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Book Review: "Reading the Future?": Legal and Ethical Challenges of Predictive Genetic Testing, by Trudo Lemmens, Mireille Lacroix and Roxanne Mykitiuk

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READING THE FUTURE?: LEGAL AND ETHICAL CHALLENGES OF PREDICTIVE GENETIC TESTING BY TRUDO LEMMENS, MIREILLE LACROIX & ROXANNE MYKITIUK (MONTREAL: LES ÉDITIONS THÉMIS, 2007) 308 pages[1].

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Reading the Future?: Legal and Ethical Challenges of Predictive Genetic Testing is a new book updating the work of a group of legal scholars who, in 2001, provided advice to the Ontario Advisory Committee on New Predictive Genetic Technologies. Together with Lisa Austin and Bita Amani, the authors made recommendations to the Advisory Committee on the management of a range of legal and ethical issues in genetic testing.

Clinical geneticist Doctor Anne Summers chaired the Advisory Committee which conducted its work from April 2000 through November 2001. The province of Ontario was at that time leading the Canadian response to a potential deluge (described by some as a "tsunami") of developments in genetic testing. These technological developments were rendered even more vexing by the way in which they were being marketed. Myriad Genetics, a Utah-based biotechnology

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company, was forging ahead in its effort to impose exclusive or restrictive licences in the international delivery of genetic tests. This business model was especially egregious because Myriad claimed exclusive rights to the genes for hereditary breast and ovarian cancer (BRCA1 and BRCA2) and sought to exercise this claim beyond its successful commercial base in the United States to Europe and Canada, where health care delivery was less commercialized.

The Advisory Committee was announced alongside the introduction of provincially funded services for the delivery of genetic testing for the hereditary cancer syndromes, services that defied the claims of Myriad Genetics. The Committee rushed to deliver its report,[3] just prior to the release of the Ministry of Health and Long-Term Care's report[4] to the Premiers' Conference of January 2002, which advanced a series of recommendations for action by government. The Ministry's report is one of several that have fostered an international dialogue about genetic testing in health care and emphasized the importance of finding a balance between support for intellectual property rights and innovation on the one hand, and support of sustainable and accessible research practices and health systems on the other.

This fraught policy context explains the book's origins and much about its content. The book starts from the premise that legislative and regulatory intervention is needed, and proposes to elaborate on systems of deliberation, oversight, and control to avert potential harms. As an analysis of what might go amiss if predictive genetic tests were to proliferate, and what might be done if governments were forced to act, this book provides a useful overview grounded in the Canadian—and especially Ontarian—context.

Framed by a brief introduction and conclusion, the book is delivered as a series of eight sections, each of which addresses an area of concern and lists recommendations to mitigate potential harms. The scope of analysis is broad: the authors are concerned primarily with the medical uses of genetic testing, but also address non-clinical uses such as

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[3] *Genetic Services in Ontario: Mapping the Future* (Toronto: Queen's Printer for Ontario, 2001) online: Ontario Ministry of Health and Long- Term Care <http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep01/genetic_report.pdf>.

[4] *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (Toronto: Queen's Printer for Ontario, 2002) online: Ontario Ministry of Health and Long-Term Care <http://www.health.gov.on.ca/english/public/pub/ministry_reports/ geneticsrep02/report_e.pdf>.

genetic testing in the workplace and impacts of predictive testing on adoption, certain aspects of research such as genetic databanks, and the intellectual property environment that supports commercial development and delivery. The analysis is grounded in a review of international policy statements, commission and committee reports, consideration of relevant Canadian legislation (focused primarily but not exclusively on Ontario), and legal scholarship.

Each section of the book can be considered independently, highlighting the value of the text as an educational resource. Students might be directed to sections of the text, or review it section by section as they are introduced to the various ways in which legal concerns and institutions intersect with developments in health technology.

The first substantive section of the book considers genetic discrimination and stigmatization in diverse contexts such as employment, insurance, financial services, adoption, education, and health services. The authors recommend legislative changes to bolster the protections provided by human rights codes as well as legislative and regulatory oversight mechanisms to monitor and control the use of genetic tests outside health care contexts. The second section provides a useful overview of the governance of research involving human subjects in Canada. Canada has, as the authors point out, a system of guidelines rather than a set of formal statutes or regulations governing the use of predictive genetic testing. While the authors recommend more regulatory oversight, the relevance of these generic issues in research governance as applied to the context of genetics is suggested only in closing, and without much conviction. Further, recent debates in research ethics and regulation that have specific relevance for genetics—such as the potential obligation to communicate genetic research results—are not discussed.

A brief section recommending "equitable access" to [beneficial] genetic services[5] is then followed by an analysis of gene patenting by Lisa Austin and Bita Amani. This section provides a helpful introduction to the range of issues in both domestic and international law that bear on patents on biotechnological inventions in general, and patents on genes in particular. However, the section was drafted in 2003 and requires updating. A page of dense text at the end of the section

[5] *Supra* note 1 at 99.

providing an update as to recent developments does not address this problem.

A discussion of commercialization and the direct marketing of genetic tests follows the section on intellectual property. Highlighting the jurisdictional challenges of commercial genetic testing, the authors recommend discussions between provincial and federal governments and across international borders in order to effectively regulate this area. Turning next to clinical issues, the authors offer a helpful review of the role of genetic counsellors in the delivery of genetic services and recommend the introduction of professional regulation for this group of clinicians.

