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Independent Articles

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Letter from
the Editor

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Pre-Mortem Interventions for the Purpose of Organ Donation: Legal Approaches to Consent
Renée Taillieu, Matthew J. Weiss, Dan Harvey, Nicholas Murphy, Charles Weijer, and Jennifer A Chandler

The administration of Pre-Mortem Interventions (PMIs) to preserve the opportunity to donate, to assess the eligibility to donate, or to optimize the outcomes of donation and transplantation are controversial as they offer no medical benefit and include at least the possibility of harm to the still-living patient. In this article, we describe the legal analysis surrounding consent to PMIs, drawing on existing legal commentary and identifying key legal problems. We provide an overview of the approaches in several jurisdictions that have chosen to explicitly address PMIs within codified law. We then provide, as an example, a detailed exploration of how PMIs are likely to be addressed in one jurisdiction where general medical consent law applies because there is no specific legislation addressing PMIs – the province of Ontario in Canada.

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A Rule-Based Solution to Opaque Medical Billing in the U.S.
Christopher A. Bobier

Patients and physicians do not know the cost of medical procedures. The result is that patients may opt for a procedure that carries minimal health benefit but significant financial cost, and a physician may push for an expensive procedure without an awareness of the financial burden it may place on the patient. Opaque medical billing thus contributes to exorbitant, rising medical costs, burdening the healthcare system and individuals. The aim of this paper is to critically assess proposals to address the problem of opaque medical billing. I argue that expanding informed consent to include out-of-pocket costs is unlikely to succeed in the courts or become part of professional practice. I then argue that recent increased price transparency rules at the federal level are ineffective for patients and fail to include physicians in greater awareness of financial burden. Fortunately, a solution is readily available. I argue that the Centers for Medicare and Medicaid Services (CMS) should pursue a rule requiring that patients be informed by the physician of a reasonable out-of-pocket expense estimate for non-urgent procedures prior to services rendered.

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Enacting Relational Public Health: Federally Qualified Health Centers During the COVID-19 Pandemic
Danielle Pacia, Johanna Crane, Carolyn Neuhaus, Nancy Berlinger, and Rachel Fabi

Federally Qualified Health Centers (FQHCs) proved to be critical points of access for people of color and other underserved populations during the COVID-19 pandemic, administering 61% of their COVID-19 vaccinations to people of color, compared to the 40% rate for the overall United States' vaccination effort. To better understand the approaches and outcomes of FQHCs in pandemic response, we conducted semi-structured interviews with FQHC health care providers and outreach workers and analyzed them using an inductive qualitative methodology.

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A Whole-Person Approach to Harm Reduction for Women

Somer Brown

Women are the fastest-growing population of people who use drugs in the US. As a group, they are more likely than men to experience stigma, poverty, and negative mental health outcomes. This article discusses the unique needs of women drug users in the US and provides suggestions on how to leverage national attention — and federal funding — to make harm reduction services in the US more gender sensitive, and, as a result, more effective in reducing harm for women who use drugs in this country.

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Lowering the Age of Consent for Vaccination to Promote Pediatric Vaccination: It's Worth a Shot

Margaret Irwin, Derek Soled, and Christy L. Cummings

This paper challenges historically preconceived notions surrounding a minor's ability to make medical decisions, arguing that federal health law should be reformed to allow minors with capacity as young as age 12 to consent to their own Centers for Diseases Control and Prevention (CDC)-approved COVID-19 vaccinations. This proposal aligns with and expands upon current exceptions to limitations on adolescent decision-making. This analysis reviews the historic and current anti-vaccination sentiment, examines legal precedence and rationale, outlines supporting ethical arguments regarding adolescent decision-making and offers rebuttals to anticipated ethical counterarguments. A minor who demonstrates capacity to make non-life-threatening medical decisions, despite parental or guardian refusal, should be given the right to receive a COVID-19 vaccine. Grounded in respect for developing adolescent autonomy, this premise already exists in other health laws for the promotion of individual and public health and may be particularly important in this post COVID-19 pandemic era, and beyond.

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Minor Consent for Vaccination: Ethically Justified, Politically Fraught

James Colgrove

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Diversion to Treatment when Treatment is Scarce: Bioethical Implications of the U.S. Resource Gap for Criminal Diversion Programs

Deniz Ariturk, Michele M. Easter, Jeffrey W. Swanson, and Marvin S. Swartz

Despite significant scholarship, research, and funding dedicated to implementing criminal diversion programs over the past two decades, persons with serious mental illness and

substance use disorders remain substantially overrepresented in United States jails and prisons. Why are so many U.S. adults with behavioral health problems incarcerated instead of receiving treatment and other support to recover in the community? In this paper, we explore this persistent problem within the context of "relentless unmet need" in U.S. behavioral health (Alegria et al., 2021). We use a common framework of bioethical principles to examine the ethical concerns that this unmet need raises for diversion-to-treatment programs. Can diversion programs that are implemented in resource-constrained service environments fulfill their ambitious promise to reduce involvement in the criminal legal system, improve clinical outcomes, promote self-determination, and enhance overall quality of life for their target populations?

