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EDITOR'S NOTE

Adrian Thorogood *

In seven short years, the *McGill Journal of Law and Health* (MJLH) has matured into one of Canada's leading legal publications, and continues to be an important forum for scholarship and debate in health law. The academic section of this issue is bookended by articles on ethical and legal concerns in genetics, addressing both old fears and unforeseen challenges. Our first article by Mark Pioro and colleagues revisits the issue of genetic discrimination. Their systematic review of judicial decisions provides a nuanced look at the creep of genetics in our language and concepts of disease, and its influence law. They explore how our evolving understanding of genetics affects fundamental legal concepts from criminal responsibility to the establishment of causation in workers' compensation and tort cases. Our final academic article, by Joly, Allen, and Granados Moreno from the Centre of Genomics and Policy explores ethical issues and legal tensions at the frontier of genomic science: population biobanking. They investigate a troubling tension between funding agencies' promotion of data access and "broad" consent to future research on one hand, and the legal requirement that research participants be meaningfully informed of research purposes and potential risks on the other. Rounding out the academic articles is a case comment from Lorian Hardcastle discussing the appropriate level of judicial deference to government decisions about health care funding and access. This question becomes increasingly important as access to health care gains growing recognition as a human right, while at the same time health systems in North America come under greater budgetary strain.

The second part of this issue is dedicated to a Special Section on Developments in the Law of Informed Consent. In May 2013, the Canadian Bar Association's annual Health Law Summit was held in Halifax, Nova Scotia. The Summit opened with an engaging panel addressing this important topic. The panellists were asked by our Editorial Board to share a summary of their presentations with our readership. This area of health law continues to fascinate legal scholars and demand creativity from lawyers and judges. Its evolution over the course of 40 years of jurisprudence and scholarship in Canada has had a profound impact not just on the practice of medicine, but also on the very nature of the physician-patient relationship. Two panellists accepted our invitation. Sarah Burningham presented on behalf of her research group at the Health Law Institute of the University of Alberta. Burningham and colleagues explore whether the law of informed consent achieves one of its primary ob-

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jectives: to ensure that patients truly understand the risks of medical procedures. The second article comes from medical malpractice lawyers Paul McGivern and Natalia Ivolgina, lawyers at the Vancouver firm Pacific Medical Law. The authors offer insights from their years of experience in litigation, and carry out a comprehensive review of the modern doctrine of informed consent that stretches from *Reibl v Hughes* to the most recent developments before the Supreme Court of Canada. As conference proceedings, the articles in this Special Section were not peer-reviewed. The views and opinions expressed are those of the authors alone, and do not reflect any positions held by the Canadian Bar Association.

It has been a great pleasure to be involved with the MJLH at this propitious point in the Journal's history. The potential of our Journal is beginning to materialize, and we continue to attract top quality work and recognition from the highest courts in the land. Our email inboxes pile high with quality submissions, and our editorial office hums with constant activity. We continue to open up our Journal to a more diverse set of voices and a broader set of issues. We recently moved to rolling online publication, allowing us to accept submissions on a year-round basis while ensuring that the work of our authors reaches our readers rapidly. In this past year, we have matured not just as a publication, but also as a student organization. Thanks to the tireless efforts of our managerial team, we have taken a central role locally and nationally in promoting debate and legal education, attested to by the full house at our 2013 Colloquium on Physician-Assisted Suicide. This year also witnessed our online team revamp the Journal's blog and social media presence, building visibility of the MJLH as a hub for discussion and debate in health law.

I would like to thank the authors, peer reviewers, and editors of Volume 7 for their contributions to this issue of the MJLH. I would also like to recognize McGill University, the Law Students' Association at McGill, and Canada's Research-Based Pharmaceutical Companies for their gracious financial support. Special thanks as well to the Volume 7 Executive – Kaitlin Soye, Daniel Mastine, Marie-Laure Tapp, and Francesca Taddeo – for your friendship, support, and unflinching dedication. I am proud to be part of such a talented and committed team. Students may run the MJLH, but we still manage to put many a professional outfit to shame. I must also recognize our readers, our *raison d'être*, and thank you for your continued interest and support. You are invited to access our content free of charge on our website (<http://mjlh.mcgill.ca/>), to subscribe to our biannual print edition, and to join the discussion on the MJLH Facebook page.

À votre santé!

UNDERSTANDING THE USE OF “GENETIC PREDISPOSITION” IN CANADIAN LEGAL DECISIONS

*Mark Pioro, Roxanne Mykitiuk, Lilith Finkler & Jeff Nisker**

Since the advent of the Human Genome Project in 1989, the ethical, legal, and social implications inherent in future genetic science and its applications have worried researchers and scholars in law and ethics. Concern that the results of genetic testing might be used to discriminate against particular individuals and groups of individuals has been paramount, prompting calls for specific legislation to protect against genetic discrimination. Against this backdrop we sought to investigate instances of genetic discrimination in Canadian legal decisions. We searched Canadian court and administrative tribunal decisions, using the key words “genetic predisposition” and its cognates, and found none that took up the issue of genetic discrimination. However, in 468 decisions, “genetic predisposition” was used by courts and tribunals when describing the causal origins of health related conditions. Genetic predisposition was cited with respect to numerous health conditions, and in various areas of law, in particular criminal, family, workers’ compensation, and tort. In several criminal law decisions, genetic predisposition served to explain the origin of a mental health condition in addressing the issue of criminal responsibility. The predominant use in family law was in describing a child’s health condition in crown

Depuis la mise en place du « Projet génome humain » en 1989, les implications éthiques, légales et sociales inhérentes au futur de la génétique et de ses applications ont soulevé une certaine inquiétude chez les chercheurs et spécialistes de l’éthique et du droit. Ces appréhensions graves sur le fait que les résultats de tests génétiques puissent être utilisés pour discriminer certains individus ou groupes de personnes en ont incité plusieurs à demander qu’on légifère de façon spécifique afin de contrer la discrimination génétique. C’est dans ce contexte que nous avons voulu enquêter sur les cas de discrimination génétique dans les décisions légales canadiennes. Nous avons effectué nos recherches parmi les décisions des cours et tribunaux administratifs canadiens, utilisant les mots-clés « prédisposition génétique » et leurs parents, mais n’avons trouvé aucune décision abordant la discrimination génétique. Cependant, « prédisposition génétique » fut utilisé dans 468 décisions pour décrire les causes d’une grande variété de problèmes de santé, et ce dans divers domaines du droit, en particulier le droit criminel, de la famille, la responsabilité extra-contractuelle et l’indemnisation de travailleurs. Dans plusieurs décisions de droit criminel, la prédisposition génétique fut utilisée comme explication

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wardship and youth protection proceedings. In workers' compensation and tort, genetic predisposition was used to argue whether the claimant's condition was inherited rather than related to the workplace or the negligence of the defendant. Genetic predisposition, when used to argue the issue of disease causation on a balance of probabilities, reflects "geneticization": the tendency to describe the underlying basis of health and disease as genetic. Geneticization, like genetic discrimination, can be problematic. Specifically, both may exaggerate the extent to which genetic information is exceptional and determinative of health and disease outcomes. Also, geneticization, like genetic discrimination, may marginalize people on a perceived genetic basis.

pour la source de troubles de santé mentale lors de la détermination de la responsabilité criminelle. L'usage le plus courant en droit de la famille fut pour décrire l'état de santé d'un enfant dans le cadre de procédures touchant la tutelle de l'état et la protection de la jeunesse. Dans le cas de la responsabilité extra-contractuelle et l'indemnisation de travailleurs, la prédisposition génétique fut utilisée dans des cas où l'on voulait déterminer si la condition d'un demandeur lui avait été transmise ou si elle était plutôt liée au lieu de travail ou à la négligence du défendeur. La prédisposition génétique, lorsqu'utilisée dans le cadre d'arguments sur la causalité d'une maladie sur la balance des probabilités, reflète la « génétisation » : la tendance à décrire l'origine de la maladie et de l'état de santé comme étant génétique. Or, la génétisation, tout comme la discrimination génétique, peut devenir problématique. Toutes deux peuvent exagérer l'étendue du caractère distinctif et déterminatif de l'état de santé qu'ont les renseignements génétiques. De plus, la génétisation et la discrimination génétique peuvent marginaliser certaines personnes sur la base d'une perception de condition génétique.

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Introduction

Since the Human Genome Project set out in 1989 to map and sequence the human genome,¹ scholars have considered the ethical, legal and social implications of the Project.² A particular concern identified early was that of “genetic discrimination”, which has been defined as “the denial of rights, privileges or opportunities on the basis of information obtained from genetically-based diagnostic and prognostic tests.”³ Genetic discrimination has been anticipated in the employment and insurance contexts in particular.⁴ In Canada, where individuals receive publicly-funded health care, discrimination has been thought more likely to occur in relation to disability⁵ or life in-

¹ James D Watson, “The Human Genome Project: Past, Present, and Future” (1990) 248:4951 *Science* 44.

² See e.g. Michael S Yesley, “What’s ELSI Got to Do with It? Bioethics and the Human Genome Project” (2008) 27:1 *New Genet Soc* 1; George J Annas, “At Law: Who’s Afraid of the Human Genome?” (1989) 19 *Hastings Cent Rep* 19:4; Roxanne Mykitiuk & Steven Penney, “Screening for Deficits: The Legal and Ethical Implications of Genetic Screening and Testing to Reduce Health Care Budgets” (1995) 3 *Health LJ* 235; Eric T Juengst, “Priorities in Professional Ethics and Social Policy for Human Genetics” (1991) 266:13 *JAMA* 1835; Lori B Andrews et al, eds, *Assessing Genetic Risks: Implications for Health and Social Policy* (Washington, DC: National Academies Press, 1994).

³ Larry Gostin, “Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers” (1991) 17:1&2 *Am J L & Med* 109 at 110.

⁴ See e.g. *ibid*; Mark A Rothstein, “Genetic Discrimination in Employment and the Americans with Disabilities Act” (1992) 29:1 *Hous L Rev* 23; Marvin R Natowicz, Jane K Alper & Joseph S Alper, “Genetic Discrimination and the Law” (1992) 50:3 *Am J Hum Genet* 465; Jill Gaubing, “Race, Sex, and Genetic Discrimination in Insurance: What’s Fair?” (1994) 80 *Cornell L Rev* 1646; C Lee, “Creating a Genetic Underclass: The Potential for Genetic Discrimination by the Health Insurance Industry” (1993) 13:1 *Pace L Rev* 189; RJ McMurray et al, “Use of Genetic Testing by Employers” (1991) 266:13 *JAMA* 1827; Kathy L Hudson et al, “Genetic Discrimination and Health Insurance: An Urgent Need for Reform” (1995) 270:5235 *Science* 391.

⁵ Trudo Lemmens, “Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?” (2000) 45:2 *McGill LJ* 347 at 352-53.

surance.⁶ We initially sought to examine Canadian case law relating to genetic discrimination, but broadened our study to explore whether and how the language and knowledge of genetics are being used in Canadian court and tribunal decisions. Our focus was on how courts and tribunals were using, if at all, genetic information relating to disease causation or a health-related condition in question, rather than other factors (for example, genetic kinship). It is information of this kind that has begun to be produced by research and reported in the scientific literature,⁷ and which has the potential to lead to genetic discrimination.⁸ Understanding how, and in what contexts, courts and administrative tribunals use genetic language and knowledge can provide insight into the legal meaning of personal genetic information as well as the processes of legal decision making through which genetic information is used and possibly, abused.

This paper argues that adversarial legal processes, in their use of genetic concepts of disease causation, contribute to and reflect the geneticization of health and disease, with "disorders, behaviours and physiological variations defined, at least in part, as genetic in origin."⁹ This occurs because scientific uncertainty in light of the multiple risk factors and mechanisms of disease, combined with the general principle that the burden of proof rests with one

⁶ *Ibid*; Bartha M Knoppers & Yann Joly, "Physicians, Genetics and Life Insurance" (2004) 170:9 CMAJ 1421.

⁷ See e.g. Marcy E MacDonald et al, "A Novel Gene Containing a Trinucleotide Repeat that Is Expanded and Unstable on Huntington's Disease Chromosomes" (1993) 72:6 Cell 971; Richard Wooster et al, "Identification of the Breast Cancer Susceptibility Gene BRCA2" (1995) 378:6559 Nature 789.

⁸ Yvonne Bombard et al, "Perceptions of Genetic Discrimination among People at Risk for Huntington's Disease: A Cross Sectional Survey" (2009) 338:b2175 BMJ; Hudson et al, *supra* note 4; Paul R Billings et al, "Discrimination as a Consequence of Genetic Testing" (1992) 50 Am J Hum Genet 476; S Taylor et al, "Investigating Genetic Discrimination in Australia: A Large-scale Survey of Clinical Genetics Clients" (2008) 74:1 Clin Genet 20. See also Steve E Humphries, Paul M Ridker & Philippa J Talmud, "Genetic Testing for Cardiovascular Disease Susceptibility: A Useful Clinical Management Tool or Possible Misinformation?" (2004) 24:4 Arterioscler Thromb Vasc Biol 628 at 628-29, 634; Ine Van Hoyweghen, Klasien Horstman & Rita Schepers, "Genetic 'Risk Carriers' and Lifestyle 'Risk Takers'. Which Risks Deserve our Legal Protection in Insurance?" (2007) 15:3 Health Care Anal 179 (both discussing the predictive and practical limits of genetic factors of disease in relation to non-genetic factors).

⁹ Abby Lippman, "Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities" (1991) 17:2 Am J L & Med 15 at 19.

of the parties on a balance of probabilities, render it sufficient (and economical) to resolve the issue of disease causation without thoroughly examining the genesis of the condition in question. The resolution of claims in this way leaves open the possibility that genetics will stand in for “hidden causes”¹⁰ of disease. For example, in a personal injury case where a condition is found to be compensable, ideas of genetic susceptibility may serve to differentiate individuals subject to common exposures where only some become or remain ill.¹¹ Likewise, where the required causal link is found not to exist, the origin of the condition may conveniently be ascribed to genetic predisposition itself.¹² While genetic discrimination was not at issue in any of the decisions we surveyed, our findings nonetheless raise concern. This is because geneticization, like genetic discrimination, may reflect a problematic view of the extent to which genetic information is exceptional, and determinative of health and disease outcomes.¹³ The next section provides background on legal and policy responses to the threat of genetic discrimination as well as how the scope of this paper was set. The paper then sets out the research methodology used to obtain and analyze the sample of decisions it considers. It first presents the results as an overview of the sample of decisions retrieved. Specifically, decisions are catalogued by jurisdiction, area of law, and the clinical condition in respect of which “genetic predisposition” is being cited. This overview sets the stage for classification of the various ways in which reference to genetic predisposition resolves different legal issues. The results are then discussed, particularly with regards to the way in which legal decision making may contribute to the geneticization of health and disease. Finally, this paper comments on the implications of geneticization in legal decision making from a disability rights perspective.

¹⁰ Michel Morange, *The Misunderstood Gene* (Cambridge, MA: Harvard University Press, 2001) at 12.

¹¹ See e.g. *Kolokathis et Industries Maintenance Empire* (22 January 2002), 114774-71-9904 at para 37, online: QCCLP <www.clp.gouv.qc.ca> [*Kolokathis*].

¹² See e.g. *Decision no 2008-1082* (10 December 2008), 2008 CanLII 85217, online: AWCAC <www.appealscommission.ab.ca>; *Decision no 2004-05655* (27 October 2004), 2004 CanLII 71273, online: BCWCAT <www.wcat.bc.ca>.

¹³ Péter Kakuk, “Genetic Information in the Age of Genohype” (2006) 9:3 *Med Health Care Philos* 325 at 335. See also Rochelle Cooper Dreyfuss & Dorothy Nelkin, “The Jurisprudence of Genetics” (1992) 45:2 *Vand L Rev* 313 (discussing genetic essentialism at 320-21); Susan M Wolf, “Beyond ‘Genetic Discrimination’: Toward the Broader Harm of Geneticism” (1995) 23:4 *JL Med & Ethics* 345 (Wolf goes farther by arguing that even when scientifically accurate, describing people in terms of genetic is still problematic, at 350).

I. Background

Individuals¹⁴ and government agencies¹⁵ have proposed a variety of legislative and policy responses to genetic discrimination and other ethical concerns stemming from developments in human genetics. International bodies have advocated for a use of genetic data that respects human rights and dignity.¹⁶ A majority of American states have restricted use of an individual's genetic information by health insurers and employers.¹⁷ At the federal level, the *American Genetic Information Nondiscrimination Act* ("GINA") of 2008¹⁸ prohibits discrimination in employment and health insurance based on genetic information. Disability discrimination and health information privacy

¹⁴ See e.g. Hudson et al, *supra* note 4; Karen Eltis, "Genetic Determinism and Discrimination: A Call to Re-Orient Prevailing Human Rights Discourse to Better Comport with the Public Implications of Individual Genetic Testing" (2007) 35:2 *JL Med & Ethics* 282; Bartha Maria Knoppers, "Overview of Law and Policy Challenges" (December 2005) 66 *La L Rev* 21.

¹⁵ See e.g. Privacy Commissioner of Canada, "Genetic Testing and Privacy" (Ottawa: PCC, 1995), online: PCC <www.priv.gc.ca/information/02_05_11_e.pdf>; United Kingdom, Department of Health, "Our Inheritance, Our Future: Realising the Potential of Genetics in the NHS" (London: DH, 2003), online: Department of Health <www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4019239.pdf>; United States, Department of Health & Human Services, *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services. Report of the Secretary's Advisory Committee on Genetics, Health, and Society* (Bethesda, SACGHS, 2008), online: DHHS <oba.od.nih.gov/oba/sacghs/reports/sacghs_oversight_report.pdf>.

¹⁶ See e.g. Universal Declaration on the Human Genome and Human Rights, UNESCO (11 November 1997); International Declaration on Human Genetic Data, UNESCO (16 October 2003); Resolution 2004/9 on Genetic Privacy and Non-discrimination, E/RES/2004/9, ECOSOC (21 July 2004).

¹⁷ National Conference of State Legislatures, "Genetics and Health Insurance State Anti-Discrimination Laws" (January 2008), online: NCLS <www.ncsl.org/issues-research/health/genetic-nondiscrimination-in-health-insurance-laws.aspx>; National Conference of State Legislatures, "Genetic Employment Laws" (January 2008), online: NCLS <www.ncsl.org/issues-research/health/genetic-employment-laws.aspx>.

