Symposium Articles

352
INTRODUCTION
Genome Justice: Genetics and Group Rights
Rebecca Tsosie and Joan L. McGregor

356
Population Genomics and Research Ethics with Socially Identifiable Groups
Joan L. McGregor
In this paper, the author questions whether the research ethics guidelines and procedures are robust enough to protect groups when conducting genetics research with socially identifiable populations, particularly with Native American groups. The author argues for a change in the federal guidelines in substance and procedures of conducting genetic research with socially identifiable groups.

371
Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?
Radhika Rao
This article compares three frameworks for legal regulation of the human body. Property law systematically favors those who use the body to create commercial products. Yet contract and privacy rights cannot compete with the property paradigm, which alone affords a complete bundle of rights enforceable against the whole world. In the face of researchers' property rights, the theoretical freedom to contract and the meager interest in privacy leave those who supply body parts vulnerable to exploitation.

383
Human Genetics Studies: The Case for Group Rights
Laura S. Underkuffler
In this essay, the author focuses on an underlying theoretical issue which she believes seriously affects our collective response to the idea of group rights in the genetic-control context. That issue is to what extent are our responses to claims of group rights hampered by our bringing to the table (consciously or unconsciously) a model which is structured to acknowledge only individual concerns? Put another way, to what extent are our objections to group rights in this context a product of our inability (or refusal) to imagine the idea of group rights, rather than the product of truly substantive concerns?

396
Cultural Challenges to Biotechnology: Native American Genetic Resources and the Concept of Cultural Harm
Rebecca Tsosie
This article examines the intercultural context of issues related to genetic research on Native peoples. In particular, the article probes the disconnect between Western and indigenous concepts of property, ownership, and privacy, and examines the harms to Native peoples that may arise from unauthorized uses of blood and tissue samples or the information derived from such samples. The article concludes that existing legal and ethical frameworks are inadequate to address Native peoples’ rights to their genetic resources and suggests an intercultural framework for accommodation based on theories of intergroup equality and fundamental human rights.

412
Narratives of Race and Indigeneity in the Genographic Project
Kim TallBear
In its quest to sample 100,000 “indigenous and traditional peoples,” the Genographic Project deploys five problematic narratives: (1) that “we are all African”; (2) that “genetic science can end racism”; (3) that “indigenous peoples are vanishing”; (4) that “we are all related”; and (5) that Genographic “collaborates” with indigenous peoples. In so doing, Genographic perpetuates much critiqued, yet long-standing notions of race and colonial scientific practice.

425
The Human Genome as Common Heritage: Common Sense or Legal Nonsense?
Pilar N. Ossorio
This essay identifies two legal lineages underlying the common heritage concept, and applies each to the human genome. The essay notes some advantages and disadvantages of each approach, and argues that patenting of human genes would be allowable under either approach.
Partnership in U.K. Biobank: A Third Way for Genomic Property?
David E. Winickoff

A property analysis of the U.K. Biobank reveals a new imagination of the genomic biobank as a national common-pool resource. U.K. Biobank’s treatment of property and governance exhibit both strengths and weaknesses that may be instructive to genome project planners around the world.

Indoependent

Individuality and Human Beginnings: A Reply to David DeGrazia
Alfonso Gómez-Lobo

The author argues that individuality does not require indivisibility and that twinning can be explained as the reprogramming of blastomeres that already have begun to differentiate in accordance with the needs of the unified organism that originates at conception.

Discontinuity and Disaster: Gaps and the Negotiation of Culpability in Medication Delivery
Sidney Dekker

This paper shows how discontinuities in the process of drug delivery enable but also underdetermine the isolation of a culprit in adverse medication events. A case example illustrates how we are forced to abandon conceptualizations of blame that assume a dichotomy (either culpable or not), and shift instead to a more nuanced version that estimates the degree to which an actor desired, generated, or could have foreseen the outcome, and the extent to which constraints external to the actor altered the event. The paper concludes that meaningful safety interventions in a system as diverse, socially embedded and complex as health care delivery cannot just build on “good science” (e.g., good methods) to generate “root” causes. Rather, they need to somehow be sensitive to how and which narratives of success and failure are created, as these constrain which countermeasures are likely to be encouraged, funded, and accepted.

Off the Grid: Vaccinations Among Homeschooled Children
Donya Khalili and Arthur Caplan

To protect public health, states require that parents have their children immunized before they are permitted to attend public or private school. But for homeschooled children, the rules vary. With the spectacular growth in the number of homeschooled students, it is becoming more difficult to reach these youth to ensure that they are immunized at all. These children are frequently unvaccinated, leaving them open to infection with diseases that are all but stamped out in the United States with immunization requirements. States should encourage parents to get their homeschooled students vaccinated through enacting the same laws as those used for public school students. This could be done by enforcing current laws through neglect petitions or by requiring that children be immunized before participating in school sponsored programs. As most states require some filing to allow parents to homeschool their children, it would be easy to enact laws requiring that homeschooled children be immunized or exempted before completing registration.

