

**The Journal of Law, Medicine & Ethics (JLME):** Material published in *The Journal of Law, Medicine & Ethics (JLME)* contributes to the educational mission of the American Society of Law, Medicine & Ethics, covering public health, health disparities, patient safety and quality of care, and biomedical science and research, and more.

#### 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

**Letters to the Editors:** Comments on articles in the Journal should be addressed to the Editor at the editorial office or emailed to thutchinson@aslme.org.

**Submission Guidelines:** For submission guidelines, please contact the editorial office at thutchinson@aslme.org. Submission guidelines are also available online at <http://jlme.sagepub.com>.

**The Journal of Law, Medicine & Ethics (ISSN 1073-1105 (J812))** is published quarterly—in March, June, September and December—by SAGE Publications, 2455 Teller Road, Thousand Oaks, CA 91320 in association with the American Society of Law, Medicine & Ethics. Send address changes to the Journal of Law, Medicine & Ethics, c/o SAGE Publications, 2455 Teller Road, Thousand Oaks, CA 91320.

Copyright © 2016, the American Society of Law, Medicine & Ethics. All rights reserved. No portion of the contents may be reproduced in any form without written permission from the publisher.

**Subscription Information:** All subscription inquiries, orders, back issues, claims, and renewals should be addressed to SAGE Publications, 2455 Teller Road, Thousand Oaks, CA 91320; telephone: (800) 818-SAGE (7243) and (805) 499-0721; fax: (805) 375-1700; e-mail: journals@sagepub.com; <http://www.sagepublications.com>. Subscription Price: Institutions: \$864. For all customers outside the Americas, please visit <http://www.sagepub.co.uk/customerCare.nav> for information. Claims: Claims for undelivered or damaged copies must be made no later than six months following month of publication. The publisher will supply replacement issues when losses have been sustained in transit and when the reserve stock will permit.

**Member Subscription Information:** American Society of Law, Medicine & Ethics member inquiries, change of address, back issues, claims, and membership renewal requests should be addressed to Membership Director, American Society of Law, Medicine & Ethics, 765 Commonwealth Avenue, Suite 1704, Boston, MA 02215; telephone: (617) 262-4990 ext. 15; fax: (617) 437-7597. Requests for replacement issues should be made within six months of the missing or damaged issue. Beyond six months and at the request of the American Society of Law, Medicine & Ethics, the publisher will supply replacement issues when losses have been sustained in transit and when the reserve stock permits.

**Abstracting and Indexing:** Please visit <http://jlme.sagepub.com> and, under the "More about this journal" menu on the right-hand side, click on the Abstracting/Indexing link to view a full list of databases in which this journal is indexed.

**Copyright Permission:** Permission requests to photocopy or otherwise reproduce material published in this journal should be submitted by accessing the article online on the journal's Web site at <http://jlme.sagepub.com> and selecting the "Request Permission" link. Permission may also be requested by contacting the Copyright Clearance Center via their Web site at <http://www.copyright.com>, or via e-mail at [info@copyright.com](mailto:info@copyright.com).

**Advertising and Reprints:** Current advertising rates and specifications may be obtained by contacting the advertising coordinator in the Thousand Oaks office at (805) 410-7772 or by sending an e-mail to [advertising@sagepub.com](mailto:advertising@sagepub.com). To order reprints, please e-mail [reprint@sagepub.com](mailto:reprint@sagepub.com). Acceptance of advertising in this journal in no way implies endorsement of the advertised product or service by SAGE, the journal's affiliated society(ies), or the journal editor(s). No endorsement is intended or implied. SAGE reserves the right to reject any advertising it deems as inappropriate for this journal.

**Supplements:** Address all correspondence to Barbara Eisenberg, SAGE Publications, Thousand Oaks, California 91320, (805) 410-7763 (phone), [reprint@sagepub.com](mailto:reprint@sagepub.com) (e-mail).

**Change of Address for Non-Members:** Six weeks' advance notice must be given when notifying of change of address. Please send the old address label along with the new address to the SAGE office address above to ensure proper identification. Please specify the name of the journal.