¹⁸ Pub L 110-233, 122 Stat 881.

legislation also provides some protection against genetic discrimination.¹⁹ In Europe, Article 11 of the *EU Convention on Human Rights and Biomedicine*²⁰ prohibits genetic discrimination and Article 12 restricts the use of genetic testing to health-related purposes. These regulations in the United States and Europe are implemented in a variety of national instruments pertaining to health information privacy and non-discrimination.²¹ Aside from preventing and remedying genetic discrimination, these measures may allay fear of undergoing genetic tests based on concern that discrimination would result.²² In Canada, no formal legislative response has been made regarding genetic discrimination. Scholars and agencies have, however, contemplated various courses of action including strengthening existing privacy and human rights legislation, and creating separate legislation to address the issue.²³

¹⁹ National Human Genome Research Institute, “Existing Federal Anti-Discrimination Laws and How They Apply to Genetics” (28 February 2012), online: NHGRI <www.genome.gov/12513979>; *Americans with Disabilities Act*, 42 USC § 12101 (1990); *Health Insurance Portability and Accountability Act of 1996*, Pub L 104-191, 110 Stat 1936.

²⁰ Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 4 April 1997, 2137 UNTS 171, Eur TS164.

²¹ Nancy J King, Sukanya Pillay & Gail A Lasprogata, “Workplace Privacy and Discrimination Issues Related to Genetic Data: A Comparative Law Study of the European Union and the United States” (2006) 43:1 Am Bus LJ 79 at 82-83.

²² See Louise A Keogh et al, “Is Uptake of Genetic Testing for Colorectal Cancer Influenced by Knowledge of Insurance Implications?” (2009) 191:5 Med J Aust 255.

²³ See e.g. Trudo Lemmens, Daryl Pullman & Rebecca Rodal, Genome Canada, “Revisiting Genetic Discrimination Issues in 2010: Policy Options for Canada”, Policy Brief No. 2, (Ottawa: GPS, 2010), online: Genome Canada <www.genomecanada.ca/medias/pdf/en/GPS-Policy-Directions-Brief-2-EN.pdf>; Trudo Lemmens, Mireille Lacroix & Roxanne Mykitiuk, *Reading the Future?: Legal and Ethical Challenges of Predictive Genetic Testing* (Montréal: Les Éditions Thémis, 2005); Jo Ann Watton, “Fighting Genetic Discrimination in Canada: A New Coalition Takes Up the Cause” (2008) 22:6 GeneWatch 21, online: Council For Responsible Genetics <www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=229>; Québec, Conseil de la santé et du bien-être, “La santé et le bien-être à l’ère de l’information génétique: enjeux individuels et sociaux à gérer” (Québec: Conseil de la santé et du bien-être, 2001), online: FQRSC <www.fqrcs.gouv.qc.ca/upload/editeur/etique/avissante_bienetre.pdf>; Privacy Commissioner of Canada, *supra* note 15; Ontario Law Reform Commission, “Report on Genetic Testing” (Toronto: Queen’s Printer, 1996),

Against this backdrop of concern about genetic discrimination, we investigated whether Canadian case law since the inception of the Human Genome Project indicates a record of allegations of genetic discrimination.²⁴ We performed Quicklaw searches of the “All Canadian Court Cases” and “All Boards and Tribunals” databases for “genetic discrimination” as a phrase, which revealed no results. A CanLii search also produced no results. We then searched both “genetic” and “discrimination” separately and found no cases that raised the issue of genetic discrimination. We also reviewed the academic literature addressing genetic discrimination in Canada and found two noteworthy cases not identified from our keyword search. Although these cases do not discuss genetic discrimination as an issue, they provide background on how Canadian law might approach claims of genetic discrimination.

The 1990 Superior Court of Québec decision in *Audet v Industrielle-Alliance*²⁵ concerned a life insurance policy-holder who died in an automobile collision. His widow claimed benefits under the policy, but the company refused to pay having discovered that the insured had a genetic condition; Steinert disease (a type of muscular dystrophy transmitted in an autosomal dominant pattern). The insured in applying for coverage had denied having any physical or mental anomalies. The court decided in favour of the insurance company and declared the insurance policy void, holding that even though the insured was almost completely asymptomatic, the condition constituted an anomaly and the insured made a false declaration. The facts of this case involve what could be described as genetic discrimination on the part of the insurer, as it sought to deny coverage on the basis of the claimant’s genetic condition.

online: Osgoode Hall Law Library <ia700601.us.archive.org/5/items/reportongenetic00onta/reportongenetic00onta.pdf>; Canadian Biotechnology Advisory Committee, “Protecting Privacy in the Age of Genetic Information” (Ottawa: CBAC, August 2004), online: Government of Canada Publications <publications.gc.ca/collections/Collection/Iu44-19-2004E.pdf> .

²⁴ See Roxanne Mykitiuk et al, “The Potential for Misusing ‘Genetic Predisposition’ in Canadian Courts and Tribunals” (2011) 183:14 CMAJ 1601 [Mykitiuk et al, “The Potential for Misusing”]. This 2011 CMAJ study is based on the same comprehensive electronic search results as the present paper. The short 2011 study analyzes references to genetic predisposition in Canadian legal decisions. It discusses the health conditions cited, the areas of law and legal issues involved, and the purpose of referring to genetic predisposition.

²⁵ *Audet v Industrielle-Alliance, compagnie d’assurance sur la vie*, [1990] RRA 500, [1990] JQ no 2532 (QL) (Qc Sup Ct).

The Supreme Court of Canada decision in *Boisbriand*,²⁶ though it does not involve genetic testing, raised the issue of discrimination on the basis of perceived or future disability. This decision would be relevant to a claim of genetic discrimination because the claimant would have to show that he or she was treated differentially based on a prohibited ground of discrimination. As genetic discrimination involves denying the rights of a person who may not have any clinical symptoms of disability at the time, he or she would have to establish that perceived or future disability is covered by the terms “disability” or “handicap” contained in Canadian human rights legislation. In *Boisbriand*, several employers had refused to hire or retain individuals who, upon medical examination not involving genetic testing, were shown to have particular health conditions. These included Crohn’s disease and an anomaly of the spinal column.²⁷ The conditions, while not affecting functional capability with respect to employment, were nonetheless of concern to the (potential) employers. In defending against allegations of discrimination, the employers argued that a condition not affecting function is not a “handicap” for the purposes of the Québec *Charter of human rights and freedoms*.²⁸ The court, however, took a liberal and purposive approach to interpreting “handicap” based on the quasi-constitutional nature of the Québec *Charter* and on the interpretation of human rights legislation throughout Canada. The court held that “handicap” in the Québec *Charter* includes perceived disabilities. *Boisbriand* has been cited in numerous decisions throughout Canada on the point that disability in human rights legislation includes perceived disability.²⁹ It does not, however, examine when instances of discrimination based on perceived disability are justifiable. This issue would be of importance in the case of refusal to insure or employ someone on the basis of a genetic predisposition or condition.

²⁶ *Québec (Commission des droits de la personne et des droits de la jeunesse) v Montréal (City); Québec (Commission des droits de la personne et des droits de la jeunesse) v Boisbriand (City)*, 2000 SCC 27, [2000] 1 SCR 665.

²⁷ *Ibid* at para 3.

²⁸ RSQ, c C-12 [Québec *Charter*].

²⁹ See e.g. *Vetricsek v 642518 Canada Inc (Algonquin Careers Academy)*, 2010 HRTO 757 at para 35, [2010] OHRTD no 697 (QL); *Petterson v Gorcak*, 2009 BCHRT 439 at para 449, [2009] BCHRTD no 439 (QL); *Vantage Contracting Inc v Marcil*, 2004 ABQB 247 at paras 31-32, 27 Alta LR (4th) 262; *Tanzos v AZ Bus Tours Inc*, 2007 CHRT 33 at para 32, [2007] DCDP no 33 (QL); *New Brunswick (Human Rights Commission) v Griffin’s Pub Ltd*, 2005 NBQB 403 at para 14, 143 ACWS (3d) 899; *Evans v Health Care Corp of St John’s*, 2003 NLCA 13, 121 ACWS (3d) 508.

While our search for decisions of Canadian courts and tribunals dealing with genetic discrimination did not yield any cases directly on point, this does not suggest that incidents of genetic discrimination do not take place. Indeed, studies examining the experiences of those who have developed, or are at risk of developing, a genetic condition have illustrated that discrimination may be occurring.³⁰ Our results demonstrate that within the scope of the search we conducted (as described below) we could not identify legal cases of genetic discrimination. Our search did, however, yield legal decisions raising related issues warranting analysis and discussion.

II. Research Methodology

This paper's methodology is guided by the principles of content analysis, whereby "a scholar collects a set of documents, such as judicial opinions on a particular subject, and systematically reads them, recording consistent features of each and drawing inferences about their use and meaning."³¹ Doing so permits researchers to notice and reflect on patterns in jurisprudence that occur in large numbers of decisions.³² The major limitation of this method stems from the fact that legal decisions do not contain complete and accurate facts and reasons arising from the disputes they concern.³³ Therefore, it is generally not well-suited for predicting legal outcomes, and caution is required in attaching meanings to observations made.³⁴ This very quality, however, makes content analysis effective for studying how judges or adjudicators write decisions, and connecting resulting knowledge with "other parts of the social, political, or economic landscape."³⁵

The first step of content analysis is selection of cases.³⁶ In order to understand how courts and tribunals understand genetic arguments of disease cau-

³⁰ The following studies were conducted wholly or partly in Canada: Bombard et al, *supra* note 8; Billings et al, *supra* note 8. See also for an international perspective Hudson et al, *supra* note 4; Taylor et al, *supra* note 8.

³¹ Mark A Hall & Ronald F Wright, "Systematic Content Analysis of Judicial Opinions" (2008) 96:1 Cal L Rev 63 at 64.

³² *Ibid* at 78. See also Matthew Herder, "Demythologizing PHOSITA: Applying the Non-Obviousness Requirement under Canadian Patent Law to Keep Knowledge in the Public Domain and Foster Innovation" (2009) 47:4 Osgoode Hall LJ 695 at 712.

³³ Hall & Wright, *supra* note 31 at 100.

³⁴ *Ibid.*

³⁵ *Ibid.*

³⁶ *Ibid* at 79.

sation, we conducted a keyword search for the terms “genetic predisposition”, and cognates “genetic pre-disposition”, “genetically predisposed”, “genetically pre-disposed”, and “prédisposition génétique” (hereinafter referred to collectively as “genetic predisposition”), on Quicklaw, CanLii, and jugements.qc.ca.³⁷ We chose these keywords for our search because they yielded a rich yet manageable sample of decisions to analyze, which contain the unifying theme of reference to the role of genetic factors in health and disease. We complemented these results by searching the websites of individual tribunals listed on these services, where available. This yielded additional results, as the decisions of only some tribunals for some years are available on Quicklaw and CanLii. This was the case with, for example, the Pension Appeals Board (“PAB”) and the British Columbia Workers’ Compensation Appeal Tribunal (“BC WCAT”). Duplicate decisions were removed.

We then coded the decisions citing genetic predisposition for numerous variables, including federal/provincial jurisdiction, area of law, the clinical condition in respect of which a genetic predisposition was cited, the party reported in the decision as raising the issue of genetic predisposition, the legal issue which reference to genetic predisposition served to address, and the outcome of the proceeding. In a large subset of decisions, genetic predisposition was clearly linked with an argument relating to disease causation made in support of a particular legal outcome. In these decisions we noted whether reference to genetic predisposition helped or harmed the interests of the parties (in particular the individual with the supposed predisposition): the existence of the predisposition was being affirmed or denied; genetic predisposition was viewed as a sufficient, necessary, or contributory cause of the health condition; or the reference supported or opposed legally significant disease causation. We use “legally significant cause” as shorthand to refer to the factual finding concerning disease causation required by the party seeking to fulfill the burden of proof. For example, the legally significant cause in a personal injury negligence claim is the negligent conduct of the defendant, in workers’ compensation it is injury “arising out of and in the course of employment”, and in Crown wardship applications it is the conduct of parents that supports the Crown’s submissions regarding the best interests of the child.

³⁷ See Mykitiuk et al, “The Potential for Misusing”, *supra* note 24 at 1601.

The final step in content analysis is to analyze the coded cases.³⁸ We employ a descriptive approach, mapping the terrain of legal references to genetic predisposition.³⁹ We provide numerous examples and excerpts from the decisions in order to allow the reader to interpret the decisions, and to provide more insight than coding and counting can on its own. For example, this type of description can indicate the weight a decision maker places on statements concerning genetic predisposition in a way that quantitative content analysis cannot.

III. Overview of Search Results

In this section we briefly survey the results of our search, noting in particular the conditions for which genetic predisposition was cited, the jurisdictions in which the cases took place, and the areas of law involved. A variety of conditions form the object of reference to genetic predisposition in the results. A few of the interesting features regarding the conditions cited are as follows. Eighteen decisions contain reference to a genetic predisposition to two or more distinct clinical conditions. For example, a board medical advisor reporting to a panel of the BC WCAT, noted both that the worker "may have a genetic pre-disposition"⁴⁰ to obesity, and with respect to diabetes, that "there is a genetic pre-disposition to the disorder."⁴¹ Likewise, in *Children's Aid Society for the Districts of Sudbury and Manitoulin v PL*,⁴² a psychiatrist witness referred to the possibility that the child may have "a genetic predisposition toward either a mood or anxiety disorder."⁴³ In total there were 490 references to a particular genetic predisposition made in 468 decisions from 1984 to May 31, 2010.⁴⁴

Regarding the types of conditions cited, 188 references to genetic predisposition were to musculoskeletal conditions.⁴⁵ The most cited of this type of condition was osteoarthritis (40 references), degenerative disc disease (32), carpal tunnel syndrome (24), and Dupuytren's contracture (23). Mental

³⁸ See Hall & Wright, *supra* note 31 at 79.

³⁹ *Ibid* at 90.

⁴⁰ *Decision no 2007-03289* (24 October 2007), online: BCWCAT <www.wcat.bc.ca> at 13.

⁴¹ *Ibid*.

⁴² 2007 ONCJ 621, 170 ACWS (3d) 549, [2007] OJ no 5118 (QL) [*Manitoulin*].

⁴³ *Ibid* at para 13.

⁴⁴ See Mykitiuk et al, "The Potential for Misusing", *supra* note 24 at 1601-02.

⁴⁵ See *ibid*.

health conditions follow, with 100 references in the results. Mental health conditions include various mood disorders (39), schizophrenia (12), alcoholism (8), and substance abuse (7). Other types of conditions include respiratory (31), cancer (26), neurological (23), allergy (23), dermatological (21), and others.

Some references were not specific to a particular condition. For example, in *Brewers' Distributor Ltd v Brewery, Winery & Distillery Workers Union, Local 300*,⁴⁶ a decision concerning entitlement of employees to extended health benefits, the labour arbitrator wrote, "what use an employee makes of this benefit, including whether he or she exhausts it, will vary with the individual's circumstances, which may include age and disability, as well as general health, lifestyle, genetic predispositions and many other personal characteristics."⁴⁷

In two decisions, reference to genetic predisposition was to a clearly non-medical condition. For example, in a decision setting forth reasons for a criminal sentence, the judge reproduced part of a report of an assessment of the accused by a psychologist. The report states that the accused "has a penchant for externalizing responsibility, holds grudges, and perceiving himself as mistreated. This is exacerbated by his drug abuse and a strong genetic predisposition authored by his father's side of the family (including mental disorder and violent criminality)."⁴⁸ An excerpt of a radio broadcast reported in a decision concerning a complaint about that broadcast states: "Host: The topic of a recent conference hosted by Focus on the Family: Freedom from homosexuality is possible. It's not a genetic predisposition and it's not just a choice."⁴⁹

The results break down by jurisdiction as follows: 175 decisions were from Ontario, 134 from British Columbia, 79 from Québec, 31 from Alberta, 15 federal, 12 from Manitoba, 9 from Newfoundland and Labrador, 8 from

⁴⁶ [2003] BCCAAA no 217 (QL).

⁴⁷ *Ibid* at para 95. See also *Mortimer v Cameron* (1992), 32 ACWS (3d) 928, [1992] OJ no 764 (QL) (Ont Ct J (Gen Div)) [cited to QL] (referring to "genetic predisposition to a particular disease" as one factor determining average Canadian male mortality in the context of calculating damages for loss of future income, at 83).

⁴⁸ *R v Eckland*, 2004 BCPC 298 at para 10, [2004] BCJ no 1747 (QL).

⁴⁹ *CFYI-AM re Focus on the Family* (28 June 2001), 99/00-0724 at Appendix A, online: CBSC <www.cbsc.ca>.

Nova Scotia, 2 from Prince Edward Island, 1 from Saskatchewan, 1 from New Brunswick, and 1 from the Yukon.⁵⁰ The areas of law involved are: 355 labour/employment law decisions, including 339 workers' compensation decisions; 44 tort; 18 criminal; 18 family; 12 insurance; 8 pension and benefit; 5 tax; 3 human rights; and 5 others.⁵¹

The frequency with which particular conditions, areas of law, and jurisdictions appear in the results is influenced by various factors. One such factor is the prevalence of the condition in society. For example, a Statistics Canada study has noted that nearly half of workplace injuries in Canada were related to "overexertion or strenuous movements and falls."⁵² This suggests one reason why musculoskeletal conditions, which arise largely within labour law, are prevalent in our results.⁵³ In addition, the Statistics Canada study noted that individuals reporting three or more chronic conditions were more likely to be injured than others.⁵⁴ Because these chronic conditions are sometimes explained in terms of genetic origin, this risk factor also accounts for some of our results.

The degree to which a condition lends itself to litigation or adjudication influences the extent to which it appears in reported legal decisions. For example, the legal issues associated with criminal responsibility naturally lend themselves to consideration of conditions affecting mental health. In our study, 17 of 19 references to genetic predisposition in criminal law pertained to mental health conditions (this includes alcoholism and substance abuse). Finally, variation among Canadian jurisdictions can be explained: a larger population suggests that more adjudicative decisions will be rendered. Availability of electronically searchable decisions also varies by jurisdiction.

IV. Use of Genetic Predisposition by Area of Law

With the above picture of the decisions as background, we turn to analyzing the role of genetic predisposition in the resolution of legal issues. This

⁵⁰ See Mykitiuk et al, "The Potential for Misusing", *supra* note 24 at 1603.

⁵¹ See *ibid* at 1601.

⁵² Statistics Canada, "Study: Work Injuries", *The Daily* (Ottawa: 10 July 2007), online: Statistics Canada <www.statcan.gc.ca/daily-quotidien/070710/dq070710-eng.pdf> at 2.

⁵³ 176 references to musculoskeletal conditions occurred in labour law out of 188 total references to musculoskeletal conditions.