Informed Consent: Physician Inexperience is a Material Risk for Patients
Richard J. Veerapen

This paper examines the case for an expanded interpretation of the concept of “material risk” such that it necessitates voluntary disclosure of physician inexperience with a specific medical procedure. Informed consent law in the United States, Canada, and most commonwealth jurisdictions has become a driver of standards of risk disclosure by physicians during the informed consent process. The legal standard of risk disclosure expected of a physician hinges on the interpretation of the entity called “material risk.” Any impairment of the physician related to drug usage, disease, or alcohol which compounds the risk of a procedure is very likely to be considered material by a patient. This paper argues that physician inexperience is a factor that a reasonable patient would attach significance to and that it should therefore be viewed as a “material risk” requiring disclosure.

Columns

Currents in Contemporary Ethics
Stephen S. Hanson

Teaching Health Law
Charity Scott

Recent Developments in Health Law
Harvard Law and Health Care Society and the staff of the American Journal of Law & Medicine

Calendar
Dear Editor

Re-assent “Yes” – At Menarche “No”

O’Lonergan and Zodrow argue in their article “Pediatric Assent: Subject Protection Issues among Adolescent Females Enrolled in Research” (JLME 34, no. 2) that minor females who are enrolled in long-term research studies should be “re-assented” at menarche.1 The goal is to “establish parity between the research and treatment contexts with regard to the right to information that is relevant in the decision-making process pertinent to sexual and reproductive health matters.”2 Menarcheal minors are singled out for re-assent because “the bald biological fact is that adolescent girls can conceive and bear children...the risks to sexual and reproductive health will be born by the girl primarily” and “the onset of menarche offers a relatively discrete event to which changes in policies and procedures can be attached.”3 True, but do the authors accomplish their goal?

The debate about the age at which investigators ought to be required to obtain assent from minors is not new. It has been raging since the publication of the Belmont Report’s vague directive to treat all individuals as “autonomous agents,” capable of “independent decision making” and protect individuals with “diminished autonomy” from harm.4 In the name of “respect for persons,” the ethical foundation laid out in the Belmont report obliges investigators to re-assent minors when their ability to act as autonomous agents changes. To honor beneficence, investigators must obtain re-assent from minors when the risk-benefit ratio associated with research participation changes. Finally, justice requires that the re-assent process neither invites unreasonable self-inclusion or exclusion nor places an undue burden of risk upon minor participants. Obtaining re-assent at menarche does not achieve any of these aims or meet generally accepted standards of informed consent.

The mean age at menarche in the United States is approximately 12 years.5 However, the normal range extends from ten to 16 years.6 Early matures tend to become sexually active at a younger age than their later maturing peers.7 However, cognitive development does not necessarily advance in tandem with physiological development.8 Hence, there is no reason to believe that a majority of post-menarcheal ten-year-olds would be more capable of acting as “autonomous agents” than a majority of pre-menarcheal ten- or 14-year-olds. By contrast, studies of normal adolescent development demonstrate that pre-menarcheal 14-year-olds are usually more capable of acting as “autonomous agents” than post-menarcheal ten-year-olds.9 Thus, investigators who wish to meet their responsibility of moving from one classroom to another. This suggests that there is a consensus in that most youngsters are cognitively and socially mature enough to act as “autonomous agents” and make “independent decisions.”

Less than five percent of middle school students are sexually active, but more than 50 percent will become so during the first two years of high school.10 Hence, the reproductive risk for a post-menarcheal ten-year-old is not substantially greater than that of a pre-menarcheal 16-year-old.11 Thus, investigators who wish to meet their beneficence-based obligations should take their cues from epidemiologists, not physiologists. Again, middle school is an ideal benchmark.12

Finally, is a menarche-based re-assent process just? Consider the sexually active minor who is enrolled in a minimal-risk study that involves a potentially teratogenic drug. She relies on condoms, which her boyfriend keeps because she does not want to risk parental discovery. However, when she is asked to give her re-assent for participation, she learns that she will have to drop out of the study if she is not willing to use a more effective method of contraception or abstain from sexual intercourse. Her rights to obtain confidential reproductive health care will safeguard the process of obtaining the requisite contraceptive supplies.14 The Health Insurance Portability and Accountability Act limits her parents’ access to her reproductive health information.15 But what about her justice-based right to be protected from undue risk? If by fear of parental discovery she elects to drop out of the study, how can her decision be explained without raising parental suspicion? Participation does not impose these risks on older, truly sexually autonomous individuals or younger, non-sexually active individuals. In this case, investigators who wish to meet their justice-based obligations should take their cues from pediatricians, not physiologists. Again, middle school is an ideal benchmark. Most middle-schoolers and their parents are psychosocially mature enough to think hypothetically about the implications of sexual activity. By this age a majority of students have had sufficient experience with members of the opposite sex to realize that there are aspects of these relationships they do not want their parents to know about. Yet parents rarely have any reason to be suspicious of or concerned about their “children” at this age. Hence most are willing to accept the concept of confidentiality on the grounds that “other” minors may need the protection it affords. Here a well-designed re-assent process can prevent the ethical dilemma described above and promote healthy development. Once it has been agreed that future decisions about participation will be made autonomously by the minor and investigator, if parents subsequently find
they are not willing or able to respect their minor’s right to confidentiality, then investigators can be confident that it is not the decision about research participation that has imposed an undue burden of risk.

