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Editorial Office

Journal of Law, Medicine & Ethics, 765 Commonwealth Avenue, Suite 1704, Boston, MA 02215 USA
Phone: 617-262-4990; Fax: 617-437-7596
E-mail: thutchinson@aslme.org

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**Determination of Death by Neurologic
Criteria in the United States: The Case
for Revising the Uniform Determination
of Death Act**
*Ariane Lewis, Richard J. Bonnie,
Thaddeus Pope, Leon G. Epstein,
David M. Greer, Matthew P. Kirschen,
Michael Rubin, and James A. Russell*

Although death by neurologic criteria (brain death) is legally recognized throughout the United States, state laws and clinical practice vary concerning three key issues: (1) the medical standards used to determine death by neurologic criteria, (2) management of family objections before determination of death by neurologic criteria, and (3) management of religious objections to declaration of death by neurologic criteria. The American Academy of Neurology and other medical stakeholder organizations involved in the determination of death by neurologic criteria have undertaken concerted action to address variation in clinical practice in order to ensure the integrity of brain death determination. To complement this effort, state policymakers must revise legislation on the use of neurologic criteria to declare death. We review the legal history and current laws regarding neurologic criteria to declare death and offer proposed revisions to the Uniform Determination of Death Act (UDDA) and the rationale for these recommendations.

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**Dementia, Healthcare Decision
Making, and Disability Law**
Megan S. Wright

Persons with dementia often prefer to participate in decisions about their health care, but may be prevented from doing so because healthcare decision-making law facilitates use of advance directives or surrogate decision makers for persons with decisional impairments such as dementia. Federal and state disability law provide alternative decision-making models that do not prevent persons with mild to moderate dementia from making their own healthcare decisions at the time the decision needs to be made. In order to better promote autonomy and well-being, persons with dementia should be accommodated and supported so they can make their own healthcare decisions.

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**Federal Indian Law as a Structural
Determinant of Health**
Aila Hoss

Federal Indian law is the body of law that defines the rights, responsibilities, and relationships between three sovereigns, Tribes, states, and the federal government. This area of law has defined, oftentimes poorly, the contours of treaty rights, criminal and civil jurisdiction, economic development, among other issues. Much has been documented in terms of the implications of social, legal, political, and economic systems that perpetuate inequities amongst American Indian and Alaska Native populations. There has also been substantial research on health inequalities. Yet, there has been less discussion on the role of law in perpetuating these adverse health outcomes in these populations. The social and structural determinants of health are the factors and conditions, such as housing, education, and politics, that create health disparities. For years, law has been described as a tool to promote health and even a determinant of health. And while research has explored Tribal health laws and federal Indian health policies, more needs to be analyzed in terms of the role of foundational principles of federal Indian law in perpetuating health disparities. This article argues that federal Indian law is a structural determinant of health by linking health disparities to the constructs of this body of law.

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Generic Drug Policy and Suboxone to Treat Opioid Use Disorder

*Rebecca L. Haffajee and
Richard G. Frank*

Despite some improvements in access to evidence-based medications for opioid use disorder, treatment rates remain low at under a quarter of those with need. High costs for brand name products in these medication markets have limited the volume of drugs purchased, particularly through public health insurance and grant programs. Brand firm anti-competitive practices around the leading buprenorphine product Suboxone — including product hops, citizen petitions and Risk Evaluation and Mitigation Strategy abuses — helped to maintain high prices by extending brand exclusivity periods and hindering generic drug entry. Remedies to address costly anti-competitive activities include adoption of the proposed CREATES Act and modernization of the Hatch-Waxman Act by the Congress, and implementation of substantive modifications to the Food and Drug Administration citizen petition filing procedures. Given the persistence of these abuses, prescriptive changes are favorable to the procedural and clarifying steps thus far favored by the federal government. Extrapolating from the 37% price declines attributable to generic entry for buprenorphine tablets in 2011, our calculations suggest that implementing these remedies to facilitate generic competition with Suboxone film would have resulted in savings of approximately \$703 million overall and \$203 million to Medicaid in 2017.

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The Case for Disclosure of Biologics Manufacturing Information

Yaniv Heled

Ten years after the enactment of the Biologics Price Competition and Innovation Act (BPCIA), competition in biologics markets remains scant and far from sufficient for lowering prices of biologics to the level of 80-90% price drops seen in generic drug markets. This reality is not a result of one or two cardinal reasons, but many. If lowering the price of biologics is the goal and competition is the means by which we seek to achieve that goal, then there does not seem to be a quick fix to address all of the many impediments to competition that plague biologics markets. Yet, certain changes to how the Food and Drug Administration (FDA) evaluates and approves biologics may go a long way toward the creation of meaningful competition in biologics markets. One such change would be making original biologics' manufacturing information available to follow-on manufacturers.

As recognized by several commentators, access to biologics manufacturing information is key to increasing competition in biologics markets. Without access to such information, making follow-on biologics is difficult and expensive, if not outright impossible. This is expected to be especially true for the highly anticipated class of interchangeable biologics, none of which has been approved by the FDA to date. Yet, it has long been the position of the brand-name pharmaceutical industry (Industry) that biologics manufacturing information is proprietary and, thus, may not be shared. Congress has subscribed to the Industry's position, prohibiting the FDA from disclosing regulatory filings submitted by developers of original biologics, including manufacturing information, to third parties. That prohibition not only undermines competition in biologics markets, but is also wasteful, potentially unethical, and poses unnecessary risks to the health and safety of patients.