# THE JOURNAL OF LAW, MEDICINE & ETHICS

VOLUME 44:1 • SPRING 2016

## BOARD OF EDITORS

- |  |   |
|--|---|
| Anita Allen-Castellitto, J.D., Ph.D.<br><i>University of Pennsylvania Law School</i>                           | Zita Lazzarini, J.D., M.P.H.<br><i>University of Connecticut Health Center</i>            |
| Troyen A. Brennan, M.D., J.D., M.P.H.<br><i>CVS Caremark<br/>Harvard School of Public Health</i>               | Theodore R. LeBlang, J.D.<br><i>Southern Illinois University<br/>School of Medicine</i>   |
| Baruch A. Brody, Ph.D.<br><i>Baylor College of Medicine</i>  | Robert J. Levine, M.D.<br><i>Yale University</i>  |
| Arthur L. Caplan, Ph.D.<br><i>University of Pennsylvania Medical Center</i>                                    | Wendy K. Mariner, J.D., LL.M., M.P.H.<br><i>Boston University School of Public Health</i> |
| R. Alta Charo, J.D.<br><i>University of Wisconsin Law School</i>   | Maxwell J. Mehlman, J.D.<br><i>Case Western Reserve University</i>                        |
| James F. Childress, M.A., Ph.D.<br><i>University of Virginia</i>   | Alan Meisel, J.D.<br><i>University of Pittsburgh School of Law</i>                        |
| Ellen Wright Clayton, M.D., J.D.<br><i>Vanderbilt University School of Medicine</i>                            | Christine I. Mitchell, R.N., M.S.,<br>M.T.S., FAAN<br><i>Children's Hospital Boston</i>   |
| Bernard M. Dickens, Ph.D.,<br>LL.D., LL.M.<br><i>University of Toronto Faculty of Law</i>                      | Jonathan D. Moreno, Ph.D.<br><i>University of Pennsylvania</i>                            |
| Nancy Neveloff Dubler, LL.B.<br><i>Montefiore Medical Center</i>   | E. Haavi Morreim, Ph.D.<br><i>University of Tennessee College<br/>of Medicine</i>         |
| Ezekiel J. Emanuel, M.D., Ph.D.<br><i>University of Pennsylvania</i>   | Thomas H. Murray, Ph.D.<br><i>The Hastings Center</i>                                     |
| Norman C. Fost, M.D., M.P.H.<br><i>University of Wisconsin Medical School</i>                                  | Wendy E. Parmet, J.D.<br><i>Northeastern University School of Law</i>                     |
| Barry Furrow, J.D.<br><i>Drexel University Earle Mack School of Law</i>  | Edmund D. Pellegrino, M.D.<br><i>Georgetown University Medical Center</i>                 |
| Jay A. Gold, M.D., J.D., M.P.H.<br><i>MetaStar, Inc.</i>   | Stephen G. Post, Ph.D.<br><i>Stony Brook University</i>                                   |
| Lawrence O. Gostin, J.D., LL.D. (Hon.)<br><i>Georgetown University Law Center<br/>Johns Hopkins University</i> | Philip R. Reilly, M.D., J.D.<br><i>Third Rock Ventures</i>                                |
| Ana Smith Iltis, Ph.D.<br><i>Wake Forest University</i>  | Arnold J. Rosoff, J.D.<br><i>University of Pennsylvania –<br/>Wharton School</i>          |
| Sandra H. Johnson, J.D., LL.M.<br><i>Saint Louis University School of Law</i>                                  | Karen H. Rothenberg, J.D., M.P.A.<br><i>University of Maryland School of Law</i>          |
| Jeffrey P. Kahn, Ph.D., M.P.H.<br><i>Johns Hopkins University</i>  | Margaret A. Somerville, A.M., FRSC<br><i>McGill University</i>                            |
| Marshall B. Kapp, J.D., M.P.H.<br><i>Florida State Colleges of Medicine and Law</i>                            | Daniel P. Sulmasy, O.F.M.,<br>M.D., Ph.D.<br><i>University of Chicago</i>                 |
| Nancy M. P. King, J.D.<br><i>University of North Carolina<br/>School of Medicine</i>                           | Susan M. Wolf, J.D.<br><i>University of Minnesota Law School</i>                          |
| John D. Lantos, M.D.<br><i>Center for Practical Bioethics</i>  | Stuart J. Youngner, M.D.<br><i>Case Western Reserve University</i>                        |

THE JOURNAL OF  
LAW, MEDICINE & ETHICS  
C O N T E N T S

VOLUME 44:1 • SPRING 2016

SYMPOSIUM

**Part II:  
Harmonizing  
Privacy Laws  
to Enable  
International  
Biobank  
Research**

Guest Edited by  
Mark A. Rothstein  
and Bartha Maria  
Knoppers

1  
*Letter from  
the Editor*

Cover image ©Corbis

This introduces part two of *JLME's* first ever two-part symposium. The first half of this symposium appeared in our Winter 2015 issue.