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"A Most Equitable Drug": How the Clinical Studies of Convalescent Plasma as a Treatment for SARS-CoV-2 Might Usefully Inform Post-Pandemic Public Sector Approaches to Drug Development

Quinn Grundy, Chantal Campbell, Ridwaanah Ali, Matthew Herder, and Kelly Holloway

Interventional clinical studies of convalescent plasma to treat COVID-19 were predominantly funded and led by public sector actors, including blood services operators. We aimed to analyze the processes of clinical studies of convalescent plasma to understand alternatives to pharmaceutical industry biopharmaceutical research and development, particularly where public sector actors play a dominant role. We conducted a qualitative, critical case study of purposively sampled prominent and impactful clinical studies of convalescent plasma during 2020-2021. We found that studies were mobilized and scaled at record pace due to well-connected investigators who engaged in widespread sharing of clinical trials resources, regulatory facilitators, and public funding and infrastructure. Clinical studies also served to build public sector and health system capacity and generate clinical trials and blood services infrastructure. Key insights from these studies can be used to enhance the likelihood of success of future models of biopharmaceutical production, designed in the service of ensuring equitable access to biopharmaceuticals, should the political will and financing to support such models someday follow.

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Do Physicians Have a Duty to Support Secondary Use of Clinical Data in Biomedical Research? An Inquiry into the Professional Ethics of Physicians

Martin Jungkunz, Anja Köngeter, Eva C. Winkler, and Christoph Schickhardt

Secondary use of clinical data in research or learning activities (SeConts) has the potential to improve patient care and biomedical knowledge. Given this potential, the ethical question arises whether physicians have a professional duty to support SeConts. To investigate this question, we analyze prominent international declarations on physicians' professional ethics to determine whether they include duties that can be considered as good reasons for a physicians' professional duty to support SeConts. Next, we examine these documents to identify professional duties that might conflict with a potential duty of physicians to support SeConts. We come to the intermediary conclusion that based upon the pros and cons provided in the documents on physicians' professional ethics a professional duty to support SeConts is justified. We then analyze practice-related concerns about the support of SeConts expressed in the bioethical and empirical literature and offer mitigation measures. We conclude that if these measures are taken, physicians have a professional duty to support SeConts.

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Diverting Data and Drugs: A Narrative Review of the Mallinckrodt Documents

Antoine Lentacker, Kelly Pham, and Jason M. Chernesky

U.S. law imposes strict recording and reporting requirements on all entities that manufacture and distribute controlled substances. As a result, the prescription opioid crisis has unfolded in a data-saturated environment. This article asks why the systematic documentation of opioid transactions failed to prevent or mitigate the crisis. Drawing on a recently disclosed trove of 1.4 million internal records from Mallinckrodt Pharmaceuticals, a leading manufacturer of prescription opioids, we highlight a phenomenon we propose to call data diversion, whereby data ostensibly generated or collected for the purpose of regulating the distribution of controlled substances were repurposed by the industry for the opposite aim of increasing sales at all costs. Systematic data diversion, we argue, contributed substantially to the scale of drug diversion seen with opioids and should become a focus of policy intervention.

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Addressing Unmet Social Needs and Social Risks — A Qualitative Interview-Based Assessment of Parent Reported Outcomes and Impact from a Medical Legal Partnership

Erin Talati Paquette, Jennifer Kusma Saper, Hassan Khan, Sasha Becker, Zecilly Guzman, Valerie Alvarez Renteria, Sarah Hess, and Karen Sheehan

Medical legal partnerships address individual legal needs that can create impediments to health. Little is known about outcomes from medical legal partnerships and their relationship to access to justice. This paper reports outcomes from one medical legal partnership from the perspective of the client, with specific emphasis on impact on health and concepts related to access to justice. We suggest a conceptual model for incorporating medical legal partnerships into a broader framework about access to justice.

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Church Against State: How Industry Groups Lead the Religious Liberty Assault on Civil Rights, Healthcare Policy, and the Administrative State

Joanna Wuest and Briana S. Last

Industry-funded religious liberty legal groups have sought to undermine healthcare policy and law while simultaneously attacking the rights of sexual and gender minorities. Whereas past scholarship has tracked religiously-affiliated healthcare providers' growing political power and attendant transformations to legal doctrine, our account emphasizes the political donors and visionaries who have leveraged religious providers and the U.S. healthcare system's delegated structure to transform social policy and bureaucratic agencies more generally. We collect and analyze industry-funded litigation briefs, track statutory and constitutional developments in federal courts, and employ a historical institutionalist analysis of the U.S. healthcare system. Case studies include: 1) the Affordable

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Next Issue:

**A Tribute
to Professor
Charity Scott**

Care Act's implementation; 2) the Department of Health and Human Services (HHS) interpretations of its rules and relevant congressional statutes; 3) the professional civil service; and 4) state and federal COVID-19 public health policies. We find that industry-funded religious liberty legal organizations have successfully limited the rights of sexual and gender minorities and access to reproductive healthcare while also curtailing the administrative authority of agencies including HHS. Our case studies highlight the threat that industry-funded religious liberty legal organizations pose for effective healthcare regulation, reproductive healthcare access, and civil rights enforcement for sexual and gender minorities.

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