⁵⁴ *Ibid*. A combination of such conditions might include, for example, migraine, arthritis, and multiple chemical sensitivity.

inquiry is best organized by area of law, given the unique legal issues raised in each, and the differing functions genetic predisposition serves in settling these respective issues. Each area of law we discuss presents a progressively more detailed analysis of and reliance on genetic predisposition. We begin with criminal law and family law, followed finally by personal injury law, where reference to genetic predisposition often played a major role in determining entitlement to compensation and/or benefits. This essay focuses on the role of genetic knowledge in legal accounts of causation. While in many cases it is not clear whether reference to genetic predisposition was dispositive of the outcome, genetic predisposition is nonetheless often employed in a manner that directly addresses the issue at hand. In this way, whether genetic predisposition is presented as an excerpt of a piece of evidence, a summary of a party's argument, or the adjudicator's own line of reasoning (and it is sometimes difficult to tell which of these accounts for a particular reference), it is useful to analyze the way the concept itself is functioning to make legal sense of the individual's condition.

A. Criminal Law

As in other areas of law, criminal law decisions refer to the notion of genetic predisposition as a convenient means of resolving legal issues, and in doing so tend to ascribe genetic etiology to conditions of unknown origin. We discuss the two main types of criminal law issues that emerged in our results: criminal responsibility and sentencing. In addition to these two main types of criminal law issue, there was one criminal law decision that alluded to the issue of genetic discrimination. We describe this case in order to highlight that the bulk of our results deal with more common, conventional issues normally associated with criminal law. The 2001 judgment of the Ontario Court of Justice in *R v TT*⁵⁵ resulted from an application by the Crown to take a DNA sample from a young offender who pleaded guilty to a charge of robbery. The court dismissed the application, finding that the Crown had not established on a balance of probabilities that the interest of society in the identification of those who commit offences outweighed the privacy interest of the accused. Part of the judgment, citing findings of the Ontario Law Reform Commission and the work of American legal scholars, expresses concern that retained DNA samples may be tested in the future for susceptibility to disease. One such passage states that:

⁵⁵ (2001), 50 WCB (2d) 467, [2001] OJ no 2936 (QL) (Ont Ct J).

It is the current policy not to test for genetic predisposition to diseases, and the current legislation contains significant safeguards. But the fact is that biological material is retained and kept for future testing according to future policies, which may change from the current ones. The legislation may also change, although legislative changes would take longer than policy changes, especially given potential for charter pitfalls.⁵⁶

In contrast with this decision, the others did not refer to the privacy implications of DNA sampling or the potential for discrimination.

i. Criminal Responsibility

Seven criminal law decisions cite genetic predisposition to a mental condition in relation to the issue of criminal responsibility. In our discussion, criminal responsibility includes the inter-related issues of voluntariness of conduct, the defence of not being criminally responsible by reason of mental disorder ("NCR-MD"), and the likelihood of recurrence of either of these types of conduct. In the decisions that follow, genetic predisposition is framed as a necessary or contributory cause of the accused's actions, driving arguments about criminal responsibility. The ability to explain the accused's actions in this way facilitates legal decision making in the absence of scientific certainty about the accused's condition.

The following provides background for appreciating the use of genetic predisposition in these decisions. One of the requirements to establish criminal responsibility is voluntariness. The Supreme Court of Canada has written that:

Even before the advent of the Charter, it became a basic concern of the criminal law that criminal responsibility be ascribed only to acts that resulted from the choice of a conscious mind and an autonomous will. In other words, only those persons acting in the knowledge of what they were doing, with the freedom to choose, would bear the burden and stigma of criminal responsibility.⁵⁷

⁵⁶ *Ibid* at para 32.

⁵⁷ *R v Ruzic*, 2001 SCC 24 at para 34, [2001] 1 SCR 687, 197 DLR (4th) 577.

The defence of automatism alleges a lack of voluntariness. The majority judgment of the Supreme Court of Canada in *R v Stone*⁵⁸ stated that:

Two forms of automatism are recognized at law: insane automatism and non-insane automatism. Involuntary action which does not stem from a disease of the mind gives rise to a claim of non-insane automatism. If successful, a claim of non-insane automatism entitles the accused to an acquittal...

On the other hand, involuntary action which is found, at law, to result from a disease of the mind gives rise to a claim of insane automatism. It has long been recognized that insane automatism is subsumed by the defence of mental disorder, formerly referred to as the defence of insanity.⁵⁹

The Criminal Code precludes criminal responsibility where the accused's mental disorder "rendered the person incapable of appreciating the nature and quality of the act or omission or of knowing that it was wrong."⁶⁰ The party raising the issue of NCR-MD must prove it on a balance of probabilities.⁶¹

The 2005 Ontario Court of Justice decision of *R v Luedecke*⁶² uses the concept of genetic predisposition in distinguishing between these two types of automatism. In this case, the accused admitted to having sexual contact with the complainant without her consent. He argued that he engaged in this conduct while asleep, and that this constituted non-insane automatism. A psychiatrist specializing in sleep disorders who assessed the accused, testified that he believed the accused did not commit the act consciously because he was in a state of parasomnia.⁶³ He explained that the likely causes of the sexual contact occurring while in a state of parasomnia included a genetic component, stating "there was a genetic predisposition, as both his mother and brother have had a number of such episodes [sleepwalking],"⁶⁴ alongside triggering factors such as physical activity and exercise, sleep deprivation,

⁵⁸ [1999] 2 SCR 290, 173 DLR (4th) 66 [cited to SCR].

⁵⁹ at paras 157-58.

⁶⁰ RSC 1985, c C-46.

⁶¹ *Ibid*, ss 16(2)-(3).

⁶² 2005 ONCJ 294, 35 CR (6th) 205, 68 WCB (2d) 49.

⁶³ *Ibid* at para 23.

⁶⁴ *Ibid* at para 18.

alcohol consumption, and stress.⁶⁵ He also testified that the accused's condition was not a mental illness in a medical sense.⁶⁶

Although the judge found that the accused did not have a mental disorder according to the legal definition, the accused was nevertheless acquitted. In reaching this conclusion the judge noted that the accused had not engaged in similar criminal conduct in the past, but rather had experienced similar episodes within consensual relationships.⁶⁷ The accused was also taking measures to prevent recurrence of such episodes, suggesting that he would not pose a "continuing danger" to society.⁶⁸ The judge avoided characterizing the accused's condition as an "internal cause" of his conduct (which would suggest that it amounted to a mental disorder), instead stating that somnambulism is not well-suited to the "internal cause theory" of mental disorders.⁶⁹

The Ontario Court of Appeal overturned the trial court's decision, noting in particular:

While the cause of parasomnia may not fit within the "external/internal" causal dichotomy described in the case law, Dr. Shapiro's evidence establishes that the predisposition for parasomnia, found in some three per cent of the adult population, is hereditary. A genetic predisposition is the epitome of an internal cause. Although that disposition does not cause the particular automatistic event, it does predispose the individual to that condition thereby increasing the risk of recurrence. The trial judge erred in discounting the significance of this internal cause of the respondent's condition. He did so based on a misapprehension of the "sleepwalking" case law and a failure to consider evidence relevant to the causal inquiry.⁷⁰

The Court of Appeal directed that a new trial take place on the issue of whether the respondent's automatism should lead to an acquittal or a finding

⁶⁵ *Ibid* at para 15.

⁶⁶ *Ibid* at para 50.

⁶⁷ *Ibid* at para 48.

⁶⁸ *Ibid* at paras 47-48.

⁶⁹ *Ibid* at para 46.

⁷⁰ *R v Luedecke*, 2008 ONCA 716 at para 106, 93 OR (3d) 89, 269 OAC 1.

of NCR-MD. Mr. Luedecke was subsequently found NCR-MD and the Ontario Review Board ordered that Mr. Luedecke be discharged absolutely.⁷¹

The legal argument and reference to genetic predisposition in *R v Tee-pell*⁷² is similar to that in *R v Luedecke*, but was unsuccessful as the accused was found guilty. The accused had argued he was not conscious while he engaged in non-consensual sexual intercourse with the complainant. A medical expert's explanation of the causes of parasomnia featured genetic predisposition:

For almost all of the cases that have been published, you will find that there is this unusual ... juxtaposition of someone who first of all has genetic predisposition to develop sleepwalking, who then has these factors primed (I call sleep deprivation and stress priming factors) Then there needs to be an actual trigger ... something has to go bump in the night. It could be a noise, it could be simply be being pushed. In some individuals, they snore themselves awake. All of that has to happen simultaneously and the chances of it having happened in the past or in the future are quite remote.

None of the transcripts of the testimony, even Dr. Shapiro's report, indicate any significant sleep deprivation or what I would call acute stress.⁷³

This excerpt suggests that even if there is a genetic predisposition to sleepwalking, an episode of parasomnia may be unlikely to recur.

Risk of recurrence is relevant not only where non-insane automatism is alleged, but also to the defence of NCR-MD. The association of genetic predisposition with risk of recurrence of conduct relating to the NCR-MD defence was made in two 1999 British Columbia Supreme Court decisions in the case of *R v Campagna*.⁷⁴ The accused was charged with dangerous driving causing the death of two people. The Crown and defence jointly submitted that the accused was suffering from a mental disorder at the time of the incident. Until about two days before the incident, she had consumed an

⁷¹ *R v Luedecke*, 2010 ONCJ 59, [2010] OJ No 804 (QL) at paras 16-18.

⁷² [2009] OJ no 3988 (QL) (ONCJ).

⁷³ *Ibid* at para 206.

⁷⁴ (1999), 43 WCB (2d) 375, 46 MVR (3d) 35, [1999] BCJ no 2022 (BC SC) [*Campagna* trial decision]; [1999] BCJ no 2023 (QL) (BC SC) [*Campagna* sentencing hearing].

over-the-counter appetite suppressant which led to her first episode of mania and psychosis.⁷⁵ The trial decision relates the testimony of a psychiatrist witness who explained the accused's mental state as "induced by an over-the-counter appetite suppressant, together with a strong genetic predisposition towards a mood disorder."⁷⁶ Another psychiatrist witness came to a different conclusion. The judgment states:

Dr. Vath was troubled with the diagnosis that the accused may have suffered from a true genetic bipolar disease. The accused had little history of any significant pre-existing symptoms and the symptoms that she did experience shortly before the date of the accident had rapidly cleared with treatment and because of this concern he discussed this case with Dr. David Dunner, an internationally recognized expert in the area of bipolar disorder. It was Dr. Dunner's opinion that even in healthy persons, excessive stimulant substances can induce psychosis and Dr. Dunner recommended that the accused's progress be monitored.⁷⁷

Though the court found the accused NCR-MD without much difficulty, the cause of the incident came up again at the sentencing hearing. The Crown argued that the accused should be given a discharge with conditions, citing one of the psychiatrist witnesses who found:

[T]hat the accused suffered an intense, extreme psychosis, more likely caused by the latent genetic bipolar disorder rather than substance induced, confirmed by the fact that this accused exhibited such mental disorder over a considerable period of days after the incident and that, therefore, the accused ought to be monitored for some time in the future because there is the possibility of this serious risk of conduct recurring.⁷⁸

The court disagreed with the Crown's position and ordered an absolute discharge, noting that it cannot avoid doing so based on speculation or suspicion alone.⁷⁹ Earlier in the decision the court cited the testimony Dr. Vath

⁷⁵ *Campagna* trial decision, *supra* note 74 at paras 19, 21.

⁷⁶ *Ibid* at para 21.

⁷⁷ *Ibid* at para 25.

⁷⁸ *Campagna* sentencing hearing, *supra* note 74 at para 41.

⁷⁹ *Ibid* at para 43.

gave at trial as having “totally eliminated any such predisposition to bipolar mood disorder on behalf of the accused.”⁸⁰

As in *Campagna*, the language of genetic predisposition bolstered a finding of NCR-MD in the decision of *R v Carmichael*,⁸¹ where the accused was charged with murdering his 11 year-old son. It appeared that mental illness, specifically depression, was the only explanation for the act.⁸² Regarding the nature of the illness, the judgment stated: “I heard that there is a significant family history of depression and other mental illnesses, and I heard evidence of a genetic predisposition to the development of depression. Mr. Carmichael’s twin brother had strikingly similar episodes of depressive illness which originated in work pressure, which for Mr. Carmichael involved financial pressures as well.”⁸³

A similar but unsuccessful argument involving genetic predisposition was made in *R v Warsing*,⁸⁴ a case involving a young man charged with murdering two younger step-siblings and attempting to murder his step-mother:

At the present trial, Dr. Wanis testified that the accused had a genetic predisposition for Bipolar Affective Disorder which often first presents in the late teens. Coupled with significant stressors relating to the divorce of his biological parents, his inability to attend university, and the pending separation of the Warsings, this predisposition led to a manic episode. The manic episode was manifested by an inability to sequence thoughts and actions, as well as by delusional thinking.

According to Dr. Wanis, the accused, acting on command hallucinations, killed the children thinking that he was saving them from a divorce experience. In addition, the accused, while still in a delusional state, then concluded that Mrs. Warsing killed the children and acted violently towards her. Dr. Wanis opined that the accused was unable, in the circumstances, to appreciate the

⁸⁰ *Ibid* at para 4.

⁸¹ [2005] OJ no 4781 (QL) (Ont Sup Ct) [*Carmichael*]

⁸² *Ibid* at para 6.

⁸³ *Ibid* at para 16.

⁸⁴ 2000 BCSC 388, [2000] BCJ no 452 (QL).

nature and quality of his acts, or their consequences, or that they were wrong.⁸⁵

The judge did not ascribe much weight to this testimony, and in the end found that while the accused had a mental disorder, it did not amount to a defence under s 16(1) of the Criminal Code, because it did not affect his capacity.⁸⁶ *R v Warsing* and the preceding cases considering mental disorder are examples of where an environmental trigger was required for the condition which caused the criminal action to manifest itself. This construction of genetic predisposition makes sense given the context of these cases, which requires trying to determine the trigger of an accused's mental state at a given time. Other legal contexts give rise to different constructions of genetic predisposition.

ii. Aggravating and Mitigating Factors in Sentencing

Genetic predisposition was cited as both an aggravating and a mitigating factor in the following two sentencing hearings, though the reasons did not necessarily make clear connections between genetic predisposition and a sentence. For example, in *R v Eckland* part of a psychological assessment report stated that the accused:

[h]as a lengthy history of drug and alcohol abuse, treatment and relapse. Although he has completed some programs (institutional and community) targeting his anger and controlling behaviour, his habits of threatening and behaving petulantly persist. He has a penchant for externalizing responsibility, holds grudges, and perceiving himself as mistreated. This is exacerbated by his drug abuse and a strong genetic predisposition authored by his father's side of the family (including mental disorder and violent criminality).⁸⁷

The reference to genetic predisposition here seems to suggest that the accused would be less likely to respond to rehabilitative efforts and more likely to repeat offensive behaviour.

⁸⁵ *Ibid* at paras 99-100.

⁸⁶ *Ibid* at paras 133, 148.

⁸⁷ *Supra* note 48 at para 10.

In *R v KLM*,⁸⁸ it appears that awareness of a genetic predisposition could be considered by the courts as a mitigating factor. The accused was convicted of impaired driving causing bodily injury and impaired driving causing death. The reasons for arriving at the resulting sentence state that:

K.L.M. has the ability and, it appears, the commitment to succeed in her own rehabilitation. She has pursued counselling on her own. She has abstained from alcohol since the accident. She recognizes that she may have a genetic predisposition towards alcoholism. Though her own alcohol issues remain untreated, she has attended Alcoholics Anonymous meetings with her mother for help in dealing with her father's alcoholism.⁸⁹

iii. Conclusions

Though we have not aimed to comprehensively survey the implications of genetic knowledge in criminal cases, our search results allow us to draw some initial conclusions. Whereas an American study has noted that defence lawyers have, largely unsuccessfully, used arguments concerning behavioural genetic predispositions to negate criminal responsibility,⁹⁰ for example by arguing that it led to an “overpowering compulsion” which should excuse the accused from liability,⁹¹ our study illustrates that genetic predisposition is being used in a more conventional and flexible manner. It is used in a conventional manner in that it is being cited in connection with common and unelaborate legal arguments, and in a flexible manner in that its significance takes shape in consideration of the evidence as a whole. Thus if the totality of evidence shows that otherwise criminal behaviour was involuntary, a genetic predisposition could suggest an internal cause and support a finding of NCR-MD. In sentencing, whether in NCR-MD or other cases, the idea of genetic predisposition may be related to likelihood of recurrence. The ultimate finding of likelihood will depend on various factors, including whether or not the trigger of an incident is rare and avoidable, and whether the accused is likely to seek and benefit from treatment.

⁸⁸ 2004 BCPC 200, 77 WCB (2d) 500, [2004] BCJ no 1396 (QL).

⁸⁹ *Ibid* at para 44.

⁹⁰ Nita A Farahany & James Coleman, “Genetics and Responsibility: To Know the Criminal from the Crime” (2006) 69:1 & 2 Law & Contemp Probs 115 at 115-16.

⁹¹ *Ibid* at 119.

B. Family Law

Similar to criminal law, the family law context makes use of particular arguments involving genetic predisposition in order to resolve legal issues where a party has a health condition of uncertain origin. The family law decisions we identified included Crown wardship applications, youth protection orders, contested adoption applications, child custody disputes, and a divorce proceeding. We begin by discussing Crown wardship and youth protection decisions, followed by other family law decisions.

i. Crown Wardship and Youth Protection Decisions

The following decisions highlight the flexibility with which genetic predisposition may be employed, sometimes implying poor parenting capabilities and other times adequate capabilities; sometimes serving as an alternate explanation to an environmental condition; and sometimes interacting with environmental conditions. In *Children’s Aid Society of Ottawa v MB*,⁹² an application for Crown wardship of two children, one of the parenting behaviours warranting the application was that the mother was overfeeding them. Both parents and one physician witness represented genetic predisposition as a contributory cause of the children’s obesity, while disagreeing about the nature of the environmental factor that triggered or exacerbated the condition. The mother denied overfeeding the children and the father only admitted some responsibility on his part, while partly ascribing the condition to predisposition.⁹³ In contrast, the physician witness reported that “[w]hile other factors including genetic predisposition and mother’s gestational diabetes may have contributed to the boys’ obesity, there would nevertheless seem to be convincing evidence that overfeeding was a major contributor to both boys’ trouble.”⁹⁴ The court noted that the “inescapable conclusion in this case is that both children were seriously overfed,” which formed part of the rationale for the removal of the children from the custody of their parents.