Symposium Articles

7  
**Locating Biobanks in the Canadian  
Privacy Maze**

*Katie M. Saulnier and Yann Joly*

Although Canada has not yet enacted any biobanking-specific privacy law, guidance and oversight are provided via various federal and provincial health and privacy-related laws as well as via ethics and policy documents. The primary policy document governing health research, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, provides the framework for the strong role of Research Ethics Boards in Canada, and limits research funding from Canada's three main federal funding agencies to those who agree to adhere to its policies. The broad consent model is gaining traction in Canada, although lack of legal and constitutional precedence for the broad consent or opt-out options makes this an evolving issue. In general, data is required to be coded; more specific security measures are outlined in guidelines that may be implemented by local policy. International sharing is allowed, and Canada meets the European Union's standards for receipt of data and samples.

20  
**Biobanking in Estonia**

*Aime Keis*

Estonia is a democratic, parliamentary republic with a health care system that is built on the principle of compulsory, solidarity-based insurance and the all-round availability of services of private service providers. Estonia has specific biobank legislation as well as oversight via data protection laws. Its population-based biobank, the Estonian Genome Center (EGCUT), established in 2001, is one of the largest biobanks in Europe, and its database may be used only for scientific research, public health research, and statistics. The EGCUT can issue data to a third party, but only in coded form. This comprehensive database of genotypic, phenotypic, health, and genealogical information represents about 5% of Estonia's adult population, and is the largest cohort ever gathered in Estonia. Government approval is required for international data sharing, and sharing can be further limited by the requirement of ethics approval and permission from Estonian government.

24  
**Biobanks as a Central Part of the  
Finnish Growth and Genomic  
Strategies: How to Balance Privacy in  
an Innovation Ecosystem?**

*Sirpa Soini*

Finland has aimed to make itself an international leader in genomic research and related business and, in working towards that goal, has enacted biobank legislation. The Biobank Act requires biobanks to gain approval, be supervised, and register at the national level. Numerous other laws may also apply in any given research setting, such as the Personal Data Act, the Medical Research Act, and the Act on Medical Use of Human Organs and Tissues. In terms of privacy protection, anonymization is generally not permitted under Finnish law and therefore most biobanks pseudonomize data and samples. However, the broad understanding of what is identifiable data in Finland has created difficulties in sharing with non-EU countries. Furthermore, consent to biobank research is only applicable to the sample and related data, not to data stored in other health-related registries, and consent is only to the field of research for that particular biobank. These restrictions impede the sharing of samples and data for research.

35  
**Privacy Laws and Biobanking  
in Germany**

*Nils Hoppe*

While the possibility of enacting a sui generis Biobank Act has been debated in Germany at great length, as of yet the country has not implemented any biobank-specific legislation. Instead, oversight is available via a network of research and privacy laws, including those of the European Union. The Nationale Kohorte, Germany's large-scale, population-based epidemiological research biobank, is funded by the Federal Ministry of Education and Research, and there are currently 108 registered biobanks throughout Germany. The current system, including the structure and study design of the Nationale Kohorte, privileges the protection of personal information even at the cost of socially desirable research; it remains to be seen if forthcoming legislation will shift this balance.

45

**Biobanking and Privacy in India**

*Sachin Chaturvedi, Krishna Ravi Srinivas, and Vasantha Muthuswamy*

Biobank-based research is not specifically addressed in Indian statutory law and therefore Indian Council for Medical Research guidelines are the primary regulators of biobank research in India. The guidelines allow for broad consent and for any level of identification of specimens. Although privacy is a fundamental right under the Indian Constitution, courts have limited this right when it conflicts with other rights or with the public interest. Furthermore, there is no established privacy test or actionable privacy right in the common law of India. In order to facilitate biobank-based research, both of these lacunae should be addressed by statutory law specifically addressing biobanking and more directly addressing the accompanying privacy concerns. A biobank-specific law should be written with international guidelines in mind, but harmonization with other laws should not be attempted until after India has created a law addressing biobank research within the unique legal and cultural environment of India.

