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THE JOURNAL OF

LAW, MEDICINE & ETHICS

VOLUME 44:3 • FALL 2016

THE JOURNAL OF

LAW, MEDICINE & ETHICS

CONTENTS

VOLUME 44:3 • FALL 2016

Symposium Articles

SYMPOSIUM

Contemporary Challenges in Informed Consent: Law, Research Practice, and Ethics

Guest Edited by Michele Goodwin and Harriet A. Washington

365
Letter from the Editor

Cover image ©Getty Images

371
Vulnerable Subjects: Why Does Informed Consent Matter?
Michele Goodwin

This special issue of the *Journal Law, Medicine & Ethics* takes up the concern of informed consent, particularly in times of controversy. The dominant moral dilemmas that frame traditional bioethical concerns address medical experimentation on vulnerable subjects; physicians assisting their patients in suicide or euthanasia; scarce resource allocation and medical futility; human trials to develop drugs; organ and tissue donation; cloning; xenotransplantation; abortion; human enhancement; mandatory vaccination; and much more. The term "bioethics" provides a lens, language, and guideposts to the study of medical ethics. It is worth noting, however, that medical experimentation is neither new nor exclusive to one country. Authors in this issue address thorny subjects that span borders and patients: from matters dealing with children and vaccination to the language and perception of consent.

381
Limning the Semantic Frontier of Informed Consent
Harriet A. Washington

It is the researcher's responsibility to provide accurate, complete, and unbiased verbal and written information yet, as this essay discusses, challenges to meaningful research consent abound in the communication between researcher and subject. This discussion of these challenges is far from exhaustive, but it will flag some of the potholes that researchers must anticipate on the sometimes rocky road to eliciting meaningful consent. These include, but are not limited to, inadequate scientific literacy, poorly written consent forms, and even the deployment of scientific terms and seductive acronyms like CURE and MIRACL. Studies with acronyms, for example, enroll five times as many patients as those without, are more likely to be published by prestigious journals, and have higher Jadad methodologic quality scores although they are no more likely to conclude with positive findings. Other barriers to researcher-subject communication include: widely differing beliefs and customs, semiotics, socioeconomic status, iatrophobia, and dramatically different histories of treatment in the medical-research arena.

394
Achieving Informed Consent for Cellular Therapies: A Preclinical Translational Research Perspective on Regulations versus a Dose of Reality
Aileen J. Anderson and Brian J. Cummings

A central principle of bioethics is "subject autonomy," the acknowledgement of the primacy of the informed consent of the subject of research. Autonomy requires informed consent — the assurance that the research participant is informed about the possible risks and benefits of the research. In fact, informed consent is difficult when a single drug is being tested, although subjects have a baseline understanding of the testing of a pharmacological agent and the understanding that they can stop taking the drug if there were an adverse event. However, informed consent is even less easily achieved in the modern arena of complex new molecular and cellular therapies. In this article, we argue that as science confronts new issues such as transplantation of stem cell products, which may live within the participant for the rest of their lives, researchers must carefully consider and constantly re-examine how they properly inform subjects considering participation trials of these novel therapeutic strategies.

For example, the manufacture of a vial of a cell product that consists of a collection of growing cells is very different than the production of a vial of identical pills, which can be presumed to be identical. The scientific concepts on which these cellular approaches are based may seem alien and incomprehensible to a research subject, who thinks of a clinical trial as simply the selection and testing of the most efficacious pharmaceutical agent already proven to work in preclinical animal studies. The research subject would be wrong.

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THE JOURNAL OF
LAW, MEDICINE & ETHICS

CONTENTS

VOLUME 44:3 • FALL 2016

402
Realizing Informed Consent in Times of Controversy: Lessons from the SUPPORT Study
Robert J. Morse and Robin Fretwell Wilson

This Essay examines the elegantly simple idea that consent to medical treatment or participation in human research must be "informed" to be valid. It does so by using as a case study the controversial clinical research trial known as the Surfactant, Positive Pressure, and Oxygenation Randomized Trial ("SUPPORT"). The Essay begins by charting, through case law and the adoption of the common rule, the evolution of duties to secure fully informed consent in both research and treatment. The Essay then utilizes the SUPPORT study, which sought to pinpoint the level of saturated oxygen that should be provided to extremely low birth weight infants to demonstrate modern complexities and shortcomings of the duty to secure informed consent. This Essay shows how the duty is measured by foreseeability of risks and benefits in human research and why federal regulators believed the trade-offs in risk and benefits from differing oxygen levels administered in the support study were foreseeable. It then explores the contours of the duty to secure informed consent when applied to researchers who also serve as treating physicians, highlighting how common law duties differ in jurisdictions that apply the professional standard and those that apply the patient-centered material risk standard. This Essay provides new insight into what the law must do to make real the notion that [e]very human being of adult years and sound mind has a right to determine what shall be done with his body."