Three other decisions also consider how genetic predisposition, along with parental conduct inviting scrutiny by child welfare agencies, contributed to a child’s unhealthy condition. In *Catholic Children’s Aid Society of Ham-*

⁹² 148 ACWS (3d) 416, [2006] OJ no 1962 (QL) (Ont Sup Ct J) [*Children’s Aid Society of Ottawa*].

⁹³ *Ibid* at para 38.

⁹⁴ *Ibid* at para 49.

ilton-Wentworth v SM,⁹⁵ evidence showed the child's father suffered from anti-social personality disorder and had continuing involvement with the criminal justice system. One psychiatrist witness reported "T.C.B. [the child] needs to be protected from exposure to individuals who engage in unlawful and dishonest activities to hopefully prevent him from engaging in such activities, despite his genetic predisposition and vulnerability."⁹⁶ Part of the court's conclusion reads: "T.C.B. should have the opportunity to be placed with an adoptive family who will be responsive to his ongoing needs. It is likely that he has ADHD and it is also likely that he will at least be susceptible to other difficulties given his difficult genetic background and that fact that he was born prematurely."⁹⁷ Thus the genetic susceptibility of the child was used as a reason to remove him from circumstances that would trigger that susceptibility.

A similar argument was made in the case of *X (Dans la situation de)*,⁹⁸ an interim youth protection application. Here, one of the justifications for state intervention concerned an episode triggered by the mother's "lack of judgment"⁹⁹ in discussing menstrual hygiene against her daughter's will:

La psychologue décrit X comme étant une enfant au tempérament anxieux. Il s'agit selon elle d'une jeune fille fragile et insécure. L'enfant aurait, compte tenu du désordre mental dont souffre chacun de ses parents, des prédispositions génétiques à développer une maladie mentale. Madame Pothier est d'avis que le trouble obsessionnel-compulsif dont souffre X est la conséquence d'un état de stress post-traumatique qu'elle a subi. Selon les informations qu'elle a obtenues, dont celles provenant des propos de X, les enseignements de la mère de l'enfant au sujet de l'hygiène menstruelle est l'élément déclencheur du choc post-traumatique qui a provoqué le T.O.C.. La psychologue précise que l'événement n'est pas en soi porteur de traumatisme mais c'est l'interprétation qu'en fait l'enfant qui entraîne les répercussions déjà décrites.

⁹⁵ [2002] OJ no 2760 (QL) (Ont Sup Ct J).

⁹⁶ *Ibid* at para 41.

⁹⁷ *Ibid* at para 44.

⁹⁸ 2006 QCCQ 10753, [2006] JQ no 11954 (QL) (Youth Div).

⁹⁹ "un manque de jugement", *ibid* at para 53.

La psychologue Pothier est catégorique; il est nécessaire que les contacts de l'enfant et de sa mère soient suspendus tant et aussi longtemps que la maladie de X ne sera pas parfaitement contrôlée.¹⁰⁰

A subsequent decision discussing the same facts also touched on this episode:

À l'occasion du témoignage qu'elle a rendu le 28 mars 2006, madame Pothier a expliqué qu'elle est d'avis que l'enfant a développé des troubles obsessionnels compulsifs après avoir vécu un état de stress traumatique. Selon elle, les propos que lui a tenus sa mère au sujet des menstruations sont l'événement traumatique à l'origine de son trouble. Elle ajoute que ce n'est pas l'événement en soi qui est porteur de traumatisme, mais plutôt l'interprétation qu'en a faite X. Un peu plus tard, la psychologue fait également état des prédispositions génétiques qui favorisent le développement d'une maladie mentale chez X. La psychologue explique qu'un enfant dont les deux parents souffrent de maladie mentale court 50% de risques de développer lui aussi une telle maladie. Elle ajoute que la naissance de X, survenue dans des conditions traumatisantes a pu causer des séquelles à l'enfant qui ont laissé des empreintes au niveau de son cerveau et de sa mémoire corporelle. Elle émet l'hypothèse que les événements survenus en octobre 2005 ont pu réveiller la mémoire corporelle de sa naissance et ainsi déclencher des émotions fortes.¹⁰¹

¹⁰⁰ *Ibid* at paras 38-39. To paraphrase: The psychologist described X as a child with an anxious temperament. She behaved like a young, fragile, and insecure girl. The child, taking account of the mental disorder suffered by each of her parents, has the genetic predispositions to develop a mental illness. Ms. Pothier's opinion is that X suffers from obsessive-compulsive disorder as a result of post-traumatic stress. According to the information she has obtained, including that originating from X, the mother's instructions regarding menstrual hygiene were the trigger for post-traumatic shock that caused the O.C.D. The psychologist specifies that the event was not in itself cause of the trauma but the child's interpretation that in fact led to the impacts already described.

The psychologist Pothier is adamant: it is necessary that the contacts of the child and her mother are suspended for as long as the disease X is not perfectly under control.

¹⁰¹ *Protection de la jeunesse – 061*, 2006 QCCQ 12335 at para 78, [2006] JQ no 13429 (Youth Div). To paraphrase: On the occasion of her testimony on March

In contrast with the previous decisions, the two following decisions refer to genetic predisposition as separate from and in opposition to parental conduct. In *Manitoulin*, which concerned two children, the court noted that “[c]ontrary to the assertions that were made throughout the proceedings, the expert opinion is that N.-A.L.’s difficulties were not genetic in origin, but largely caused by environmental factors. This means that as between ‘nature’ and ‘nurture’, the evidence points to ‘nurture’.”¹⁰² The difficulties referred to include an alleged “genetic predisposition toward either a mood or anxiety disorder.”¹⁰³

Likewise, in the decision in *RM (Re)*,¹⁰⁴ genetic predisposition was considered a causal explanation of a child’s condition, as an alternative to parental fault. The decision concerned an application by the Crown for permanent guardianship of two children. In contrast with *PL*, however, the parent cited genetic predisposition in denying her adverse impact on one of her children’s health. The decision states:

With respect to C.P.’s teeth, the pediatric dentist had to perform four fillings, two extractions, six crowns and one pulpectomy, which he blamed on insufficient brushing and poor oral hygiene. When asked about this during their testimony, K.P. responded, ‘You can only do so much. C.P. wanted to brush his teeth by himself.’ L.M. claims she was told by a professional, ‘Don’t worry, they are only baby teeth and they will fall out.’ She also claimed that her children had a genetic predisposition towards bad teeth.¹⁰⁵

28, 2006, Ms. Pothier said she believes the child developed obsessive-compulsive disorder after experiencing traumatic stress. According to her, the remarks her mother made about menstruation are the traumatic event causing her disorder. She adds that it is not the event itself that carries trauma, but rather its interpretation by X. A little later, the psychologist also reported genetic predispositions that favour the development of mental illness in X. The psychologist says that children whose parents suffer from mental illness run a 50% risk of developing such illness. She added that the birth of X, which occurred in traumatic circumstances, could cause sequelae in the child that left imprints in her brain and body memory. She speculates that the events in October 2005 could awaken the body memory of her birth and thus trigger strong emotions.

¹⁰² *Supra* note 42 at para 13.

¹⁰³ *Ibid.*

¹⁰⁴ 2005 ABPC 222, [2005] WDFL 3793, [2005] AWLD 3085.

¹⁰⁵ *Ibid* at para 13.

In effect, the mother used genetic predisposition to argue that her child's dental condition was likely to develop regardless of her conduct, and that she should therefore not be seen as responsible for the condition. Due to their common issues, these Crown wardship and youth protection cases reveal patterns in the way genetic predisposition is used in legal decisions featuring causal arguments about health conditions. A further variety of uses are observed in other types of family law proceedings.

ii. Other Family Law Decisions

In *Marrocco v Marrocco*,¹⁰⁶ a divorce proceeding, the main issue was whether the mother of the child (who had custody), could relocate with the child several hundreds of kilometres away from the father (who had access to the child). In denying the proposed relocation, the court considered and rejected the argument that the child needed to move because of his allergies. Genetic predisposition was used to suggest that the child's allergic condition would develop and could be relieved in the same manner as his mother's:

Dr. Krop concludes 'considering his maternal health history, and his own genetic predisposition to allergy, and asthma, there is a strong likelihood that he may develop sensitivities to chemicals similar to his mother. This is particular likely as he lives in the same polluted area as his mother'. It is not clear if Dr. Krop took into account Johnny's paternal medical history. Mr. Marrocco says he 'grew out of' his own childhood asthma symptoms. Dr. Krop recommends that Johnny move out of the Windsor area 'for the same reasons I recommend his mother moving'. In doing so, Dr. Krop seems to equate the mild symptoms of Johnny with the much more significant symptoms of his mother. Based upon the degree of Johnny's symptoms, and notwithstanding the possibility of future 'Multiple Chemical Sensitivity' it seems to me unlikely Dr. Krop would be recommending that Johnny needs to move to Muskoka, but for the fact that he thinks Mrs. Marrocco needs to move there.¹⁰⁷

It is noteworthy that this case warranted speculation on the prognosis of the child's asthma, whereas many more decisions in our sample required analysis of past causes of disease.

¹⁰⁶ 161 ACWS (3d) 275, [2007] OJ no 4026 (QL) (Sup Ct (Fam Div)).

¹⁰⁷ *Ibid* at para 44.

Further highlighting the variety of ways in which genetic predisposition can be framed in response to the nature of a claim, two oppositions to adoption applications use the concept in a unique manner. Specifically, the decisions reference not a particular condition, but the totality of conditions, whether disease-related or neutral traits, that a person may develop. In *Nguyen v McGinn*,¹⁰⁸ the “natural mother”¹⁰⁹ of a child opposed the application of the child’s lawful guardians to adopt her. A psychologist witness reported:

Genetic factors, additionally, are becoming a focus of attention regarding pre-disposition for various behaviours, ways of interacting and how individuals learn. Although environment still plays a very important part on how a particular child perceives the world, these genetic predispositions (nature versus nurture) are assumed to have greater importance than they did some years ago. It is my opinion that Natasha’s cultural and genetic requirements would be most optimally met in her mother’s care. Residence in a Caucasian home, however loving, would be second best.¹¹⁰

The court found the arguments on both sides approximately equal, but decided that the “cultural and genetic factors” were “of over-riding importance in this case and dictate the return of the child” to her natural mother, over a transition period.¹¹¹

Similarly in *DHC v RS*,¹¹² the maternal grandmother opposed an adoption application by the child’s interim guardians. The judgment stated:

While acknowledging that a two-parent family would likely be in a position to better raise a child, the psychologist believed that a child would gain higher self-esteem and more complete identity development if raised by its natural parents by being able to adopt and feel comfortable with racial characteristics and attributes and genetic predispositions including physical appearance

¹⁰⁸ (1989), 97 AR 38, 15 ACWS (3d) 432, [1989] AJ no 515 (QL) (Alta QB) [*Nguyen* cited to QL].

¹⁰⁹ This is the term used by the court.

¹¹⁰ *Nguyen*, *supra* note 108 at 7.

¹¹¹ *Ibid* at 10.

¹¹² (1990), 106 AR 196, 26 RFL (3d) 301, [1990] AJ no 1289 (QL) (Alta QB).

and medical history similar to its own, a reinforcing feedback from the child's total environment.¹¹³

In this case the court decided that it was in the child's best interests to be adopted by his interim guardians, largely because his grandmother's household was not a "nurturing, secure environment."¹¹⁴ The court also noted that it felt the interim guardians could address any problems of identification the child may face in the future.¹¹⁵ As in the criminal law cases, the preceding family law decisions illustrate that ideas of genetics are used within conventional legal argument, and that they will be considered as one among many factors in the overall decision.

Finally, in transitioning to a discussion of civil law cases where the cause of a condition is the main issue at hand, and where arguments concerning genetic factors have a more decisive role, one additional family law case is instructive. *Ivans v Ivans*,¹¹⁶ was an uncontested divorce proceeding where the unsettled issue was entitlement to and quantum of spousal support. The husband argued that in order to claim support in connection with her disability (schizoaffective disorder), the wife must establish that her disability was caused by the marriage. The decision states:

In my view, the husband's argument fails on the basis of the case law alone. Moreover, in this particular case, it cannot be said with certainty whether or not there is a causal connection between the illness and the marriage. The doctor's evidence was that there exists in some individuals a genetic predisposition to this type of illness and the actual manifestation of the illness may be precipitated by various stressors within the life of the individual at a given time. The early 20's and the mid-30's are particular times of vulnerability. In the present case, the wife's illness manifested itself in the early 30's and at a time when she was suffering from particular stresses related to the marriage and the family obligations that she had; notably the move to Ottawa at the instance of her husband and the terminal illness of her mother. However, it is not possible to say with certainty that these stresses were the precipitating factor or that the illness would

¹¹³ *Ibid* at para 15.

¹¹⁴ *Ibid*.

¹¹⁵ *Ibid* at para 29.

¹¹⁶ (1992), 35 ACWS (3d) 708, 82 Man R (2d) 101, [1992] MJ no 432 (QL) (Man QB (Fam Div)) [cited to QL].

not have manifested itself even had she remained a single person. Thus, while there is no certainty that there is a causal connection between the marriage and the illness, conversely there is no certainty that there is not a connection. This illustrates the folly of the causal connection test which in many cases is equivalent to trying to answer the age old question 'Why is a duck?'.¹¹⁷

While it was uncertain whether the wife's condition was triggered by the marriage, the court stated that a causal link was not necessary to merit an award of support, though it would be one factor to take into account. This is in contrast to the cases we discuss next, wherein the legal issues to be decided lend much more significance to the causal origins of health conditions.

C. Personal Injury Law

Causation is a major issue in cases involving individuals seeking compensation for injuries they have sustained or diseases they have developed. In tort law, parties are required to compensate victims only for the consequences of their wrongdoing.¹¹⁸ Similarly, private insurance contracts and various statutory insurance regimes promise the payment of benefits relating to injuries associated with participation in various activities, such as motor vehicle use,¹¹⁹ military service,¹²⁰ or employment.¹²¹ In all of these areas where causation is in dispute, courts apply common law principles developed in the tort law context, to the extent that they have not been specifically overruled by statute. Workers' compensation law makes use of some such departures from the common law, though these are exceptional. It also employs some unique language in describing concepts analogous to those in the common law. A basic review of the relevant principles precedes consideration of different accounts of causation in these areas of law.

¹¹⁷ *Ibid* at 4.

¹¹⁸ See *Clements v Clements*, 2012 SCC 32 at paras 7-8, 346 DLR (4th) 577, [2012] SCJ No 32 (QL).

¹¹⁹ See e.g. The Automobile Accident Insurance Act, RSS 1978, c A-35; Automobile Insurance Act, RSQ, c A-25.

¹²⁰ *Pension Act*, RSC 1985, c P-6.

¹²¹ See e.g. *Workers Compensation Act*, RSBC 1996, c 492 [BC WCA]; *Workers' Compensation Act*, RSA 2000, c W-15 [AB WCA].

i. Relevant Legal Principles

To satisfy the basic test for causation in tort, the plaintiff must establish that the injury would not have occurred “but for” the defendant’s wrongdoing.¹²² This rule also applies in situations involving injuries with multiple causes.¹²³ The Supreme Court of Canada has also held that where the “but for” test is unworkable due to the operation of multiple contributory causes to the injury, causation is established if the tortious conduct “materially contributed to the occurrence of the injury.”¹²⁴ The Supreme Court of Canada has explained:

It is not now necessary, nor has it ever been, for the plaintiff to establish that the defendant’s negligence was the sole cause of the injury. There will frequently be a myriad of other background events which were necessary preconditions to the injury occurring. To borrow an example from Professor Fleming (*The Law of Torts* (8th ed. 1992) at p. 193), a “fire ignited in a waste-paper basket is . . . caused not only by the dropping of a lighted match, but also by the presence of combustible material and oxygen, a failure of the cleaner to empty the basket and so forth”. As long as a defendant is part of the cause of an injury, the defendant is liable, even though his act alone was not enough to create the injury. There is no basis for a reduction of liability because of the existence of other preconditions: defendants remain liable for all injuries caused or contributed to by their negligence.¹²⁵

This principle has implications for the remedy available to the injured party. Compensation in tort aims to restore the plaintiff to his or her “original position.”¹²⁶ Certain causal factors may render a particular plaintiff more susceptible to injury than others, making return to his or her original position

¹²² *Resurfice Corp v Hanke*, 2007 SCC 7 at para 21, [2007] 1 SCR 333, 278 DLR (4th) 643.

¹²³ *Ibid.*

¹²⁴ *Athey v Leonati*, [1996] 3 SCR 458 at para 15, 140 DLR (4th) 235 [*Athey*]. But see Lynda M Collins & Heather McLeod-Kilmurray, “Material Contribution to Justice? Toxic Causation after *Resurfice Corp. v. Hanke*” (2010) 48 Osgoode Hall LJ 411 at 439, arguing that this formulation of causation has since been rejected by the Supreme Court of Canada. Nevertheless, because of its influence on the decisions we cite, we have included it.

¹²⁵ *Athey*, *ibid* at para 17 [emphasis in original].

¹²⁶ *Ibid* at para 32.

more costly to the defendant. The “thin skull” rule “makes the tortfeasor liable for the plaintiff’s injuries even if the injuries are unexpectedly severe owing to a pre-existing condition. The tortfeasor must take the victim as the tortfeasor finds him or her, and is therefore liable even though the plaintiff’s losses are more dramatic than they would be for the average person.”¹²⁷ In contrast,

The so-called “crumbling skull” rule simply recognizes that the pre-existing condition was inherent in the plaintiff’s “original position”. The defendant need not put the plaintiff in a position better than his or her original position. The defendant is liable for the injuries caused, even if they are extreme, but need not compensate the plaintiff for any debilitating effects of the pre-existing condition which the plaintiff would have experienced anyway.¹²⁸

The formulations of the thin skull and crumbling skull rules both refer to pre-existing conditions. While a pre-existing condition may be at issue in either scenario, the difference is that in a thin skull situation, the pre-existing condition leads to an indivisible injury which the defendant caused.¹²⁹ An example is a disc herniation resulting from the combination of a weak back and involvement in two automobile collisions.¹³⁰ The pre-existing condition (weak back) and the tortious causes (automobile collisions) are not to be separately accounted for as they resulted in a single injury (disc herniation). In a crumbling skull situation, the effect of the pre-existing condition is divisible from the consequences, if any, of the defendant’s conduct.¹³¹ A basic example is where one cause leads to an arm injury, and another a leg injury.¹³²

These principles all apply, with some qualification, in workers’ compensation law. Workers’ compensation exists as an historical compromise between employers and workers. From the worker’s perspective, he or she gives up the right to sue in tort for full legal damages in return for the ability to recover compensation through a more streamlined process, without having to establish that the employer was negligent or to combat various defences

¹²⁷ *Ibid* at para 34.