58

**Mexican Regulation of Biobanks**

*Lourdes Motta-Murguía and Garbiñe Saruwatari-Zavala*

Biobank-based research in Mexico is mostly governed by research and data protection laws. There is no direct mention of biobanks in either statutory or regulatory law besides a requirement that the Federal Ministry of Health and a Mexican institution devoted to scientific research approve the transfer of biological materials outside of Mexico for population genetics research purposes. Such requirements are the basis of Genomic Sovereignty in Mexico, but such requirements have not prevented international collaboration. In addition, Mexican law singles out genetic research in informed consent provisions, but it does not specify whether all biobank-based research is genetic research. In order to facilitate international collaboration on biobank-based research, Mexico should directly address biobanking in its laws, building on the research framework and data protection framework already in place.

68

**Regulating Privacy and Biobanks in the Netherlands**

*Aart C. Hendriks and Rachèl E. van Hellemond*

The Netherlands does not have any specific legislation pertaining to human biological materials and data collection by biobanks. Instead, these issues are governed by a patchwork of laws, codes of practices, and other ethical instruments, where special emphasis is given to the right to privacy and self-determination. While draft legislation for biobanking was scheduled to enter into force in 2007, as of mid-2015 such legislation was still under consideration, with the intent that it would focus particularly on individual self-determination, the interests of research, the use of bodily materials collected by biobanks for criminal law purposes, and dilemmas around results that are clinically relevant for biobank participants. Under the current framework, the amount of privacy protection afforded to data is linked to its level of identifiability. International sharing of personal data to non-EU/European Economic Area countries is allowed if these countries provide adequate protection.

85

**Biobank and Genomic Research in Uganda: Are Extant Privacy and Confidentiality Regimes Adequate?**

*Obiajulu Nnamuchi*

Not many African countries have been able to develop a robust system for regulating health research within their respective jurisdictions, particularly in the realm of biobanking and genomics. This is not without reason. Aside from underdevelopment and all that it entails or perhaps in consequence thereof, countries in the region have been unable to make significant strides in medical research. But there are exceptions. Amongst the few seeming success stories is Uganda. Nonetheless, although the country has developed what appears to be a functional framework to govern genomic research and biobanking, the consistency of key provisions with international standards, especially those pertaining to privacy of research participants and confidentiality of their health information, is not at all clear. Yet, making this determination – the main objective of this article – is critical in determining the adequacy of protection available to human research subjects in the country.

96

**Biobank Report: United Kingdom**

*Jane Kaye, Jessica Bell, Linda Briceno, and Colin Mitchell*

The United Kingdom is a leader in genomics research, and the presence of numerous types of biobanks and the linking of health data and research within the UK evidences the importance of biobank-based research in the UK. There is no biobank-specific law in the UK and research on biobank materials is governed by a confusing set of statutory law, common law, regulations, and guidance documents. Several layers of applicable law, from European to local, further complicate an understanding of privacy protections. Finally, biobanks frequently contain data in addition to the samples; the legal framework in the UK generally differentiates between data and samples and the form of the data affects the applicability of legal provisions. Biobanks must be licensed by the Human Tissue Authority; certain projects must be reviewed by Research Ethics Committees, and all projects are encouraged to be reviewed by them. Data Access Committees in biobanks are also common in the UK. While this confusing array of legal provisions leaves privacy protections in biobanking somewhat unclear, changes at the EU level may contribute to harmonization of approaches to privacy.

106

**Biobanking Research and Privacy Laws in the United States**

*Heather L. Harrell and Mark A. Rothstein*

Privacy is protected in biobank-based research in the US primarily by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the Federal Policy for Protection of Human Subjects (Common Rule). Neither rule, however, was created to function in the unique context of biobank research, and therefore neither applies to all biobank-based research. Not only is it challenging to determine when the HIPAA Privacy Rule or the Common Rule apply, but these laws apply different standards to protect privacy. In addition, many other federal and state laws may be applicable to a particular biobank, researcher, or project. US law also does

THE JOURNAL OF  
LAW, MEDICINE &  
ETHICS  
CONTENTS  
VOLUME 44:1 • SPRING 2016

not directly address international sharing of data or specimens outside of the EU-US Safe Harbor Agreement, which only applies to receipt of data by certain US entities from EU countries, and is in the process of revision. Although new rules would help clarify privacy protections in biobanking, any implemented changes should be studied to determine the sufficiency of the protections as well as its ability to facilitate or hinder international collaborations.