419
The New Federalism: State Policies Regarding Embryonic Stem Cell Research
Nefi D. Acosta and Sidney H. Golub

Stem cell policy in the United States is an amalgam of federal and state policies. The scientific development of human pluripotent embryonic stem cells (ESCs) triggered a contentious national stem cell policy debate during the administration of President George W. Bush. The Bush "compromise" that allowed federal funding to study only a very limited number of ESC derived cell lines did not satisfy either the researchers or the patient advocates who saw great medical potential being stifled. Neither more restrictive legislation nor expansion of federal funding proved politically possible and the federal impasse opened the door for a variety of state-based experiments. In 2004, California became the largest and most influential state venture into stem cell research by passing "Prop 71," a voter initiative that created a new stem cell agency and funded it with $3 billion. Several states followed suit with similar programs to protect the right of investigators to do stem cell research and in some cases to invest state funding in such projects. Other states devised legislation to restrict stem cell research and in five states, criminal penalties were included. Thus, the US stem cell policy is a patchwork of multiple, often conflicting, state and federal policies.

437
Informed Consent, Body Property, and Self-Sovereignty
Radhika Rao

Recent cases involving biosamples taken from indigenous tribes and newborn babies reveal the emptiness of informed consent. This venerable doctrine often functions as a charade, a collective fiction which thinly masks the uncomfortable fact that the subjects of human research are not actually afforded full information regarding the types of research that may be contemplated, nor do they provide meaningful consent. But if informed consent fails to provide adequate protection to the donors of biological materials, why not turn to principles of property law? Property is power, yet current law permits everyone *except* for those who donate biological materials to possess property rights. The reluctance to invoke property probably stems from fears of resurrecting slavery and the commodification of human beings. But ironically, avoidance of property transforms the subjects of human research into objects that can be owned only by others, resulting in new forms of oppression and exploitation. Human research subjects are autonomous individuals who should not only possess the power to contribute their biological materials, but also the right to help control the course of research, and to share in the resulting benefits or profits. Conferring body property might enable research subjects to regain power and a measure of self-sovereignty.

445
Involuntary Consent: Conditioning Access to Health Care on Participation in Clinical Trials
Ruqaiijah A. Yearby

American bioethics has served as a safety net for the rich and powerful, often failing to protect minorities and the economically disadvantaged. For example, minorities and the economically disadvantaged are often unduly influenced into participating in clinical trials that promise monetary gain or access to health care. This is a violation of the bioethical principle of "respect for persons," which requires that informed consent for participation in clinical trials is voluntary and free of undue influence. Promises of access to health care invalidate the voluntariness of informed consent not only because it unduly induces minorities and the economically disadvantaged to participate in clinical trials to obtain access to potentially life saving health care, but it is also manipulative because some times the clinical trial is conducted by the very institutions that are denying minorities and the economically disadvantaged access to health care. To measure whether consent is voluntary and free of undue influence, federal agencies should require researchers to use the Vulnerability and Equity Impact Assessment tool, which I have created based on the Health Equity Impact Assessment tool, to determine whether minorities and the economically disadvantaged are being unduly influenced into participating in clinical trials in violation of the "respect for persons" principle.

462
Lowering the Age of Consent: Pushing Back against the Anti-Vaccine Movement
Allison M. Whelan

This article examines the rise of the anti-vaccination movement, the proliferation of laws allowing parental exemptions

THE JOURNAL OF
LAW, MEDICINE & ETHICS

CONTENTS

VOLUME 44:3 • FALL 2016

to mandatory school vaccines, and the impact of the movement on immunization rates for all vaccines. It uses the ongoing debate about the Human Papillomavirus (HPV) vaccine as an example to highlight the ripple effect and consequences of the anti-vaccine movement despite robust evidence of the vaccine's safety and efficacy. The article scrutinizes how state legislatures ironically promote vaccination while simultaneously deferring to the opposition by promulgating broad opt-outs from mandatory vaccine laws. This article concludes by offering an alternative legislative approach to specifically combat the anti-vaccine movement's impact on HPV vaccination rates. Lowering the age of consent has not been widely attempted or proposed and provides an alternative statutory mechanism to push back against vaccine resistance.

474
Health and Big Data: An Ethical Framework for Health Information Collection by Corporate Wellness Programs
Ifeoma Ajunwa, Kate Crawford, and Joel S. Ford

This essay details the resurgence of wellness program as employed by large corporations with the aim of reducing healthcare costs. The essay narrows in on a discussion of how Big Data collection practices are being utilized in wellness programs and the potential negative impact on the worker in regards to privacy and employment discrimination. The essay offers an ethical framework to be adopted by wellness program vendors in order to conduct wellness programs that would achieve cost-saving goals without undue burdens on the worker. The essay also offers some innovative approaches to wellness that may well better serve the goals of healthcare cost reduction.