¹²⁸ *Ibid* at para 35 [emphasis in original].

¹²⁹ See *ibid* at paras 24-25.

¹³⁰ *Ibid* at paras 1-6.

¹³¹ *Ibid* at paras 24-25.

¹³² *Ibid* at para 24.

available to the employer. From the employer’s perspective, certain liabilities involving employees are replaced by payments to the Injury Fund.¹³³

Notwithstanding the historical compromise, applications for compensation are often met with contention. Because injuries are compensable only if they are work-related, causation is often in dispute. This is evident in the decisions of the various workers’ compensation appeals tribunals throughout Canada. Though the appeals process is distinct from that of a court, it contains elements that are analogous to personal injury litigation in tort. Primarily, for entitlement to compensation, causation must be established. Statutes describe the requirement of work-relatedness in the language of “arising out of and in the course of employment.”¹³⁴ Consistent with the tort principle of material contribution to the occurrence of injury, where multiple causal factors may have contributed to an injury, the condition will be found to be compensable if the occupational exposure was a “significant” causal or contributory factor.¹³⁵ Similarly, adjudicators look for significant acceleration, activation, advancement, or aggravation of a pre-existing condition.¹³⁶ The amount of compensation to be received for particular injuries is set out in de-

¹³³ *Husky Oil Operations Ltd v MNR*, [1995] 3 SCR 453 at paras 124-25, 128 DLR (4th) 1, citing *Reference re: Workers’ Compensation Act, 1983 (Nfld)*, 44 DLR (4th) 501, 67 Nfld & PEIR 16 (NLCA), aff’d [1989] 1 SCR 922, 26 DLR (4th) 765.

¹³⁴ See e.g. *Workers Compensation Act*, CCSM c W200, s 4(1); *Workplace Safety and Insurance Act, 1997*, SO 1997, c 16, Schedule A, s 13(1) [ON *WSIA*]. See similarly *Workers’ Compensation Act*, SNU 2007, c 15, s 10 and *Workers’ Compensation Act*, SNWT 2007, c 21, s 10, both of which describe compensable injuries as “arising out of and during the course of employment”. The Yukon statute uses “work-related” (*Workers’ Compensation Act*, SY 2008, c 12, s 4(1) [YK *WCA*]).

¹³⁵ See e.g. *Decision no 2003-01384* (9 July 2003), 2003 CanLII 69913, online: BCWCAT <www.wcat.bc.ca> (using the language of “significant cause” at 6); *Decision no 398/92* (16 June 1992), 1992 CanLII 5812, online: OWSIAT <www.wsiat.on.ca> (“significant causal factor” at 6); *Decision no 1919/09*, 2009 ONWSIAT 2661, online: OWSIAT <www.wsiat.on.ca> (“significant contributing factor” at para 28); *Decision no 2007-4682* (19 July 2007), 2007 CanLII 70361, online: NBWHSCC <www.whsc.nf.ca> (“significant contributing factor” at 5).

¹³⁶ See e.g. *Decision no 2003-04042* (9 December 2003), online: BCWCAT <www.wcat.bc.ca>; *Decision no 09082* (April 2009), online: NLWHSCRD <whscrd.gov.nl.ca> (“significant aggravation” at 9).

tail in legislation¹³⁷ and tribunal policy.¹³⁸ The rules conform to the thin skull principle in that conditions resulting from individual vulnerabilities or pre-existing conditions are generally fully compensable. Where a distinct pre-existing condition already affects the worker's employment, compensation will only be available to the extent that a subsequent compensable injury worsens the condition.¹³⁹

Statutory provisions modify or specify the application of these general principles in certain circumstances. For example, in most provinces legislation requires that where evidence is approximately equal, the tribunal is to resolve issues in favour of workers.¹⁴⁰ Several other provisions have to do with occupational diseases, a category of injury for which workers may receive compensation.¹⁴¹ For example, though injuries are generally compensable if occupational factors are significant contributors, Manitoba and Prince Edward Island legislate a "dominant causation" test with respect to the com-

¹³⁷ See e.g. An Act respecting industrial accidents and occupational diseases, RSQ, c A-3.001, Chapter III [An Act respecting industrial accidents].

¹³⁸ See e.g. Ontario Workplace Safety and Insurance Board, "Operational Policy Manual: Benefit Payments" (Ontario: WSIB, 2013), online: WSIB <www.wsib.on.ca/en/community/WSIB/230/PolicyLanding/24346?vgnextoid=2f3d8588e7a4e110VgnVCM1000000e18120aRCRD>.

¹³⁹ See e.g. BC *WCA*, *supra* note 121 s 5(5); Workers' Compensation Board of British Columbia, "Rehabilitation Services and Claims Manual, vol 1" (British Columbia: WCB, 2002), online: WorkSafeBC <www.worksafebc.com/publications/policy_manuals/rehabilitation_services_and_claims_manual/volume_i/default.asp> at 22.20; Workers' Compensation Board of British Columbia, "Rehabilitation Services & Claims Manual, vol 2" (British Columbia: WCB, 2002), online: WorkSafeBC <www.worksafebc.com/publications/policy_manuals/rehabilitation_services_and_claims_manual/volume_ii/default.asp> at 44.10 [RSCM II]; *Workplace Health, Safety and Compensation Act*, RSNL 1990, c W-11, s 43.1 [NL *WHSCA*]; *Workers' Compensation Act*, RSNB 1973, c W-13, s 7(5)(b) [NB *WCA*]; *Decision no 2004-224* (12 March 2004), 2004 CanLII 70776, online: AWCAC <www.appealscommission.ab.ca> at para 27; *Decision no 2011-01198* (13 May 2011), 2011 CanLII 51258, online: BCWCAT <www.wcat.bc.ca> at paras 48-49.

¹⁴⁰ BC *WCA*, *supra* note 121, s 99; *Workers' Compensation Act*, SS 1979, c W-17.1, s 25(2) [SK *WCA*]; ON *WSIA*, *supra* note 134, s 119(2); NL *WHSCA*, *supra* note 139, s 60(1); *Workers' Compensation Act*, SNS 1994-95, c 10, s 187 [NS *WCA*]; *Workers Compensation Act*, RSPEI 1988, c W-7.1, s 17 [PEI *WCA*]; YK *WCA*, *supra* note 134, s 19.

¹⁴¹ See e.g. YK *WCA*, *ibid*, s 3(1) "injury" (d); BC *WCA*, *supra* note 121, s 6(1).

pensability of occupational diseases.¹⁴² Also, some jurisdictions exclude "ordinary diseases of life" from the scope of occupational diseases.¹⁴³ This perhaps targets illnesses such as influenza, which (even though they may in fact be transmitted via a co-worker) are not contracted on account of the nature of the workplace per se. These diseases have been recognized as occupational diseases for individuals such as healthcare workers, who face a particular risk of illness in light of the nature of their work.¹⁴⁴ Certain diseases shown to be more prevalent among workers in particular occupations than in the general population are listed in schedules and appendices as entitling exposed workers to a presumption of causation.¹⁴⁵ In other words, the usual requirement to establish causation is reversed and evidence must affirmatively disprove causation if the employer is to avoid a finding of compensability. A small number of conditions are deemed to have been caused by certain workplace exposures. An example from Ontario is asbestosis. If a worker was involved in mining, milling, or manufacturing involving asbestos fibres, and later develops asbestosis, the disease will be deemed to have been caused by the nature of the worker's employment.¹⁴⁶ In these cases no argument on causation is involved.

A unique issue arising within workers' compensation is cost relief. Once initial entitlement to compensation is established, employers may obtain relief if it is found that fully attributing the worker's injury to that employer's account (thereby raising the employer's insurance premiums), would be unfair or unduly burdensome.¹⁴⁷ Benefits paid to the worker would not be fully attributed to the account of the individual employer. Such relief is available in various circumstances, including where the injury is partly owing to prior

¹⁴² *Workers Compensation Act*, RSM 1987, c W200, CCSM c W200, s 4(4) [MB *WCA*]; PEI *WCA*, *supra* note 140, s 3(10).

¹⁴³ MB *WSIA*, *supra* note 142, s 1(1) "occupational disease"; YK *WCA*, *supra* note 134, s 3(1) "injury".

¹⁴⁴ *RSCM II*, *supra* note 139 at 26.03.

¹⁴⁵ See e.g. BC *WCA*, *supra* note 121, s 6(3), Schedule B; AB *WCA*, *supra* note 121, s 24(6); *Workers' Compensation Regulation*, Alta Reg 325/2002, Schedule B; ON *WSIA*, *supra* note 134, s 15(3); *General*, O Reg 175/98, Schedule 3 [*General*]; *An Act respecting industrial accidents*, *supra* note 137, s 29, Schedule I; NS *WCA*, *supra* note 140, s 12(3); *Workers' Compensation General Regulations*, NS Reg 22/96, Appendix B.

¹⁴⁶ ON *WSIA*, *supra* note 134, s 15(4); *General*, *supra* note 145, Schedule 4. See also NS *WCA*, *supra* note 140, s 35.

¹⁴⁷ See e.g. AB *WCA*, *supra* note 121, ss 91(4), 95, 97.

employment,¹⁴⁸ a disaster or similar event,¹⁴⁹ or to a pre-existing condition or disability.¹⁵⁰ Because the thin skull rule precludes apportionment on the basis of personal makeup or risk factors, this added layer of analysis promotes fairness to employers while not taking away from recovery by disabled workers.

Having outlined causation and related issues in the context of personal injury law, we can proceed to analyzing the decisions. As was done in the sections pertaining to criminal law and family law, we have sorted examples by the way in which genetic predisposition is cited in relation to disease causation. Thus, examples vary by whether they tend to support or harm the injured party's case; genetic predisposition is considered a necessary, sufficient, or contributory¹⁵¹ cause of the injured party's condition; and having a genetic predisposition supports or opposes legally significant causation. Though some statements do not fall neatly within a particular category, many do. Overall, the decisions support our argument that genetic concepts are a convenient medico-legal mechanism through which to adjudicate the issue of causation where medical complexity is at issue. Other details from the cases, such as who presented the argument featuring genetic predisposition and how the decision maker considered that argument in reaching an ultimate decision, are also considered where relevant.

¹⁴⁸ See e.g. NS WCA, *supra* note 140, s 18; An Act respecting industrial accidents, *supra* note 137, s 328.

¹⁴⁹ NL WHSCA, *supra* note 139, s 116; NB WCA, *supra* note 139, s 65; An Act respecting industrial accidents, *supra* note 137, s 330; ON WSIA, *supra* note 134, s 98; SK WCA, *supra* note 140, s 144; BC WCA, *supra* note 121, s 39(1)(d).

¹⁵⁰ An Act respecting industrial accidents, *supra* note 137, s 329; Manitoba, Workers Compensation Board, "Policy Manual: Cost Relief/Cost Transfers" (Winnipeg: WCB, 2011), online: MWCB <www.wcb.mb.ca/sites/default/files/files/31_05_10_CostReliefCostTransfer.pdf> at s 31.05.10; BC WCA, *supra* note 121, s 39(1)(e); Ontario, Workplace Safety and Insurance Board, "Operational Policy Manual: Second Injury and Enhancement Fund" (Hamilton: WSIB, 2006), online: OWSIB <www.wsib.on.ca/en/community/WSIB/OPMDetail?vgnextoid=1365fcea9bfc7210VgnVCM100000449c710aRCRD> [SIEF Policy].

¹⁵¹ That is, the predisposition together with other factors amount to an unnecessary but sufficient cause for the development of the disease. This type of causal condition has been described as "an *insufficient* but *non-redundant* part of an *unnecessary* but *sufficient* condition" or to use the first letters of the italicized words, an "in_s condition" (JL Mackie, *The Cement of the Universe: A Study of Causation* (Oxford: Clarendon, 1980) at 62).

ii. Genetic Predisposition as a Contributory or Necessary Cause of Injury

Several decisions feature references to genetic predisposition that support an injured party's case. In many of these statements, genetic predisposition is presented as a contributory or necessary cause of the individual's ultimate injury. Accordingly, an environmental factor is also described as part of the origin of the condition.¹⁵² The 2001 tort decision of the British Columbia Supreme Court in *EB v Order of the Oblates of Mary Immaculate in the Province of British Columbia*¹⁵³ concerned the occurrence of sexual abuse by a staff member at a residential school. Regarding some of the psychological injuries suffered by the plaintiff, a medical expert report was quoted as stating:

I feel that some of his difficulties including symptoms suggestive of PTSD, that is flashbacks, nightmares, intrusive thoughts, strange experiences etc., as well as his sex-related problems including acting out against young girls are most likely sequelae of the sexual abuse he suffered during his childhood. His other problems such as substance abuse could be a combination of a genetic predisposition, other social or emotional experiences, and sexual abuse.¹⁵⁴

Under cross-examination, the same witness stated that by "looking at what kind of family he came from and genetic and environmental and social

¹⁵² Decisions containing this sort of statement, but which we do not discuss in detail include: *NP c SAAQ* (19 April 2005), SAS-Q-096423-0303, 2005 CanLII 70841, online: TAQ <www.taq.gouv.qc.ca> at para 30; *Decision no 737/91* (17 August 1995), [1995] OWCATD no 846 (QL) at para 50, 1995 CanLII 8158, online: OWSIAT < www.wsiat.on.ca >; *Decision no 1358/97* (30 November 1998), [1998] OWSIATD no 2185 (QL), 1998 CanLII 17325, online: OWSIAT <www.wsiat.on.ca> at para 61-62; *Campbell v Vancouver (City of)*, 2001 BCSC 350 at para 34, 103 ACWS (3d) 621 (quoting a previous decision not in our sample); *Decision no 321/91* (22 June 1994), [1994] OWCATD no 492 (QL) at para 23, online: OWSIAT <www.wsiat.on.ca>; *Decision no 161/04* (18 November 2004), 2004 ONWSIAT 2379 at paras 18, 26, [2004] OWSIATD 2284 (QL), online: OWSIAT <www.wsiat.on.ca> ; *Mitchell v Mason Estate* (2002), 117 ACWS (3d) 648, [2002] OJ no 4030 (QL) at para 94 (Ont Sup Ct J); *Morgan v Metropolitan Toronto (Municipality of)* (2006), 153 ACWS (3d) 749, 44 CCLT (3d) 198, [2006] OJ no 4951 (QL) at para 348 (Ont Sup Ct J); *Decision no 2003-04042*, *supra* note 136.

¹⁵³ 2001 BCSC 1783, 110 ACWS (3d) 289, [2001] BCTC 1783.

¹⁵⁴ *Ibid* at para 196.

[factors]”¹⁵⁵ he believed the plaintiff was at a high risk of becoming an alcoholic, but also stated that “the combination of sexual abuse and his genetic vulnerability made things worse for a period of time.”¹⁵⁶ Justice Cohen found the plaintiff’s alcoholism to have resulted from the sexual assaults.¹⁵⁷ This decision shows that viewing genetic predisposition as one aspect of multifactorial disease causation does not preclude the consideration of social and environmental factors alongside genetic traits. The trial decision in favour of the plaintiff was overturned by the BC Court of Appeal on the basis that it erred in finding the defendant vicariously liable for the conduct of the individual who committed the sexual assaults.¹⁵⁸

This type of causal argument is sometimes described in terms of underlying risk and trigger. In *Kolokathis et Industries Maintenance Empire*,¹⁵⁹ an injured worker appealed a denial of his claim for recognition of ulcerative colitis as an occupational injury. The worker alleged that his condition was caused by medication taken in the course of treating a prior occupational injury. One of the worker’s treating physicians submitted a report to the tribunal, which the tribunal found convincing. The report stated, in part:

Is there a direct causal link between the accident and this man’s illness? I believe the answer to this question is yes. Mr. Kolokathis probably has a genetic predisposition to ulcerative colitis. The colitis was triggered off by the medication he was taking for his pain which included the anti-inflammatory medication ANSAID. ANSAIDS, and in particular Voltaren, although they may not be the etiological factor for inflammatory bowel disease, may be the triggering mechanism for the disease process.¹⁶⁰

In arriving at a finding of occupational causation, the tribunal cited the Supreme Court of Canada’s decision in *Snell v Farrell*, wherein the court held that the law does not require “certainty” of causation, but only what

¹⁵⁵ *Ibid* at para 198.

¹⁵⁶ *Ibid* at para 197.

¹⁵⁷ *Ibid* at para 255.

¹⁵⁸ *EB v Order of the Oblates of Mary Immaculate in the Province of British Columbia*, 2003 BCCA 289, 227 DLR (4th) 298, 14 BCLR (4th) 99.

¹⁵⁹ *Kolokathis*, *supra* note 11.

¹⁶⁰ *Ibid* at para 37.

amounts to a probability of 51%.¹⁶¹ The quoted medical report demonstrates an example of the way in which medical language concerning causation aids legal inquiry into "but for" and "material contribution" formulations of causation.

The notions of trigger and underlying risk factors were also employed in *FN c SAAQ*.¹⁶² In this case, an individual involved in a motor vehicle accident appealed a decision of the Société de l'assurance automobile du Québec refusing to recognize a causal link between the collision and the appellant's subsequent development of Type I diabetes. An excerpt of the appellant's argument concerning his appeal stated:

Ce dommage survient généralement à la suite d'une prédisposition génétique, c'est-à-dire dans le cas où la personne a reçu, par hérédité, une susceptibilité de réagir ainsi au niveau de son pancréas. Dans la présente affaire, le violent coup subi à l'abdomen lors de l'accident a nécessairement entraîné un bris de cellules bêta considérable, ce qui a précipité l'apparition du diabète. Le sinistre a donc constitué un facteur précipitant sans lequel le diabète chez la victime ne serait jamais apparu ou, à tout le moins, ne serait pas apparu à cette époque.¹⁶³

The Tribunal administratif du Québec, in dismissing the appeal, noted that no medical evidence was submitted in support of this argument. The appellant stated that his physician had noted the possibility of the relationship, but refused to write a medical opinion to that effect.¹⁶⁴ The panel held that the appellant had failed to satisfy the required burden of proof on a balance of probabilities.¹⁶⁵

¹⁶¹ *Ibid* at para 41, citing *Snell v Farrell*, [1990] 2 SCR 311 at para 34, 72 DLR (4th) 289, 107 NBR (2d) 94.

¹⁶² (1 August 2001), SAS-Q-065751-0007, 2001 CanLII 36580, online: TAQ <www.taq.gouv.qc.ca>.