This article makes the case for FDA sharing of original biologics manufacturing information with follow-on biologics developers. It is informed by the similar legal and commercial circumstances in the area of pesticides and the regulatory regime established by Congress in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which is administered by the Environmental Protection Agency (EPA). The article reviews the FIFRA regime, including its upholding as constitutional by the United States Supreme Court, and then examines its applicability to the area of biologics. The article concludes with a proposal for a similar regime to be incorporated into the pathway for approval of follow-on biologics as a means of increasing competition in biologics markets.

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Health Reform and Higher Ed: Campuses as Harbingers of Medicaid Universality and Medicare Commonality
Sallie Thieme Sanford

Between 2010 and 2016, the percentage of uninsured higher education students dropped by more than half. All the Affordable Care Act's key access provisions contributed, but the most important factor appears to be the Medicaid expansion. This article is the first to highlight this phenomenon and ground it in data. It explores the reasons for this dramatic expansion of coverage, links it to theoretical frameworks, and considers its implications for the future of health reform. Drawing on Medicaid universality scholarship, I discuss potential consequences of including the educationally privileged in this historically stigmatized program. Extending this scholarship, I argue that the student experience and its reverberating effects portend support for emerging proposals to make Medicare a more common option. Woven into both analyses is the role of the Trump-era retrenchment, notably the administration's promotion of Medicaid "work or community engagement" requirements and of cheap, skimpy plans. Higher education students were an afterthought in the ACA's debates, and yet the law has profoundly impacted their coverage options. Students are now much more likely to have health insurance, and for it to be comprehensive. Looking to the next decade, the student experience harbingers support for both Medicaid universality and Medicare commonality.

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**Maybe If We Turn It Off and Then Turn
It Back On Again?** Exploring Health Care
Reform as a Means to Curb Cyber Attacks
Deborah R. Farringer

The health care industry has moved at a rapid pace away from paper records to an electronic platform across almost all sectors — much of it at the encouragement and insistence of the federal government. Such rapid expansion has increased exponentially the risk to individuals in the privacy of their data and, increasingly, to their physical well-being when medical records are inaccessible through ransomware attacks. Recognizing the unique and critical nature of medical records, the United States Congress established the Health Care Industry Cybersecurity Task Force under the Cybersecurity Information Sharing Act of 2015 for the purpose of reviewing cybersecurity risks within the health care industry and identifying who will lead and coordinate efforts to address such risks among the various agencies. The Task Force has since issued a report setting forth six high-level imperatives that the health care industry needs to achieve in order to combat cybersecurity, and, notably, many of the vulnerabilities plaguing the industry identified in the Report as requiring correction are not necessarily related to specific flaws in the current cybersecurity framework, but rather susceptibilities presented by the infrastructure and associated regulatory regime that has evolved over the last few decades over the health care industry generally. That is, the current health care infrastructure by its nature exacerbates cybersecurity risk. Between a lack of information sharing of industry threats, risks, and mitigations, disparate leadership and governance goals for cybersecurity, the confluence and contradiction of existing federal and state laws, fragmentation in the fee-for-service delivery system, lack of care coordination, and disparate resources across and among sectors, the industry suffers from heightened cyber risk. Solutions that are reactive to problems within the current infrastructure will likely have little long term impact toward reducing cybersecurity vulnerabilities because they do not address the underlying system challenges. All of these confluences causes one to wonder whether if in fact the current health care delivery infrastructure is a contributing factor to the incidents of cybersecurity attacks and the exorbitant costs associated with resolving data breaches, should Congress look not just to curb breach incidents, but to address root cause systematic challenges in the health industry infrastructure that create increased exposure of cybersecurity threats? This article argues that cybersecurity risks will continue to be heightened and more costly to the health care industry as compared to other industries unless and until some general system redesign is achieved that allows for (1) greater sharing of resources among industry participants to ensure the same protections are implemented at all levels of the industry, which can be strengthened through greater interoperability of systems across the health care industry; and (2) increased focus and attention on the importance of cybersecurity issues as a priority among system reforms.

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Feminist Perspectives in Health Law
Seema Mohapatra and Lindsay F. Wiley

This essay argues that feminist legal theory offers an important, and underutilized, perspective to examine health law and policy. We use several theoretical frameworks developed by feminist legal theorists including relational autonomy, intersectionality, vulnerability theory, and the feminist critique of the public-private divide to demonstrate the utility of these theories to health law analysis. These frameworks provide insights relevant not only to issues that obviously relate to gender, but also to matters of choice, quality, and access that are less obviously gender-related. We map three key areas of existing scholarship and future inquiry at the intersection of health law and feminist legal theory: (I) patient choice and relational autonomy, (II) patriarchy, power and patient safety, and (III) access to health care and healthy living conditions at the public-private divide. Uniting these areas of inquiry is a nagging question central to the relationship between critical legal scholarship (including feminist scholarship) and pragmatic action to combat injustice: Can we use legal rights to achieve our aims even as we recognize them as tainted tools that have propped up oppressive social structures? A feminist agenda for health law and policy must grapple with this dilemma.