The penultimate section considers some of the legal issues arising in the clinical delivery of genetic testing services, including issues of consent, disclosure, privacy and confidentiality, and the specific issues that arise in genetic testing of minors, incapable persons, and those with reduced capacity. This section briefly addresses a host of highly complex issues including consent for multiplex testing, the web of duties that arise from the familial nature of genetic testing, the capacity for genetic testing to provide unexpected results, the duties of confidentiality and disclosure, and rights of patients *not* to know. The final section examines the storage of genetic material and information, with consideration of personal, clinical, and research uses. Legislation is recommended to protect the privacy of stored genetic information, and to establish standards for collection, access, duration of retention, and disposal and follow-up for stored samples.

Throughout the book, the authors are attentive to legal and policy debates. These include how a "right not to know" can be upheld given the familial nature of genetic information that may breach one family member's desire to remain ignorant, and whether clinicians are obligated to communicate unexpected findings to patients, especially when these findings do not have clinical relevance. Yet the ethical debates that surround these legal and policy issues are considered to a lesser degree. What is the ethical underpinning of any 'right not to know'? Does such a right, if it exists, derive from the right to autonomy, as is typically and narrowly argued, or is it a more expansive right that derives from a right to privacy, as Graeme Laurie has argued?[6] Can

[6] See Graeme T. Laurie, "In Defence of Ignorance: Genetic Information and the Right Not to Know" (1999) 6 European Journal of Health Law 119 and "Protecting and Promoting Privacy in

advance warning and informed consent protect against the potential harms of the *unintended* findings of genetic testing (*e.g.*, misattributed paternity), or does advance notification fail to resolve the issue, as argued by Erica Lucast?[7] While the omission of these debates is understandable—a single tome can only do so much—it limits the appeal of the book for more advanced readers. Further, I wonder whether this omission might be even more instrumental by limiting consideration of the legal remedies that might be required. If a right not to know resides in a right to privacy, the right might be observed even without express consent, with the burden placed on those who would disclose knowledge of no clear clinical significance to justify the infringement. Similarly, if advance warning and informed consent cannot avert the harms of unintended knowledge, how can these harms be mitigated, and what might be required to avoid the generation of unintended results?

The book offers a sustained analysis of the breadth of legal and policy issues that might arise from developments in predictive genetic testing. It also reads as a sustained call for intensive legislative, regulatory, and policy development in the area of predictive genetic testing. And this is where policy analysts (of whom the reviewer is one) part company with legal scholars. The conflicted policy context that birthed this book is no longer with us, and in my view, the justification for intensive governmental action is no longer obvious. In Ontario, the permanent Advisory Committee that was recommended by Anne Summer's Committee, and established shortly thereafter, has been allowed to die a slow death of neglect: Orders-in-Council are still standing, but no meetings have been called. Claims of a "tsunami" of genetic tests identifying an array of highly significant clinical risks have gone silent. Finally, the Byzantine business model promoted by Myriad Genetics has been chastened by widespread opprobrium.

When Summer's Committee was convened, claims about expansive growth in predictive capacity using genetic information were circulating widely. Auspicious individuals like the Director of the US National Human Genome Research Institute, Francis S. Collins, offered

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an Uncertain World: Further Defences of Ignorance and the Right Not to Know" (2000) 7 European Journal of Health Law 185.

[7] See Erica K. Lucast, "Informed Consent and the Misattributed Paternity Problem in Genetic Counseling" (2007) 21 Bioethics 41.

clinical scenarios, such as the story of "John" who took a battery of genetic tests in 2010 leading to personalized pharmacologic treatments, intensive surveillance, and profound behaviour change.[8] Thus, the authors are specifically concerned with *predictive* genetic testing, arguing that, "genetic information is most often risk information, used for predicting future health status rather than for direct diagnostic purposes."[9] In my view, this latter claim is in error as most clinical uses of genetic testing are diagnostic. Clear differences between predictive and diagnostic uses of genetic testing are hard to sustain. Many individuals who use "predictive" tests to identify hereditary risks for BRCA1/2 already have cancer; for them, results are both diagnostic and predictive of future risks (*e.g.*, of secondary cancers), and have both health and reproductive implications.[10]

More importantly, the book originated in a call to consider remedies when the potential harms of predictive genetic testing were believed to be both likely and serious. Thus, the authors provide only a brief justification for the special attention given to genetic testing, suggesting that genetic data is somewhat unique, and that the contexts for the circulation of genetic testing intensify the need for oversight. They provide no clear rationale for the protective measures that they suggest. Is there a real and pressing need for legislation to curb genetic discrimination? Does commercial genetic testing require specific oversight or regulation that is different in kind or focus from other regulatory initiatives? Is additional legislation required to protect the privacy of genetic information? Finally, are the measures suggested proportional to the harms to be averted?

In the spring of 2000, the authors were given an impossible task: to provide a comprehensive overview of the legal and ethical challenges that might arise from then-anticipated developments in predictive genetic testing. The authors did a commendable job in the short time available by providing a thorough analysis of many of these issues to be included in the final report. They then continued their work, seeking to complete the assigned task. The finished work represents a commendable effort to scope out and consider the range of issues

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[8] Francis S. Collins, "Shattuck Lecture: Medical and Societal Consequences of the Human Genome Project" (1999) 341 New England Journal of Medicine 28.

[9] *Supra* note 1 at 4.

[10] *Supra* note 1 at 167.

arising from developments in predictive genetic testing, and an enormous amount of valuable information was compiled. Had the authors left the manuscript in that form, I would have no quibble. But they chose to also advance policy recommendations. In 2001, the premise that strong action was needed was widely accepted. But the policy context has changed: 2007 is a fair distance from 2001.