Independent Articles

481
An Assessment of the Human Subjects Protection Review Process for Exempt Research
Jonathan D. Loe, D. Alex Winkelman, and Christopher T. Robertson

Medical and public health research includes surveys, interviews, and biospecimens — techniques that do not present substantial risks to subjects. Consequently, this research is exempt from regulation under the Federal Common Rule. Nevertheless, at many institutions, exempt research is frequently subject to the same regulatory process that is required for non-exempt research, requiring the consumption of time and resources for review by Institutional Review Board members or staff. The federal government has indicated an intention to reform and centralize this system, but has not yet specified the form that it will use instead. By examining the policies of the top 50 research institutions, this article assesses institutional practices surrounding exempt research, quantifies the extent of exempt-research review requirements, documents a problem of "over-compliance," and makes recommendations for reform.

492
Including Language Access into Medicaid ACO Design
Rachel Gershon, Lisa Morris, and Warren Ferguson

Quality health care relies upon communication in a patient's preferred language. Language access in health care occurs when individuals are: (1) Welcomed by providers regardless of language ability; and (2) Offered quality language services as part of their care. Federal law generally requires access to health care and quality language services for deaf and Limited English Proficient (LEP) patients in health care settings, but these patients still find it hard to access health care and quality language services.

Meanwhile, several states are implementing Medicaid Accountable Care Organization (ACO) initiatives to reduce health care costs and improve health care quality. Alternative payment methods used in these initiatives can give Accountable Care Organizations more flexibility to design linguistically accessible care, but they can also put ACOs at increased financial risk for the cost of care. If these new payment methods do not account for differences in patient language needs, ACO initiatives could have the unintended consequence of rewarding ACOs who do not reach out to deaf and LEP communities or offer quality language services.

We reviewed public documents related to Medicaid ACO initiatives in six states. Some of these documents address language access. More could be done, however, to pay for language access efforts. This article describes Medicaid ACO initiatives and explores how different payment tools could be leveraged to reward ACOs for increased access to care and quality language services. We find that a combination of payment tools might be helpful to encourage both access and quality.

503
The Massachusetts School Sports Concussions Law: A Qualitative Study of Local Implementation Experiences
Mitchell L. Doucette, Maria T. Bulzacchelli, Tameka L. Gillum, and Jennifer M. Whitehill

Background: Reducing the incidence and negative consequences of concussion among youth athletes is a public health priority. In 2010, Massachusetts passed legislation aimed at addressing the issue of concussions in school athletics. We sought to understand local-level implementation decisions of the Massachusetts concussion law.

Methods: A qualitative multiple-case study approach was utilized. Semi-structured interviews with school-employed actors associated with the law's implementation were used for analysis. Interview data were subjected to a conventional content analysis.

Results: A total of 19 participants from 5 schools were interviewed. Schools were purposefully selected from communities varying in socioeconomic status and population. Participants included 5 athletic directors, 5 coaches, 4 athletic trainers, 4 school nurses, and 1 health and wellness coordinator. Eight themes emerged regarding specific ways schools have implemented the law. Six themes emerged regarding factors influencing implementation.

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THE JOURNAL OF
LAW, MEDICINE & ETHICS

CONTENTS

VOLUME 44:3 • FALL 2016

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 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.*

Next Issue:

The Affordable Care Act at Six: Reaching for a New Normal

A Symposium Guest Edited by Sara Rosenbaum and Jane Hyatt Thorpe

Conclusions: All cases employ neurocognitive testing as a means to assess concussions, place decision-making authority in athletic trainers' hands, and use a 30-minute online video to disseminate concussion education. Employing athletic trainers could pose challenges to school districts with limited financial capacity, as financial assistance from the state is not provided under the law. The validity of neurocognitive testing and the effectiveness of online concussion training need further study. Cooperation from student athletes, their parents, and physicians is necessary for full implementation of the law.

514
Current Practices and the Provider Perspectives on Inconclusive Genetic Test Results for Osteogenesis Imperfecta in Children with Unexplained Fractures: ELSI Implications
Emily Youngblom, Mitzi Leah Murray, and Peter H. Byers

Genetic testing can be used to determine if unexplained fractures in children could have resulted from a predisposition to bone fractures, e.g., osteogenesis imperfecta. However, uncertainty is introduced if a variant of unknown significance (VUS) is identified. Proper interpretation of VUS in these situations is critical because of its influence on clinical care and in court rulings. This study sought to understand how VUS are interpreted and used by practitioners when there is a differential diagnosis including both osteogenesis imperfecta and non-accidental injury.

A 15-question survey was emailed to physicians who requested analysis of two genes, COL1A1 and COL1A2, from the University of Washington from 2005-2013 for patient cases involving suspicion of child abuse.

Among the 89 participants, responses differed about when genetic testing should be ordered for osteogenesis imperfecta, who should be consulted about utilization of VUS test results, follow-up procedures, and who should receive the VUS results.

There are no clear guidelines for how to interpret and follow up on VUS. In the legal setting, misinterpreted VUS could lead to unintended consequences and deleterious ramifications for family members. The need for better practice guidelines to help promote more equitable handling of these sensitive legal cases is clear.

Columns

520
CURRENTS IN CONTEMPORARY BIOETHICS
Some Lingering Concerns about the Precision Medicine Initiative
Mark A. Rothstein

526
Calendar

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