The final advantage of a middle school-based re-assent process is that like menarche it offers a relatively discrete event to which changes in policies and procedures can be attached. However, unlike menarche it can be applied to males. Although males cannot conceive, they can and do cause pregnancies. Hence, like females they have the right to understand and make autonomous decisions about their reproductive risks.

Catherine Stevens-Simon, M.D.

References
2. Id.
3. Id.
6. Id.
8. Id.
15. See O’Lonergan and Zodrow, supra note 1.
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.

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Next Issue:

Global Health Law, Ethics, and Policy
A Symposium Guest Edited by Lawrence O. Gostin and James G. Hodge

of contraception, she would be exposed to the risk of parental suspicion or discovery if she were to be discontinued from study participation. To show why this line of reasoning is not appropriate, one must divide these concerns into two distinct concerns: (a) “unreasonable self-inclusion or exclusion” and (b) “undue burden of risk.”

The assertion that re-assenting at the onset of menarche constitutes unreasonable exclusion fails. In any clinical trial involving an agent with teratogenic risks, adult women are either excluded or are required to employ effective methods of contraception (with what constitutes “effective” being defined by the trial investigators). This is universally viewed as the only reasonable approach to protect potential fetuses from the teratogenic agent and the women from the risk of bearing a child with congenital defects. Thus, the exclusion of sexually active adolescent females from research with teratogenic risks for failure to agree to use effective contraception is not unreasonable – rather, it is standard research practice.

Regarding undue risk, Stevens-Simon argues that exposing the sexually active adolescent girl to the risk of a suspicious parent or parental discovery of her sexual activity constitutes an undue burden. There are two considerations here. First, “undue burden of risk” generally refers to the undue burden of risk of participation in research, and not the risk of not participating. Second, if one construes the discontinuation from a study as a burden of risk for participation, the question is, does it constitute an undue burden of risk? With regard to the first consideration, insisting on effective contraception as a condition of research participation does involve risk, in terms of both the risk of the method itself, and the risk of parental discovery of the girl’s use of the method from which they would likely infer her sexual activity. However, the responsibility of researchers and IRBs is to minimize the burden of risks of research participation. We would argue that protecting fetuses and female participants from the teratogenic effects of an investigational agent is of paramount importance, and failing to protect them would constitute an undue burden of risk. While one cannot dismiss the potential effects of parental ire at discovery of a girl’s sexual activity, it must come second to protection from teratogenic risks. Finally, discontinuation from research for failure to employ effective contraception does constitute a burden of risk, but not an undue one as continuation in the study without utilization of effective contraception clearly poses an undue burden of risk given that it would violate standard research practices for inclusion of women of child-bearing age in clinical trials of potentially teratogenic agents.

Stevens-Simon’s third point asserts that singling out girls for re-assent when they reach menarche is not the optimal approach due to the broad age range at which adolescent girls achieve menarche and the attendant wide range of psychological and cognitive maturation. She asserts that the milestone of middle school is a more appropriate point at which re-assent should occur because (1) parents are not suspicious of adolescents at this age with regard to sexual activity and (2) the psychological maturation of adolescents in middle school is more amenable to considering the hypothetical implications of sexual activity. The suspicions of parents are not operative in this discussion because, if parents are not suspicious of their adolescents’ sexual behavior at the age of middle school, then one can only assume that they are even less suspicious in elementary school. Moreover, Stevens-Simon presents evidence of the sexual activity of early matures, and then presumes that parents are devoid of suspicions of early sexual activity in their children, a conclusion that is not based on research or logic. Thus, this reason is not a cogent one.

That adolescents in middle school can think hypothetically about the implications of sexual activity is not a reason to fail to re-assent younger menarchal girls. As Stevens-Simon points out, early matures become sexually active at younger ages. This is precisely the reason that we chose the developmentally flexible physiological milestone of menarche as the point at which girls participating in research involving teratogenic agents should be re-assented. That girls younger than middle school may be less able to think about the hypothetical implications of sexual activity is all the more reason to re-assent them.

In conclusion, we chose the selective approach to re-assent girls enrolled in research involving teratogenic agents rather than a blanket approach which would pose an undue risk to sexually active menarchal girls younger than middle school by exposing them to teratogenic risks without informing them that such risks exist. Certainly, informing girls younger than middle school about such risks will be more complicated than informing older girls. However, the alternative is not acceptable. It is our view that this selective approach targets only those girls for whom the teratogenic risks are cogent, and thus, it poses no undue risks as only those who are actually reproductively capable of being exposed to the risk are re-assented.

Theresa O’Lonergan and John J. Zodrow

References