¹⁶³ *Ibid* at para 11. To paraphrase: This damage usually occurs as a result of a genetic predisposition, that is to say, in the event that the person has inherited a susceptibility to react in the pancreas. In this case, the violent blow to the abdomen during the accident has necessarily resulted in a significant beta cell failure, which precipitated the onset of diabetes. The blaze has been a precipitating factor without which the victim's diabetes would never have appeared or, at least, would not have appeared at that time.

¹⁶⁴ *Ibid* at para 15.

¹⁶⁵ *Ibid* at paras 24-30.

Other cases also illustrate how decision makers consider genetic predisposition where extensive conflicting evidence is available. In *Decision no 935/90*,¹⁶⁶ the Ontario Workers' Compensation Appeals Tribunal ("WCAT", now the Workplace Safety and Insurance Appeals Tribunal ("WSIAT")), dismissed an appeal by a worker claiming entitlement for allegedly having developed Dupuytren's contracture¹⁶⁷ as a result of working for 34 years as a bricklayer. A plastic and reconstructive surgeon retained as a witness by the appellant reported:

In your questions to me, you ask is it probable that contracture was caused or brought on by performing heavy manual work as a brick layer for thirty-four years – my response to that would be that probably this man had a genetic predisposition to develop Dupuytren's contracture and that the repeated trauma of his work aggravated that condition.¹⁶⁸

The panel also repeatedly cited the opinion of Dr. R.M. McFarlane, a witness whom the panel described as "a leading medical expert on Dupuytren's disease."¹⁶⁹ Dr. McFarlane argued against manual labour as a cause or aggravating factor in the development of the disease. Interestingly, to this end he described the condition as a "genetic disease", using the concept of genetics to argue against occupational causation. The panel, taking the argument and evidence together concluded that "on the current state of medical science, the question of what causes or aggravates Dupuytren's disease is still unknown."¹⁷⁰ Echoing *Snell v Farrell*, the panel noted that while the "standard of proof does not require an 'exact answer', a 'mere speculative possibility' is not sufficient to find in favour of the worker."¹⁷¹ Also of interest is what the panel stated with respect to the uncertainty of the relationship between manual work and Dupuytren's:

¹⁶⁶ (3 April 1995), [1995] OWCATD no 314 (QL), 1995 CanLII 8151, online: OWSIAT <www.wsiat.on.ca> [cited to QL].

¹⁶⁷ Dupuytren's contracture is a disease marked primarily by the contracture/bending of some of the fingers toward the palm (see J Vernon Luck, "Dupuytren's Contracture: A New Concept of the Pathogenesis Correlated with Surgical Management" (1959) 41 J Bone Joint Surg Am 635 at 636).

¹⁶⁸ *Decision no 935/90*, supra note 166 at 5.

¹⁶⁹ *Ibid* at 17.

¹⁷⁰ *Ibid* at 1.

¹⁷¹ *Ibid* at 15.

Does that oblige the Tribunal to request an exhaustive investigation into the question? We think not. As noted in Decision No. 909 / 90 (1991), 20 W.C.A.T.R. 168, the statutory instruction to the Tribunal to decide cases on their real merits and justice requires a panel to consider what additional medical or other investigation ought to be pursued before it is confident that it has sufficient evidence to decide the case. However, the real merits and justice instruction also requires a panel "to consider when justice reasonably requires a halt to further investigations and to the further delays such investigations entail."¹⁷²

This last excerpt captures the limits of adjudicative inquiry into disease causation. The scope for factual investigation may be even more curtailed in court, where processes are based on an adversarial rather than an inquisitorial model of leading evidence and adjudication.¹⁷³

The above personal injury decisions illustrate that the argument that an individual has a genetic predisposition to a particular condition may support his or her case. It can do so by explaining why an environmental exposure constituting an insufficient cause of disease led to injury in the claimant (but might not do so in others). A corollary is making the argument that without demonstrating such a predisposition, the claimant cannot show that his or her condition is related to the relevant exposure or incident: that is, he or she cannot establish a vulnerability to an exposure by which other workers are not typically injured. Notwithstanding the logical plausibility of this claim, there was only one instance in our search results where it was clearly argued. In *Decision no 484/90*,¹⁷⁴ the Ontario WCAT decided an appeal from a denial of benefits in connection with an alleged disability owing to an allergy to smoke and fumes in the workplace. In considering the possibility that the worker had developed occupational asthma, the majority of the panel summarized the opinion provided by a respirologist:

Dr. Ho reported that there was no evidence of occupational asthma nor were there any specific respiratory complaints. Dr. Ho noted that the worker's chest was entirely clear and that there were no abnormal findings at all. The doctor indicated that the worker was not an atopic person (i.e., he did not have a genetic

¹⁷² *Ibid* at 17.

¹⁷³ See Gavin MacKenzie, "Breaking the Dichotomy Habit: The Adversary System and the Ethics of Professionalism" (1996) 9 Can JL & Jur 33 at 45.

¹⁷⁴ [1990] OWCATD no 626 (QL), 1990 CanLII 4596, online: OWSIAT <www.wsiat.on.ca> [cited to QL]

pre-disposition to become allergic), there were no known allergies and no previous history of asthma.¹⁷⁵

Here, the absence of susceptibility was probative in ruling out the existence of asthma, and therefore, occupational asthma. The majority dismissed the appeal, writing that “the non-specific nature of the worker’s physical complaints, the possibility of other explanations for those complaints, and the low concentration of fumes in the workplace do not indicate that the worker in this case was particularly susceptible to the low threshold exposure.”¹⁷⁶ The dissenting panel member would have allowed the appeal based on his or her weighing of the evidence.¹⁷⁷

This type of argument is rarely made, perhaps because it is often more difficult to disprove the existence of a predisposition than to prove it. Furthermore, as the burden of proof generally lies with the party seeking compensation, it is necessary only to impugn or discredit the claimant’s argument: the defending party need not conclusively resolve medical uncertainties. Finally, if it is clear that the claimant has developed the alleged condition during the period of employment and the main issue is causation, each party may prefer to focus on which factors triggered the predisposition, rather than on the nature of the predisposition itself. In contrast, if as in the above example, the predisposition and resulting condition are well-defined and well-understood, denying the existence of the former may be a viable argument.

A more common argument than denying the existence of increased risk or vulnerability, made by defendants in tort and employers in workers’ compensation, is that the risk was triggered by non-legally significant causes.¹⁷⁸

¹⁷⁵ *Ibid* at para 12.

¹⁷⁶ *Ibid* at para 39.

¹⁷⁷ *Ibid* at para 55.

¹⁷⁸ Decisions featuring this type of argument include *Decision no 2008-01239* (24 April 2008), 2008 CanLII 25521, online: BCWCAT <www.wcat.bc.ca>; *Decision no 320/87* (9 November 1989), [1989] OWCATD no 1013 (QL) at paras 28-29, 1989 CanLII 1936, online: OWSIAT <www.wsiat.on.ca>; *Haney v Malischewski* (1997), 41 BCLR (3d) 230 at paras 9, 35, 73 ACWS (3d) 247, [1997] BCJ no 1894 (BC SC); *Aubin v Tremblay* (1991), [1991] BCWLD 2055, [1991] BCJ no 2458 (QL) (BC SC); *Bonin et Cargill ltée* (21 July 2008), 2008 QCCLP 4192, online: QCPL <www.clp.gouv.qc.ca>; *Comeau v Canada (Attorney General)*, 2005 FC 1648 at para 14, 284 FTR 107, 144 ACWS (3d) 744; *Blackwater v Plint*, 2001 BCSC 997 at para 711, 93 BCLR (3d) 228, [2001] BCJ no 1446 (QL).

This approach can discredit the claimant's argument while avoiding the potentially difficult issue of whether or not the claimant had a predisposition to develop a particular disease. In *Williams v Thomas Development (1989) Corp*¹⁷⁹ a decision of the Newfoundland and Labrador Supreme Court (Trial Division), the plaintiff, a cardiologist, alleged she suffered a spinal injury as a result of a motor vehicle accident. The decision notes an alternate explanation for her injury: "The Defendants have also raised the issue of Dr. Williams being a cardiologist and the continuous wearing of lead coats, either alone or combined with some genetic predisposition to this type of injury as other possibilities for the injury."¹⁸⁰ The plaintiff was successful at trial but this decision was overturned on appeal based on the issues of duty and standard of care.¹⁸¹ That is, one of the defendants was held on appeal not to owe a duty of care to the plaintiff, and the other was found not to have breached its duty. As a result, the claim failed and the issue of causation was moot.

Similarly, in *Decision no 1919/09*,¹⁸² a worker sought entitlement for chronic obstructive pulmonary disorder ("COPD"), for which he had the confirmed genetic vulnerability of alpha 1 antitrypsin deficiency. The decision cited the policy of the Workplace Safety and Insurance Board ("WSIB"), which had set occupational dust exposure levels deemed generally to satisfy the test for occupational causation of COPD. In particular, the WSIB policy contained a general threshold as well as a lower exposure threshold to recognize that due to the susceptibility of the worker, it would take less occupational exposure to dust to cause disability than it would in another person. The panel dismissed the worker's appeal. The decision stated:

We have determined that the worker's dust exposure was not sufficient to have been a significant contributing factor in the progression of his COPD, at any level. The worker has an underlying genetic predisposition to emphysema and a significant smoking history. His dust exposure does not reach the thresholds set out in the Board policy or the COPD manual and, in our view, was insignificant relative to these factors.¹⁸³

¹⁷⁹ 2006 NLSCTD 44, 254 Nfld & PEIR 61, 146 ACWS (3d) 747.

¹⁸⁰ *Ibid* at para 28.

¹⁸¹ *Williams v Thomas Development (1989) Corp*, 2007 NFCA 54, 269 Nfld & PEIR 290, 283 DLR (4th) 273; leave to appeal to SCC refused, *Williams v Thomas Development (1989) Corp*, [2007] SCCA no 535 (QL), 2008 CanLII 3200.

¹⁸² *Supra* note 135.

¹⁸³ *Ibid* at para 28.

A similar statement appeared in *Decision no 1546/04*,¹⁸⁴ in which the Ontario WSIAT denied an appeal of a worker seeking entitlement for a low back injury that the worker claimed was a result of a fall at work. The panel did not find the worker to be a credible witness, but rather found that: "The medical evidence does establish that the worker has degenerative disc disease, including spondylosis and spondylolisthesis, which are consistent with the normal aging process, a genetic predisposition, and the worker's clinical condition of 'morbid obesity'."¹⁸⁵ This subsection has discussed one major type of reference to genetic predisposition. The next subsection considers another way of speaking about genetic predisposition, with different implications for legal decision making.

iii. Genetic Predisposition as an Alternate Cause of Injury

Genetic predisposition in the above personal injury decisions is conceived of as an increase in risk requiring a trigger in order to manifest as a clinical condition. Being found to have such a predisposition need not harm an injured individual's case: in fact, as we have shown, it can be found to help it. However, in the following examples, having a genetic predisposition to a condition is equated with a causal argument against entitlement to compensation. In effect, when a participant in the legal process takes for granted factors such as "the normal aging process",¹⁸⁶ the "normal activity of life",¹⁸⁷ or "the wear and tear of life in general",¹⁸⁸ and omits mention of them, "genetic predisposition" remains the primary causal explanation. Statements made in various decisions employ genetic predisposition as a sufficient cause of disease alternate to the legally significant factor.¹⁸⁹

¹⁸⁴ (19 November 2004), 2004 ONWSIAT 2392, [2004] OWSIATD no 2306 (QL), online: OWSIAT <www.wsiat.on.ca>.

¹⁸⁵ *Ibid* at para 74.

¹⁸⁶ *Ibid*.

¹⁸⁷ *Decision no 2008-01428* (14 May 2008), 2008 CanLII 33577, online: BCWCAT <www.wcat.bc.ca> at p. 4.

¹⁸⁸ *Decision no 1188/00* (30 April 2001), 2001 ONWSIAT 1460 at para 37, [2001] OWSIATD no 1435 (QL), online: OWSIAT <www.wsiat.on.ca>.

¹⁸⁹ See e.g. *Decision no 2005-03494* (30 June 2005), online: BCWCAT <www.wcat.bc.ca>; *Decision no 710/99* (24 January 2001), 2001 ONWSIAT 158 at para 20, [2001] OWSIATD no 233 (QL), online: OWSIAT <www.wsiat.on.ca>; *Dinyer-Fraser v Laurentian Bank*, 2005 BCSC 225 at para 138, 28 CCLT (3d) 205, 40 BCLR (4th) 39; *Decision no 02213* (June 2002),

In *Polovnikoff v Banks*,¹⁹⁰ the plaintiff alleged that his injuries resulting from an automobile collision with the defendants included a traumatic brain injury and a psychiatric disorder. The decision stated:

The defendants strenuously argued that the symptoms of a brain injury exhibited by the plaintiff were equally indicative of late stage alcoholism, a psychotic illness that involved a shared delusion with his father, or a psychotic disorder based on genetic predisposition. In my view, there is no evidence to support the defence theory that the plaintiff's symptoms stem from a spontaneously appearing psychotic disorder that he was genetically predisposed to.¹⁹¹

The court found in favour of the plaintiff.

In contrast, a similar use of genetic predisposition was successful in *Decision no 2008-1082*¹⁹² of the Appeal Commission for Alberta Workers' Compensation ("AWCAC"), where a worker had appealed a finding that he was not entitled to compensation for a back injury. A medical consultant to the Board reported:

As [first WCB medical consultant] has indicated, disc injuries and pain do not arise from long-term driving. She has quoted a study done on identical twins from Finland which indicates that this is much more likely due to degenerative disc disease rather

02056-02, online: NLWHSCRD <whsrd.gov.nl.ca>; *Decision no 2004-02756* (27 May 2004), online: BCWCAT <www.wcat.bc.ca>; *Decision no 2004-04487* (26 August 2004), online: BCWCAT <www.wcat.bc.ca>; *Decision no 2003-00481* (9 May 2003), 2003 CanLII 70178, online: BCWCAT <www.wcat.bc.ca>; *Hall v MacDougall*, 2007 BCSC 1296 at para 63, 161 ACWS (3d) 248; *Bittante v Zichy*, 2008 BCSC 728 at para 125, 168 ACWS (3d) 791; *Bas de Nylon Doris Ltée et Nicolas Ulysse Bélizaire* (19 February 2001), 128525, online: QCLP <www.clp.gouv.qc.ca> at para 48; *Decision no 2008-01512* (22 May 2008), online: BCWCAT <www.wcat.bc.ca>; *Decision no 2003-02849* (2 October 2003), online: BCWCAT <www.wcat.bc.ca>; *Decision no 2005-00539* (31 January 2005), online: BCWCAT <www.wcat.bc.ca>.

¹⁹⁰ 2009 BCSC 750, [2009] BCJ no 1128 (QL).

¹⁹¹ *Ibid* at para 341.

¹⁹² *Supra* note 12. Another decision featuring similar statements, also concerning degenerative disc disease and involving two of the same panel members is *Decision no 2008-219*, 2008 CanLII 86645, online: AWCAC <www.appealscommission.ab.ca>.

than occupation. The degenerative disc progression is more likely that of a genetic predisposition rather than from driving jobs.¹⁹³

The AWCAC noted that evidence provided by the worker's physiotherapist did not provide a causal explanation linking the injury to occupational factors.¹⁹⁴ They dismissed the worker's appeal, preferring the evidence of the Board's medical consultants.

Likewise, in *Decision no 2004-05655*,¹⁹⁵ a BC WCAT decision, a worker appealed a decision denying him entitlement for a right knee injury. The worker had previously undergone surgery for a left knee condition which was found to be compensable, and argued unrepresented that "after his meniscal surgery he walked with more weight on his right leg which caused more strain on the right meniscus and wore out the knee over the years."¹⁹⁶ A board medical advisor reported, in contrast, that there was "no medical evidence to support that the medial joint arthritis in his left knee was causative for arthritis in his right knee. The most likely cause of the degenerative arthritis in his right knee was a genetic predisposition."¹⁹⁷ The adjudicator, citing Board policy, held that "a lay judgement should not be preferred to a medical opinion on a question of medical expertise. As such, I am not prepared to substitute the worker's understanding of body physics, for the medical opinion of a doctor regarding body bio-mechanics and the most probable cause of the worker's right knee degeneration."¹⁹⁸ The appeal was denied.

In the decisions discussed in this sub-section, alleging "genetic predisposition" as a cause suggested that the injured party's condition would have occurred "but for" the occupational exposure, automobile collision, etc. While defendants argued that injured parties' conditions were a result of genetic predisposition and therefore non-compensable, plaintiffs or claimants denied the existence of a genetic predisposition.¹⁹⁹ For example, in *Decision no*

¹⁹³ *Decision no 2008-1082*, *supra* note 12 at para 23.3.

¹⁹⁴ *Ibid* at paras 24-25.

¹⁹⁵ *Supra* note 12.

¹⁹⁶ *Ibid* at 3.

¹⁹⁷ *Ibid* at 2.

¹⁹⁸ *Ibid* at 5.

¹⁹⁹ See e.g. *Decision no 2004-03193* (18 June 2004), online: BCWCAT <www.wcat.bc.ca> (worker denying he has non-occupational risk factors for inguinal hernia, including genetic predisposition); *Decision no 2004-06212* (25

2004-02756²⁰⁰ of the BC WCAT, the worker appealed a decision finding that his current medical issues were not causally related to his prior compensable claims. A Board medical advisor argued that the worker's having to undergo a particular surgical operation "was most likely due to a genetic predisposition to early degenerative disc disease."²⁰¹ The decision describes that the worker argued that his conditions "were work related, and not genetic."²⁰² The worker was unsuccessful. In *DJB v ARB*,²⁰³ a tort claim arising out of sexual assaults by the plaintiff's step-father, one of the plaintiff's claims was that her alcohol abuse was a form of injury she experienced as a result of the defendant's tortious conduct. The decision describes the testimony of a psychiatrist witness:

In his report, Dr. O'Shaughnessy stated that in general there is not a good one-to-one correlation between sexual abuse in childhood and substance abuse in adulthood. He went on to state that while the area of causality of substance abuse is clearly clouded, and considering he believed there was no evidence of genetic predisposition, then based on special circumstances, namely, had the abuse and the early introduction of alcohol by the defendant not occurred, it is unlikely the plaintiff would have developed a substance abuse disorder.²⁰⁴

November 2004), online: BCWCAT <www.wcat.bc.ca> (worker arguing that mother's hearing loss, and therefore her own, was not due to a genetic predisposition); *Decision no 2004-02471* (12 May 2004), online: BCWCAT <www.wcat.bc.ca> (worker's family physician provides evidence that he is not aware of any genetic predisposition to osteoarthritis as indicated by the worker's history); *Decision no 03251* (October 2003), 03298-07, online: NLWHSCRD <www.gov.nl.ca/whscrd> (in response to the suggestion that genetic predisposition was a factor in his condition, the worker responded, "[i]t is very wrong to state this because I did not experience hip problems prior to the injury" at 7); *Decision no 347/97* (20 June 1997), 1997 CanLII 14105, online: OWSIAT <www.wsiat.on.ca> at para 25; *Decision no 1203/03* (15 July 2003), 2003 ONWSIAT 1627 at para 43, online: OWSIAT <www.wsiat.on.ca>; *Decision no 375/01* (28 February 2003), 2003 ONWSIAT 454 at para 34, online: OWSIAT <www.wsiat.on.ca>.