128

**EU Laws on Privacy in Genomic Databases and Biobanking**

*David Townsend*

Both the European Union and the Council of Europe have a bearing on privacy in genomic databases and biobanking. In terms of legislation, the processing of personal data as it relates to the right to privacy is currently largely regulated in Europe by Directive 95/46/EC, which requires that processing be "fair and lawful" and follow a set of principles, meaning that the data be processed only for stated purposes, be sufficient for the purposes of the processing, be kept only for so long as is necessary to achieve those purposes, and be kept securely and only in an identifiable state for such time as is necessary for the processing. The European privacy regime does not require the de-identification (anonymization) of personal data used in genomic databases or biobanks, and alongside this practice informed consent as well as governance and oversight mechanisms provide for the protection of genomic data.

143

**The European Union's Adequacy Approach to Privacy and International Data Sharing in Health Research**

*Jennifer Stoddart, Benny Chan, and Yann Joly*

The European Union (EU) approach to data protection consists of assessing the adequacy of the data protection offered by the laws of a particular jurisdiction against a set of principles that includes purpose limitation, transparency, quality, proportionality, security, access, and rectification. The EU's Data Protection Directive sets conditions on the transfer of data to third countries by prohibiting Member States from transferring to such countries as have been deemed inadequate in terms of the data protection regimes. In theory, each jurisdiction is evaluated similarly and must be found fully compliant with the EU's data protection principles to be considered adequate. In practice, the inconsistency with which these evaluations are made presents a hurdle to international data-sharing and makes difficult the integration of different data-sharing approaches; in the 20 years since the Directive was first adopted, the laws of only five countries from outside of the EU, Economic Area, or the European Free Trade Agreement have been deemed adequate to engage in data transfers without the need for further administrative safeguards.

156

**Privacy and Security within Biobanking: The Role of Information Technology**

*Raymond Heatherly*

Along with technical issues, biobanking frequently raises important privacy and security issues that must be resolved as biobanks continue to grow in scale and scope. Consent mechanisms currently in use range from fine-grained to very broad, and in some cases participants are offered very few privacy protections. However, developments in information technology are bringing improvements. New programs and systems are being developed to allow researchers to conduct analyses without distributing the data itself offsite, either by allowing the investigator to communicate with a central computer, or by having each site participate in meta-analysis that results in a shared statistic or final significance result. The implementation of security protocols into the research biobanking setting requires three key elements: authentication, authorization, and auditing. Authentication is the process of making sure individuals are who they claim to be, frequently through the use of a password, a key fob, or a physical (i.e., retinal or fingerprint) scan. Authorization involves ensuring that every individual who attempts an action has permission to do that action. Finally, auditing allows for actions to be logged so that inappropriate or unethical actions can later be traced back to their source.

161

**Comparative Approaches to Biobanks and Privacy**

*Mark A. Rothstein, Bartha Maria Knoppers, and Heather L. Harrell*

Laws in the 20 jurisdictions studied for this project display many similar approaches to protecting privacy in biobank research. Although few have enacted biobank-specific legislation, many countries address biobanking within other laws. All provide for some oversight mechanisms for biobank research, even though the nature of that oversight varies between jurisdictions. Most have some sort of controlled access system in place for research with biobank specimens. While broad consent models facilitate biobanking, countries without national or federated biobanks have been slow to adopt broad consent. International guidelines have facilitated sharing and generally take a proportional risk approach, but many countries have provisions guiding international sharing and a few even limit international sharing. Although privacy laws may not prohibit international collaborations, the multi-prong approach to privacy unique to each jurisdiction can complicate international sharing. These symposium issues can serve as a resource for explaining the sometimes intricate privacy laws in each studied jurisdiction, outlining the key issues with regards to privacy and biobanking, and serving to describe a framework for the process of harmonization of privacy laws.

