improved access to pain care and additional therapeutic options. It's both medically reasonable and ethical to consider opioid therapy as a treatment option in the management of chronic, non-cancer pain for a subset of patients with severe pain that is unresponsive to other therapies (e.g., injections, other medications, integrative strategies), negatively impacts function or quality of life, and will likely outweigh the potential harms. This paper will examine opioid therapy in the setting of the opioid epidemic, why critics feel that the CDC guideline has resulted in harsh consequences for patients and their physicians, and the rationale for opioid therapy as a means of providing ethical and compassionate pain care.

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An Effective Intervention: Limiting Opioid Prescribing as a Means of Reducing Opioid Analgesic Misuse, and Overdose Deaths

Brandi C. Fink, Olivier Uyttebrouck, and Richard S. Larson

Overdose deaths involving prescription opioids killed more than 17,000 Americans in 2017, marking a five-fold increase since 1999. High prescribing rates of opioid analgesics have been a substantial contributor to prescription opioid misuse, dependence, overdose and heroin use. There was recognition approximately ten years ago that opioid prescribing patterns were contributing to this startling increase in negative opioid-related outcomes, and federal actions, including Medicare reimbursement reform and regulatory actions, were initiated to restrict opioid prescribing. The current manuscript is a description of those actions, the effect of those actions on opioid prescribing and related patient outcomes. We also describe our proposal of methods of expanding these efforts as an important piece to further reduce opioid-related misuse, dependence, and overdose death.

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Nonconsensual Dose Reduction Mandates are Not Justified Clinically or Ethically: An Analysis

Stefan G. Kertesz, Ajay Manhapra, and Adam J. Gordon,

This manuscript describes the institutional and clinical considerations that apply to the question of whether to mandate opioid dose reduction in patients who have received opioids long-term. It describes how a calamitous rise in addiction and overdose involving opioids has both led to a clinical recalibration by healthcare providers, and to strong incentives favoring forcible opioid reduction by policy making agencies. Neither the 2016 Guideline issued by the Centers for Disease Control and Prevention nor clinical evidence can justify or promote such policies as safe or effective.

268 Cannabis as a Ga

Cannabis as a Gateway Drug for Opioid Use Disorder

Arthur Robin Williams

Cannabis use in some individuals can meaningfully introduce *de novo* risk for the initiation of opioid use and development of opioid use disorder. These risks may be particularly high during adolescence when cannabis use may disrupt critical periods of neurodevelopment. Current research studying the combination of genetic and environmental factors involved in substance use disorders is poorly understood. More research is needed, particularly to identify which adolescents are most at risk and to develop effective interventions addressing contributing factors such as trauma and psychiatric comorbidity.

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Regulating Marijuana Use in the United States: Moving Past the Gateway Hypothesis of Drug Use

Jason F. Arnold and Robert M. Sade

Many studies have shown that marijuana can negatively affect the cognitive development of adolescents. For some individuals, marijuana use may also initiate opioid use, dose escalation, and opioid use disorder. States that legalize marijuana should help adolescents through regulation of advertising and availability of marijuana-infused edibles. Such policies may assist in protecting neurodevelopment of the adolescent and young adult brain. The federal government should also remove its prohibition of marijuana sales and use, leaving their regulation to state law-makers.

279 The Public Health Value of Opioid Litigation

Rebecca L. Haffajee

Opioid litigation continues a growing public health litigation trend in which governments seek to hold companies responsible for population harms related to their products. The litigation can serve to address gaps in regulatory and legislative policymaking and in market self-regulation pervasive in the prescription opioid domain. Moreover, prior opioid settlements have satisfied civil tort litigation objectives of obtaining compensation for injured parties, deterring harmful behavior, and holding certain opioid manufacturers, distributors and pharmacies accountable for their actions. In this way, opioid litigation represents progress over prior public health litigation campaigns involving tobacco, lead paint, and asbestos, which had more limited tort litigation effects. Although opioid litigation is not a comprehensive solution to the opioid crisis, it can complement other strategies and infuse much needed money, behavior changes, and public accountability for prescription opioid and related harms.

293 Is Litigation the Way to Combat the Opioid Crisis?

Richard C. Ausness

This paper examines the lawsuits brought by state and local government entities against prescription opioid producers and sellers. It examines their potential liability as well as some of the defenses they might raise. The paper also discusses multidistrict litigation and government lawsuits in state court. It concludes that litigation is not the best solution to the opioid crisis.

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Trust, Conflicts of Interest, and Concussion Reporting in College Football Players

Christine M. Baugh, Emily Kroshus, William P. Meehan, and Eric G. Campbell

Sports medicine clinicians face conflicts of interest in providing medical care to athletes. Using a survey of college football players, this study evaluates whether athletes are aware of these conflicts of interest, whether these conflicts affect athlete trust in their health care providers, or whether conflicts or athletes' trust in stakeholders are associated with athletes' injury reporting behaviors.

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A Matter of Intent: A Social Obligation to Improve Criminal Procedures for Individuals with Dementia

Jalayne J. Arias and Lauren S. Flicker

The relationship between dementia and criminal behavior perplexes legal and health care systems. Dementia is a progressive clinical syndrome defined by impairment in at least two cognitive domains that interferes with one's activities of daily. Dementia symptoms have been associated with behaviors that violate social norms and constitute criminal actions. A failure to address a gap in policies that support appropriate management of individuals with dementia reflects a failure in our social obligation to care for those who are most vulnerable amongst us. Categorical protections, informed by precedent models applied to juveniles and individuals with psychiatric illness, could help meet a social obligation to provide protections to individuals with dementia. We propose an approach that integrates affirmative defenses to mitigate criminal liability and sentencing restrictions to prevent cruel and unusual punishment.

328 COMMENTARY Marshall B. Kapp

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ticles 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

articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are

written or edited by leaders in their fields and appear in each issue of JLME.

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The Legal Consequences of Research Misconduct: False Investigators and Grant Proposals *Eric A. Fong, Allen W. Wilhite*,

Charles Hickman, and Yeolan Lee

In a survey on research misconduct, roughly 20% of the respondents admitted that they have submitted federal grant proposals that include scholars as research participants even though those scholars were not expected to contribute to the research effort. This manuscript argues that adding such false investigators is illegal, violating multiple federal statutes including the False Statements Act (18 U.S.C. §1001), the False Claims Act (31 U.S.C. §3729), and False, Fictitious, or Fraudulent Claims (18 U.S.C. §287). Moreover, it is not only the offending academics and the false investigators that face civil and criminal penalties because administrators may also be liable if they sign off on proposals and are in a position to know that false investigators might be included. Policy recommendations that should reduce the use of false investigators include changing institutional cultures, better training and oversight of the responsible conduct of research, and, most importantly, making all grant reviews double blind.

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Should I Stay or Should I Go? A Bioethical Analysis of Healthcare Professionals' and Healthcare Institutions' Moral Obligations During Active Shooter Incidents in Hospitals — A Narrative Review of the Literature

Al Giwa, Andrew Milsten, Dorice Vieira, Chinwe Ogedegbe, Kristen Kelly, and Abraham Schwab

Active shooter incidents (ASI) have unfortunately become a common occurrence the world over. There is no country, city, or venue that is safe from these tragedies, and healthcare institutions are no exception. Healthcare facilities have been the targets of active shooters over the last several decades, with increasing incidents occurring over the last decade. People who work in healthcare have a professional and moral obligation to help patients. As concerns about the possibility of such incidents increase, how should healthcare institutions and healthcare professionals understand their responsibilities in preparation for and during ASI?

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