²⁰⁰ (27 May 2004), online: BCWCAT <www.wcat.bc.ca>

²⁰¹ *Ibid* at 5.

²⁰² *Ibid* at 1.

²⁰³ (1997), 44 BCLR (3d) 154, 73 ACWS (3d) 785 (SC) [*DJB* cited to BCLR].

²⁰⁴ *Ibid* at para 62.

The court preferred the testimony of the defendant, who did not make any argument regarding the genetic predisposition of the plaintiff, but rather testified that he did not give the plaintiff alcohol until she was 16 years old, and by that time “the plaintiff had already been stealing liquor from her parents’ home and drinking it in the back of the classroom with her girlfriends.”²⁰⁵

As in *DJB v ARB*, claimants sometimes unsuccessfully attempted to deny the existence of a predisposition. In contrast, several decisions involve the successful denial of the existence of a predisposition as an alternate cause of injury. The British Columbia Supreme Court in *Campbell v Tenhave*²⁰⁶ dealt with assessment of damages in a motor vehicle accident. A central issue was whether the plaintiff’s headaches were caused by the accident. A neurologist witness called by the defendant testified that it was “[e]xtremely unlikely that the headaches are caused by the accident,”²⁰⁷ though he acknowledged that “it is possible that the general stress of the accident has acted as a trigger in a migraine syndrome for which he had a genetic predisposition.”²⁰⁸ Justice Lander rejected the ambiguous position of this witness, preferring instead the testimony of two neurologist witnesses called by the plaintiff as well as that of the plaintiff’s family physician. The judgment states:

When cross-examined by Mr. Considine, Dr. Simpson said he did not pursue the genetic predisposition aspect of this matter. I find he did not investigate the family history of Mr. Campbell in order to determine if in fact there is any such predisposition. I find as a fact there is no such predisposition on the part of the plaintiff. Mr. Campbell, the father of the plaintiff, and the medical evidence does not support Dr. Simpson’s conclusion as to a genetic predisposition on the part of the plaintiff.²⁰⁹

Justice Lander found that the headaches were caused by the accident. In another damages assessment decision, the BC Supreme Court likewise found the plaintiff’s headaches to have been caused by the motor vehicle accident at issue rather than by a genetic predisposition. The plaintiff had provided evidence to the effect that she did not have a family history of headaches.²¹⁰

²⁰⁵ *Ibid* at para 65.

²⁰⁶ [1988] BCJ no 456 (QL) (BC SC).

²⁰⁷ *Ibid* at 4.

²⁰⁸ *Ibid*.

²⁰⁹ *Ibid*.

²¹⁰ *Lindquist v Neufeld*, [1984] BCJ no 3076 (QL) at para 11 (BC SC) [*Lindquist*].

The decision states: "The evidence of the plaintiff rules out the genetic predisposition and I am left to conclude that this was caused by the soft tissue injury which she suffered."²¹¹

As a final example, in *Decision no 09235*²¹² of the Newfoundland and Labrador Workplace Health, Safety & Compensation Review Division ("WHSCRD"), a worker appealed a decision granting entitlement for a knee injury on a proportional basis due to a pre-existing arthritic condition. The respondent, the Workplace Health, Safety and Compensation Commission argued in part that the worker's osteoarthritis developed prior to the injury due to hereditary factors. The adjudicator rejected this argument:

The suggestion that there were hereditary factors is not only highly subjective, but all so [sic] demonstrably negated by the evidence. The worker has no genetic predisposition that can be documented medically throughout her family. The worker's testimony and the medical evidence available suggests that any osteoarthritic changes that happened over a period of time, happened over a long period of time to the family member in question, i.e. her father and, consequently, more supports the worker's position than the Commission's. Consequently, I place no weight on any argument relative to hereditary factors being related to the osteoarthritis.²¹³

The worker was awarded full benefits without apportionment. As the above cases have shown, where genetic predisposition itself amounts to an argument against legally significant causation, it seems more likely to draw scrutiny than when it simply serves to signify disease susceptibility where other triggering factors are being debated.

iv. Ambiguous Use of Genetic Predisposition

Considering the preceding examples of personal injury decisions, some statements reflect tension between the use of genetic predisposition on one hand as a necessary or contributory cause of disease that can be supportive of a finding of causation, and on the other hand as a sufficient cause alternate to the legally significant factor. These more ambiguous references are marked

²¹¹ *Ibid* at para 21.

²¹² (December 2009), 09184-07, online: NLWHSCRD <www.gov.nl.ca/whscred>.

²¹³ *Ibid* at 16.

by the use of disjunctive conjunctions such as “however”,²¹⁴ “while”,²¹⁵ “but”,²¹⁶ and others.²¹⁷ As an example of this tension, in *Decision no 2003-00828*²¹⁸ of the BC WCAT, the worker appealed a refusal to increase his permanent partial disability pension award because his increased levels of impairment (concerning blood clotting problems) were not related to his prior compensable injuries. The decision recounts:

The disability awards officer asked for an opinion as to whether, given the above medical and claim history, the worker’s subsequent problems dealing with clotting were directly related to the accepted deep vein thrombosis, or whether it was more likely than not related to other non-compensable factors such as genetic predisposition or lifestyle.²¹⁹

While describing genetic predisposition as a non-compensable factor, the decision goes on to state that:

Although the worker’s family history and lifestyle may in fact have pre-disposed the worker to blood clotting disorders, the Board has accepted, as do I, that in the worker’s case, the onset of his condition was caused by the nature of his employment as a carpet layer.²²⁰

The adjudicator applied this fact in concluding that the deteriorating condition of the worker was compensable and ordered, notably, a recalculation of

²¹⁴ *Decision no 2370/01* (31 January 2002), 2002 ONWSIAT 274 at para 51, online: OWSIAT <www.wsiat.on.ca>; *Decision no 2004-01988* (21 April 2004), online: BCWCAT <www.wcat.bc.ca> at 2.

²¹⁵ *Decision no 1176/05* (16 August 2005), 2005 ONWSIAT 1828 at para 22, online: OWSIAT <www.wsiat.on.ca>; *Decision no 651/96* (17 February 1998), 1998 CanLII 15371, online: OWSIAT <www.wsiat.on.ca> at para 20.

²¹⁶ *Decision no 2005-1109*, 2005 CanLII 76251 at para 18.3, online: AWCAC <www.appealscommission.ab.ca>; *Decision no 1419/09* (22 July 2009), 2009 ONWSIAT 174 at para 29, online: OWSIAT <www.wsiat.on.ca>.

²¹⁷ See e.g. *Decision no 398/92*, *supra* note 135 at para 30; *AD v MD*, 2000 OTC 52, 94 ACWS (3d) 807 at para 33, [2000] OJ no 248 (QL) (Ont Sup Ct J); *Decision no 134/87* (27 July 1988), 1988 OWCATD no 817 (QL) at para 31, 1988 CanLII 1766, online: OWSIAT <www.wsiat.on.ca>; *Sparkes-Morgan v Webb* (1999), 178 Nfld & PEIR 237 at para 222, 1999 NJ 205 (QL) (Nfld SC (TD)).

²¹⁸ (5 June 2003) 2003 CanLII 69839, online: BCWCAT <www.wcat.bc.ca>

²¹⁹ *Ibid* at 8.

²²⁰ *Ibid* at 10.

the worker's permanent partial disability award. Likewise, in *Bilodeau et Service correctionnel du Canada*,²²¹ a worker appealed a finding that he had not suffered an occupational injury causing him to miss work for mental health reasons. The Commission des lésions professionnelles ("CLP"), allowing his appeal, citing as applicable in the present case the following passage from existing jurisprudence:

Bien que la travailleuse soit porteuse d'une prédisposition génétique à l'anxiété de type panique, elle ne l'aurait sans doute jamais contractée, n'eussent été des risques particuliers de son travail. La règle du «thin skull» trouve application même s'il s'agit ici d'une maladie psychologique.²²²

This passage demonstrates some ambiguity. On one hand, genetic predisposition can explain an individual's vulnerability to injury, thereby supporting his or her claim. On the other hand, the language of "bien que" (although), suggests that having a genetic predisposition could be an obstacle to recovery in some cases.

v. Workers' Compensation Cost Relief Claims

A final use of genetic predisposition in personal injury cases remains unique to the workers' compensation process and involves the issue of cost relief. Specifically, employers attempted to obtain cost relief by arguing that the worker's injury resulted from genetic predisposition, which amounted to a pre-existing condition or disability. The examples below illustrate that the availability of cost relief is circumscribed in order to strike a balance between making individual employers accountable notwithstanding variation in the constitution of workers, and not holding a single employer responsible for the consequences of an injury beyond its control. The concept of genetic predisposition serves to align individual cases with one of these two competing policy concerns. We highlight the way in which genetic predisposition

²²¹ (2 November 2000), online: QCLP <www.clp.gouv.qc.ca>.

²²² *Ibid* at para 46. This passage was similarly employed in *Nicole Bédard v Cadrin Fleury Inc* (12 January 2001), online: QCLP <www.clp.gouv.qc.ca> at paras 62-63. To paraphrase: Although the worker carries a genetic predisposition to anxiety (panic type), she would never have become ill were it not for the particular risks of her work. The "thin skull" rule applies even where a psychological illness is at issue.

serves this function by outlining cost relief policy and decision making by province.

In Alberta, a pre-existing condition is defined as “any pathological condition which, based on a confirmed diagnosis or medical judgement, pre-dated a work-related injury.”²²³ In other words, it does not include *any* variation or deviation from statistical norms or other workers. For cost relief to be granted, the pre-existing condition must be found to have increased the period or degree of disablement.²²⁴ In one decision, a worker who had a family history of asthma herself developed occupational asthma. The panel decided that while the worker may have had a predisposition to developing asthma, this did not constitute a “pathological condition as required in the definition for a pre-existing condition” and cost relief was not granted.²²⁵

The situation in Québec is similar, where the language of “déjà handicapé” or “already handicapped” is used.²²⁶ Precedent links this language to (what is now) the WHO’s International Classification of Functioning, Disability and Health (“ICF”), and to the concept of disability (fr: déficience), which is defined as “une perte de substance ou une altération d’une structure ou d’une fonction psychologique, physiologique ou anatomique et correspond à une déviation par rapport à une norme biomédicale.”²²⁷ The tribunal

²²³ Alberta, Workers’ Compensation Board, “Policy 03-02 Part I: Aggravation of a Pre-Existing Condition” (Alberta: WCB, 26 November 1996), online: AWCBC <www.wcb.ab.ca/pdfs/public/policy/manual/printable_pdfs/0302_1.pdf> at 1.0.

²²⁴ Alberta, Workers’ Compensation Board, “Policy 05-02 Part II - Application 1: Cost Relief” (Alberta: WCB, 30 November 2010), online: AWCBC <www.wcb.ab.ca/pdfs/public/policy/manual/printable_pdfs/0502_2_app1.pdf> at 1.

²²⁵ *Decision no 2005-963*, 2005 CanLII 76428 at para 26, online: AWCAC <www.appealscommission.ab.ca>

²²⁶ *An Act respecting industrial accidents*, *supra* note 137.

²²⁷ See *Alimentation JA Drolet Inc* (8 March 2001), online: QCLP <www.clp.gouv.qc.ca> at para 15 [*Alimentation*] citing *Municipalité Petite-Rivière Saint-François et CSST Québec* (1999), online: QCLP <www.clp.gouv.qc.ca>. See also *René Matériaux composites Ltée et CSST Chaudière-Appalaches* (21 July 2003), online: QCLP <www.clp.gouv.qc.ca> at para 41 [*René Matériaux*]; *Les Silos Port-Cartier et CSST Côte-Nord* (23 December 2003), online: QCLP <www.clp.gouv.qc.ca> at para 31 [*Les Silos Port-Cartier*]; *Reboitech inc* (15 March 2004), online: QCLP <www.clp.gouv.qc.ca> at para 15 [*Reboitech*]; *CSSS de l’Énergie* (26 May 2009), 2009 QCCLP 3609, online: QCLP <www.clp.gouv.qc.ca> at para 106 [*CSSS*]; *Entreprises DF* (27 April

may also look at the effect of the disability on the workplace injury, including the nature and severity of the injury, recovery time, initial diagnosis following the injury and medical opinion in general.²²⁸ In several decisions, adjudicators found employers construing alleged personal predisposition as a disability.²²⁹ One decision even warned against using questionable "after-the-fact" reasoning to conclude that a person's genetic makeup was defective and amounted to a disability:

En outre, chaque individu a un bagage génétique qui lui est propre et il serait pour le moins hasardeux, voire dangereux, de conclure que le bagage génétique d'une personne est déficient, simplement parce qu'il a développé telle ou telle pathologie. Une prédisposition génétique, serait-elle prouvée, ce qui n'est pas le cas en l'espèce, ne constitue qu'un vague, hypothétique potentiel qui ne s'actualisera peut-être jamais. Elle ne peut, de ce fait, être assimilée à une déficience. Un facteur de risque ne constitue pas une déficience en soi.²³⁰

In this decision, cost relief on the basis of a pre-existing disability was denied where the worker contracted allergic contact dermatitis following thirty years of intermittent work in forestry. The tribunal held there was not enough evidence to demonstrate a disability beyond a supposed predisposi-

2010), 2010 QCCLP 3174, online: QCLP <www.clp.gouv.qc.ca> at para 51. To paraphrase the definition: A loss of substance or an alteration of a psychological, physiological, or anatomical structure or function that corresponds to a deviation from a biomedical norm.

²²⁸ See *Alimentation*, *supra* note 227 at para 16 citing *Hôpital Général de Montréal* (29 November 1999), online: QCLP <www.clp.gouv.qc.ca>. See also *René Matériaux*, *supra* note 227 at para 44; *Reboitech*, *supra* note 227 at para 18.

²²⁹ See e.g. *René Matériaux*, *supra* note 227 at para 39, citing several previous decisions; *Camoguid inc* (22 April 2010), 2010 QCCLP 3067, online: QCLP <www.clp.gouv.qc.ca> at para 27; *Commission scolaire de la Seigneurie des-Mille-Iles* (23 February 2010), 2010 QCCLP 1590 at para 38, online: QCLP <www.clp.gouv.qc.ca>.

²³⁰ *Reboitech*, *supra* note 227 at para 34. To paraphrase: In addition, each individual has a genetic background of their own and it would be somewhat risky, even dangerous, to conclude that the genetic makeup of a person is poor, simply because he has developed a particular disease. A genetic predisposition, were it proven, which is not the case here, constitutes only a vague, hypothetical potential that may never be realized. It cannot, therefore, be treated as a disability. A risk factor does not constitute a disability in itself.

tion. This decision (or reasoning) has been followed in other cases involving dermatitis.²³¹

A symptomatic condition is not required for a pre-existing disability to be found to exist. Rather, adjudicators seem to be satisfied where medical evidence points to a definable and identifiable condition, even if it is latent. The prevalence of this condition — or to phrase it inversely — the degree to which it is a deviation from the biomedical norm, seems to be a key factor in deciding whether it is a disability. For example, in *Alimentation*²³² 90% cost relief was granted where the worker contracted allergic dermatitis. Evidence showed the worker was atopic, meaning she had a genetic predisposition to allergic reactions stated by the employer's medical expert witness to affect 0.2 to 2% of individuals.²³³ Other decisions involving atopic workers share similar outcomes.²³⁴ Deviation from the norm also informs the analysis of other factors, such as recovery time. Employers obtained cost relief in cases where workers suffered from arthritic conditions and took substantially longer to recover from workplace injuries.²³⁵ Deviation from the norm and extended recovery time also led to findings that “mesenchymal syndrome”, a type of genetic predisposition to tendon injuries, constituted a disability for the purpose of cost relief.²³⁶

In Ontario, the policy on the Second Injury Enhancement Fund (“SIEF”) states that employers may obtain cost relief where “an accident becomes pro-

²³¹ See e.g. *Deniso Lebel inc* (7 March 2004), online: QCLP <www.clp.gouv.qc.ca> at para 29;

Les Magasins Hart inc (3 November 2005), online: QCLP <www.clp.gouv.qc.ca>; *Radiateur d'auto Drummond inc* (17 September 2009), 2009 QCCLP 6325, online: QCLP <www.clp.gouv.qc.ca>.

²³² *Supra* note 227.

²³³ *Ibid* at para 17.

²³⁴ *Les Silos Port-Cartier, supra* note 227; See also *Usine Bois Saumon inc* (29 January 2009), 2009 QCCLP 590, online: QCLP <www.clp.gouv.qc.ca>; *Meubles Laurier ltée* (12 March 2009), 2009 QCCLP 1792, online: QCLP <www.clp.gouv.qc.ca>; *Boulangerie Weston Québec ltée* (10 May 2004), online: QCLP <www.clp.gouv.qc.ca>.

²³⁵ *Transport Bourret inc* (10 May 2004), online: QCLP <www.clp.gouv.qc.ca>; *CSSS, supra* note 227.

²³⁶ *Finition Chez Soi inc* (10 June 2008), 2008 QCCLP 3354, online: QCLP <www.clp.gouv.qc.ca>; *Entreprises DF, supra* note 227.

longed or enhanced due to a pre-existing condition."²³⁷ Pre-existing condition is defined broadly as "an underlying or asymptomatic condition which only becomes manifest post-accident."²³⁸ While the policy states that employers are not entitled to cost relief where a minor pre-existing condition results in an accident of major severity, in other circumstances relief is available. The policy states that the SIEF encourages employers to hire disabled workers.²³⁹

In one decision, an Ontario panel concluded that a "pre-existing predisposition" could be considered a pre-existing condition for the purpose of cost relief.²⁴⁰ In that decision, the adjudicator found that the worker's atopy contributed to her development of an allergic reaction to garlic during the course of her employment at a food processing facility. The adjudicator held that this was a "minor" pre-existing condition and that the employer was entitled to 50% cost relief. In contrast, another Ontario decision illustrates that unusually serious consequences following an accident are not sufficient to warrant cost relief in the absence of evidence showing a particular pre-existing condition. In that decision the employer of a worker who developed cellulitis and necrotizing fasciitis as a result of a minor workplace trauma was not entitled to cost relief. The panel noted that the evidence was insufficient to establish that the worker had an underlying or asymptomatic condition or a genetic predisposition to either of these conditions.²⁴¹ The present section of this paper has canvassed the ways genetic predisposition is cited and the themes that are apparent when use of the concept is organized by area of law and the legal issue being considered. This paper can now proceed to considering the broader legal and social issues associated with reference to genetic predisposition in legal decision making.