**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:*

**Ethical and Legal Issues in Pediatrics**  
A Symposium  
Guest Edited  
by Robert M. Sade

## Independent Articles

173

### **The Forced Marriage of Minors: A Neglected Form of Child Abuse**

*Loretta M. Kopelman*

The forced marriage of minors is child abuse, consequently duties exist to stop them. Yet over 14 million forced marriages of minors occur annually in developing countries. The American Bar Association (ABA) concludes that the problem in the US is significant, widespread but largely ignored, and that few US laws protect minors from forced marriages. Although their best chance of rescue often involves visits to health care providers, US providers show little awareness of this growing problem. Strategies discussed to stop forced marriages include recommendations from the UN, the ABA, and the UK. The author anticipates and responds to criticisms that first, no duty to intervene exists without better laws and practice guidelines; and second, that such marriages are not child abuse in traditions where parental rights or familism allegedly justify them.

182

### **Whither the “Improvement Standard”? Coverage for Severe Brain Injury after *Jimmo v. Sebelius***

*Joseph J. Fins, Megan S. Wright,*

*Claudia Kraft, Alix Rogers, Marina B. Romani, Samantha Godwin, and Michael R. Ulrich*

As improvements in neuroscience have enabled a better understanding of disorders of consciousness as well as methods to treat them, a hurdle that has become all too prevalent is the denial of coverage for treatment and rehabilitation services. In 2011, a settlement emerged from a Vermont District Court case, *Jimmo v. Sebelius*, which was brought to stop the use of an “improvement standard” that required tangible progress over an identifiable period of time for Medicare coverage of services. While the use of this standard can have deleterious effects on those with many chronic conditions, it is especially burdensome for those in the minimally conscious state (MCS), where improvements are unpredictable and often not manifested through repeatable overt behaviors. Though the focus of this paper is on the challenges of brain injury and the minimally conscious state, which an estimated 100,000 to 200,000 individuals suffer from in the United States, the post-*Jimmo* arguments presented can and should have a broad impact as envisioned by the plaintiffs who brought the case on behalf of multiple advocacy groups representing patients with a range of chronic care conditions.

194

### **Contrasting Medical and Legal Standards of Evidence: A Precision Medicine Case Study**

*Gary E. Marchant, Kathryn Scheckel, and Doug Campos-Outcalt*

As the health care system transitions to a precision medicine approach that tailors clinical care to the genetic profile of the individual patient, there is a potential tension between the

clinical uptake of new technologies by providers and the legal system's expectation of the standard of care in applying such technologies. We examine this tension by comparing the type of evidence that physicians and courts are likely to rely on in determining a duty to recommend pharmacogenetic testing of patients prescribed the oral anti-coagulant drug warfarin. There is a large body of inconsistent evidence and factors for and against such testing, but physicians and courts are likely to weigh this evidence differently. The potential implications for medical malpractice risk are evaluated and discussed.

205

### **Genomic Test Results and the Courtroom: The Roles of Experts and Expert Testimony**

*Edward Ramos, Shawneequa L. Callier, Peter B. Swann, and Hosea H. Harvey*

The rapid advancement from single-gene testing to whole genome sequencing has significantly broadened the type and amount of information available to researchers, physicians, patients, and the public in general. Much debate has ensued about whether genomic test results should be reported to research participants, patients and consumers, and at what stage we can be sure that existing evidence justifies their use in clinical settings. Courts and judges evaluating the utility of these results will not be immune to this uncertainty. As scholars increasingly explore the duty of care standards related to reporting genomic test results, it is timely to provide a framework for understanding how uncertainty about genetic and genomic tests influences evidentiary considerations in the court room. Here, we explore the subtleties and nuances of interpreting genetic data in an environment of substantial discord related to the value that individuals should place on genetic and genomic tests. In conjunction, we discuss the roles courts should play in qualifying experts, expert testimony, and genetic and genomic tests given the intricate and complex nature of genetic and genomic information.

## Columns

216

### **CURRENTS IN CONTEMPORARY BIOETHICS** **How Genetics Might Affect Real Property Rights**

*Mark A. Rothstein and Laura Rothstein*

New developments in genetics could affect a variety of real property rights. Mortgage lenders, mortgage insurers, real estate sellers, senior living centers, retirement communities, or other parties in residential real estate transactions begin requiring predictive genetic information as part of the application process. One likely use would be by retirement communities to learn an individual's genetic risk for Alzheimer's disease. The federal Fair Housing Act prohibits discrimination based on disability, but it is not clear that it would apply to genetic risk assessments. Only California law explicitly applies to this situation and there have been no reported cases.

222

### **Calendar**