V. Genetic Predisposition, Causation, and Disability

To resolve issues relating to disease causation in the face of complexity and uncertainty, legal decision makers frequently turn to medical and other scientific evidence. Such evidence often provides probabilistic statements on

²³⁷ SIEF Policy, *supra* note 150.

²³⁸ *Ibid.*

²³⁹ *Ibid.*

²⁴⁰ *Decision no 1094/06* (26 July 2006), 2006 ONWSIAT 1638 at para 13, [2006] OWSIATD no 1614 (QL), online: OWSIAT <www.wsiat.on.ca>.

²⁴¹ *Decision no 2164/07* (16 October 2007), 2007 ONWSIAT 2599 at para 9, [2007] OWSIATD no 2604 (QL), online: OWSIAT <www.wsiat.on.ca>.

association between a risk factor and a disease.²⁴² Yet demonstrating an increase in risk may be insufficient in establishing that the particular party before the court or tribunal in fact developed his or her condition as a result of the particular exposure in question.²⁴³ What is required for a finding of causation in these circumstances is an inference translating or particularizing the general risk to the injured party seeking relief.²⁴⁴ Evidence that can aid in allowing such an inference to be drawn can include testimony concerning pathophysiology and possible mechanisms of disease, the claimant's particular level of exposure to the suspected causal factor, the temporal relationship between exposure and illness, his or her medical history and risk factors, and legal procedural considerations such as the credibility of witnesses.²⁴⁵

Our results demonstrate that due to its versatility, the idea of genetic predisposition can conveniently serve to justify the decision to draw this inference or not to do so. The variety of arguments made and conclusions drawn concerning genetic predisposition varied depending on how they were framed in relation to the causal issue before the legal decision maker (that is, as supporting or opposing the legally significant cause, as a necessary, sufficient, or contributory cause of the condition, and either through affirming or denying the existence of the predisposition). The effectiveness of the argument in resolving causation, in turn, reflected the evidence and argument as a whole, suggesting that genetic predisposition functions as an explanation of a conclusion regarding causation more than as a premise or substantive argument supporting that conclusion. Accordingly, decisions rarely turned on de-

²⁴² See Troyen A Brennan, "Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation" (1987) 73:3 Cornell L Rev 469.

²⁴³ Daniel A Farber, "Toxic Causation" (1987) 71:5 Minn L Rev 1219 at 1228; Clifford Fisher, "The Role of Causation in Science as Law and Proposed Changes in the Current Common Law Toxic Tort System" (2001) 9:1 Buff Env'tl LJ 35 at 126. Compare Anita Bernstein, "Formed by Thalidomide: Mass Torts as a False Cure for Toxic Exposure" (1997) 97:7 Colum L Rev 2153 at 2166 (for a rare example of a substance associated with overwhelmingly strong evidence of causation).

²⁴⁴ See Russell Brown, "The Possibility of 'Inference Causation': Inferring Cause-in-Fact and the Nature of Legal Fact-Finding" (2010) 55:1 McGill LJ 1 at 30-31.

²⁴⁵ See e.g. Katherine Lippel et al, "La preuve de la causalité et l'indemnisation des lésions attribuables au travail répétitif: rencontre des science de la santé et du droit" (1999) 17:1 Windsor YB Access Just 35 at 54-55 (discussing the role of biomedical knowledge in workers' compensation cases involving musculoskeletal injury).

tailed forays into genetic science. Rather, claimants were generally unsuccessful, for example, where they submitted anecdotal²⁴⁶ or personally researched²⁴⁷ evidence that was contradicted by medical expert testimony. Likewise, an expert witness was more likely to influence the decision maker if his or her testimony was specific to the claimant and the disease in question,²⁴⁸ or if his or her qualifications were extensive and relevant to the issues being discussed.²⁴⁹ In instances where there was limited scientific uncertainty in need of resolution, fact trumped expert testimony.²⁵⁰ Arguments concerning genetic predisposition were occasionally analyzed in some detail where family history²⁵¹ or genetic testing²⁵² were used to substantiate or evaluate claims.

This leads us to ask the question: what is it about genetic concepts that make them attractive as a proxy for risk in general? We believe it is a combination of two features. The first is that genetic information, like other forms of medical information, can link individuals with statistical likelihood of developing a particular disease. Second, genetic concepts derive their utility in

²⁴⁶ See e.g. *Decision no 2008-01934* (27 June 2008), 2008 CanLII 43525, online: BCWCAT <www.wcat.bc.ca>;

Decision no 2008-01708 (10 June 2008), 2008 CanLII 43297, online: BCWCAT <www.wcat.bc.ca>; *Decision no 2006-04298* (23 November 2006), online: BCWCAT <www.wcat.bc.ca>; *Decision no 2003-01415* (10 July 2003), 2003 CanLII 69111, online: BCWCAT <www.wcat.bc.ca>.

²⁴⁷ See e.g. *Decision no 2006-416* (4 May 2006), 2006 CanLII 78859 at para 28.2, online: AWCAC <www.appealscommission.ab.ca>; *Fernande Proulx et Pâtisserie Saint-Lambert Ltée* (19 September 2003), 207570-62-0305, online: QCLP <www.clp.gouv.qc.ca> at paras 19-32.

²⁴⁸ See e.g. *Decision no 2005-1126* (22 November 2005), 2005 CanLII 76255 at paras 38-39, AWCAC <www.appealscommission.ab.ca>; *Decision no 2003-02614-RB* (22 September 2003), online: BCWCAT <www.wcat.bc.ca>; *Decision no 1203/03*, 2003 ONWSIAT 1627 at paras 43-45, online: OWSIAT <www.wsiat.on.ca>.

²⁴⁹ See e.g. *Succession EM c SAAQ* (3 November 2008), 2008 QCTAQ 10901 at paras 46-47, SAS-M-118134-0605, 2008 CanLII 60899, online: TAQ <www.taq.gouv.qc.ca>; *Decision no 2008-00782* (11 March 2008), 2008 CanLII 18365, online: BCWCAT <www.wcat.bc.ca>.

²⁵⁰ See e.g. *DJB*, *supra* note 203.

²⁵¹ *Lindquist*, *supra* note 210; *Decision no 09235*, *supra* note 212.

²⁵² *AP c Régie des rentes du Québec* (14 March 2005), SAS-Q-103321-0312, 2005 CanLII 70668, online: TAQ <www.taq.gouv.qc.ca>; *Decision no 1121/06*, 2007 ONWSIAT 3330, online: OWSIAT <www.wsiat.on.ca>.

justifying legal inferences from their general usage as an indicator of heredity or innateness. As many traits of individuals correlate to those of their ancestors (and to ethnic groups more generally), pointing to heredity is attractive when other relevant or suspect potential causes do not demonstrate a connection. In this way, genetic concepts are able to stand in for hidden causes of disease.²⁵³

Framing narratives about health and disease in terms of genetics has particular implications: social and environmental determinants of health and disability may be downplayed.²⁵⁴ In such cases, responsibility for conditions is placed with the individuals who have them, and reform efforts, if any are possible, are relegated to the medical domain.²⁵⁵ This may be said to reflect a “medical model” of health and disability.²⁵⁶ Disability rights scholars have advocated a move away from this model toward a “social model”, which is based on the goals of substantive equality and full participation in society, and which views social factors as mediating disability.²⁵⁷ The geneticization of health and disability is analogous to what Parens & Asch describe as synecdoche in the context of her disability rights critique of prenatal genetic testing. In basing decisions on synecdoche, “a single trait stands in for the whole, the trait obliterates the whole. With both discrimination and prenatal diagnosis, nobody finds out about the rest. The tests send the message that there’s no need to find out about the rest.”²⁵⁸ In Asch’s application of the

²⁵³ See Morange, *supra* note 10 at 12.

²⁵⁴ See Cooper Dreyfuss & Nelkin, *supra* note 13 at 320-21.

²⁵⁵ See Lippman, *supra* note 9 at 18-19.

²⁵⁶ Ron Amundson, “Disability, Ideology, and Quality of Life: A Bias in Biomedical Ethics” in David Wasserman, Jerome Bickenbach & Robert Wachbroit, eds, *Quality of Life and Human Difference: Genetic Testing, Health Care, and Disability* (New York: Cambridge University Press, 2005) 101 at 101-02; Gregor Wolbring, *The Triangle of Enhancement Medicine, Disabled People, and the Concept of Health: A New Challenge for HTA, Health Research, and Health Policy* (Edmonton: Alberta Heritage Foundation for Medical Research, 2005) at 12.

²⁵⁷ Amundson, *supra* note 256; Wolbring, *ibid* at 17-18.

²⁵⁸ Erik Parens & Adrienne Asch, “The Disability Rights Critique of Prenatal Genetic Testing: Reflections and Recommendations” in Erik Parens & Adrienne Asch, eds, *Prenatal Testing and Disability Rights* (Washington: Georgetown University Press, 2000) 3 at 14. See also Adrienne Asch, “Why I Haven’t Changed My Mind about Prenatal Diagnosis: Reflections and Refinements” in Parens & Asch at 234; Adrienne Asch & David Wasserman, “Where is the Sin in Synecdoche? Prenatal

concept, the "part" is the expected disability and the "whole" is the future child. In the present context, they are, respectively, the genetic makeup of the individual (or particular variations amounting to a predisposition to a disease) and his or her overall condition or constitution (including social background and environmental exposures). The resulting message is that people are reducible to their genes.

Shainblum, Sullivan & Frank provide a general example of the way in which this synecdoche can occur in the context of workers' compensation.²⁵⁹ Using as their main examples heart disease and back pain, they illustrate that causation is often more complex and subtle than what the current workers' compensation framework takes into consideration. In determining entitlement for complex conditions, generic causation language such as "arising out of employment" provides adjudicators with leeway to determine which conditions should be compensated based on unstated policy considerations.²⁶⁰ For example, the authors explain that workplace stress has a pervasive effect on health, particularly when accompanied by low a reward (salary), as is disproportionately the case for people of low socioeconomic status.²⁶¹ The workplace is also a determinant of social status, which in turn is a determinant of health.²⁶² Yet these systemic and pervasive risk factors are generally not taken into account in considering occupational disease causation, as they are instead attributed to the worker's personal circumstances.²⁶³ Furthermore, our research suggests that notions of genetic predisposition may promote this reduction of complex causation into a simple matter of work-relatedness, while downplaying the interaction of social determinants of health with occupational and other factors. Where legal decisions refer to social and other environmental causal factors alongside genetic predisposition, they may accurately describe the complex interaction between the factors that results in various health conditions. However, pointing to a predisposition-trigger ac-

Testing and the Parent-Child Relationship" in Wasserman, Bickenbach & Wachbroit, *supra* note 256 at 172.

²⁵⁹ Esther Shainblum, Terrence Sullivan & John W Frank, "Multicausality, Non-traditional Injury, and the Future of Workers' Compensation" in Morley Gunderson & Douglas Hyatt, eds, *Workers' Compensation: Foundations for Reform* (Toronto: University of Toronto Press, 2000) 58.

²⁶⁰ *Ibid* at 82.

²⁶¹ *Ibid* at 73-75.

²⁶² *Ibid* at 71.

²⁶³ *Ibid* at 78-79.

count of causation risks oversimplification, and this is the concern associated with synecdoche.

Compounding this oversimplification is the tendency of individuals to geneticize themselves in order to obtain compensation, thereby reinforcing particular ways of conceptualizing and responding to disability.²⁶⁴ Where being found to have a genetic predisposition harms a party's claim, such as where genetic predisposition amounts to a sufficient cause of disease, he or she may argue against existence of the predisposition. However, in other instances genetic predisposition serves to explain what made a claimant particularly vulnerable to the legally significant trigger of the injury. In these circumstances he or she may rely on the notion of predisposition to bolster the claim. Similarly, in criminal law, genetic predisposition can serve to support an accused's argument of NCR-MD,²⁶⁵ and in family law it can be used by biological parents and the state to explain the genesis of children's conditions in attempting to advocate for their best interests.²⁶⁶

Another implication of these causal arguments relates to the reinforcement of the definition of disability. While in the *Boisbriand* decision (discussed in the introduction to this paper), it was the claimants who asserted that they were covered by the definition of disability under the Québec *Charter*, and their employers who denied that they were disabled, personal injury decisions essentially demonstrate the reverse pattern. That is, defendants argue that claimants were already disabled, while claimants argue that their genetic predispositions do not amount to a disability, or at least did not until they were exposed to the legally significant injuring factor. Similarly, in workers' compensation cost relief claims, employers argue that a worker's measurable variation associated with a unique sensitivity or long recovery time amounts to a pre-existing disability warranting cost relief.

²⁶⁴ This dynamic has been explored in the context of the wrongful birth and wrongful life causes of action. See Wendy F Hensel, "The Disabling Impact of Wrongful Birth and Wrongful Life Actions" (2005) 40 Harv CR-CLL Rev 141 ("Any benefits secured by individual litigants in court are thus taxed to the community of people with disabilities as a whole, placing at risk, in the drive for individual compensation, the gains secured by collective action and identity" at 144).

²⁶⁵ See e.g. *Campagna* trial decision, *supra* note 74 at para 21; *Carmichael*, *supra* note 81 at para 16.

²⁶⁶ *Children's Aid Society of Ottawa*, *supra* note 92 at para 49; *RM (Re)*, *supra* note 104 at para 13.

These contrasting arguments can partly be explained by the tendency to interpret facts in a way that advances one's legal interests in a given case. They also reflect the differing conceptions of disability upon which particular policy regimes are built. Briefly, the development of welfare regimes such as workers' compensation schemes has relied heavily on medical and economic measurements, which make use of clinical diagnoses and functional assessments in determining the nature and extent of disability.²⁶⁷ In contrast, instruments based on the sociopolitical model of disability policy look largely to the limitations of living with particular conditions, real or perceived.²⁶⁸ Viewed in this way, the varied and sometimes opposing genetic arguments made in legal decisions reveal the "fragmented" basis from which Canadian disability policy stems, and highlight the opportunity to promote a more "unified, comprehensive" approach that is clearer about the goals of and relationships among different disability policies.²⁶⁹

The above concerns regarding the geneticization of health and disease emerge in our survey of Canadian court and tribunal decisions, unlike incidents of genetic discrimination. There are several interrelated reasons that may explain why genetic discrimination has not materialized as speculated. Most importantly, the predictive value of genetic information is limited.²⁷⁰ With the exception of highly penetrant single-gene disease risk markers, such as the marker for Huntington's disease, much genetic variation is associated with only small increases in the risk of contracting particular conditions.²⁷¹ As a result, the costs and risks associated with adopting a genetic screening program often outweigh the limited benefits. The costs include running the tests themselves.²⁷² Other measures of risk of disease, such as blood pressure or smoking history, also offer predictive value.²⁷³ It may therefore be more

²⁶⁷ Lyn Jongbloed, "Disability Policy in Canada: An Overview" (2003) 13 *Journal of Disability Policy Studies* 203 at 205.

²⁶⁸ *Ibid* at 205-07.

²⁶⁹ *Ibid* at 207.

²⁷⁰ Kakuk, *supra* note 13 at 326-30; James P Evans et al, "Deflating the Genomic Bubble" (2011) 331 *Science* 861 at 861.

²⁷¹ Kakuk, *supra* note 13 at 326-28; George Davey Smith et al, "Genetic Epidemiology and Public Health: Hope, Hype, and Future Prospects" (2005) 366 *Lancet* 1484 at 1485-88.

²⁷² Humphries, Ridker & Talmud, *supra* note 8 at 630.

²⁷³ *Ibid*; Ian Kerr & Timothy Caulfield, "Emerging Health Technologies" in Jocelyn Downie, Timothy Caulfield & Colleen M Flood, eds, *Canadian Health Law and Policy*, 3d ed (Toronto: LexisNexis Canada, 2007) 509 at 516.

costly to turn away prospective employees or insurance policyholders on a scientifically questionable basis than to accept them, notwithstanding their genetic profile.²⁷⁴ Also, various organizations have raised concerns about the use of genetic information in this way.²⁷⁵ Legal decisions such as *Boisbriand* and others have set out the general prohibited discrimination test that a court would apply if a genetic discrimination challenge were to be brought.²⁷⁶ With respect to insurance, a claim of genetic discrimination would have to take into account that it is socially accepted that the purpose of insurance is to discriminate among individuals and groups based on risk, as long as this is done in a manner that is “reasonable and *bona fide*.”²⁷⁷

Recognizing the limits of genetic testing, Péter Kakuk suggests that social representations of genetic information amounting to the geneticization of health and disability, are more of a concern than genetic discrimination.²⁷⁸ Accordingly, concern over genetic discrimination, which is a form of genetic exceptionalism in policy, may further reify and overstate the significance of genetic information.²⁷⁹ Along these lines it is worth considering that the development of genetic science might counteract geneticization if it serves to highlight the limits of the predictive power and determinative nature of genetic variation. In a related vein, the science of epigenetics (modifications of the genome outside of DNA sequences) is revealing the effects of environmental influences on gene expression, including intergenerational effects.²⁸⁰ Thus, the development of epigenetics may likewise provide a scientific basis for highlighting the complexity of the causal implications of genetics.

²⁷⁴ But see JA Lowden, “Genetic Discrimination and Insurance Underwriting” (1992) 51 Am J Hum Genet 901.

²⁷⁵ See Lizabeth A Barclay & Karen S Markel, “Discrimination and Stigmatization in Work Organizations: A Multiple Level Framework for Research on Genetic Testing” (2007) 60 Human Relations 953 at 973.

²⁷⁶ See e.g. *British Columbia (Public Service Employee Relations Commission) v BCGSEU*, [1999] 3 SCR 3, 176 DLR (4th) 1; *Hydro-Québec v Syndicat des employé-e-s de techniques professionnelles et de bureau d’Hydro-Québec, section locale 2000 (SCFP-FTQ)*, 2008 SCC 43, [2008] 2 SCR 561, 294 DLR (4th) 407.

²⁷⁷ Trudo Lemmens, “Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?” (2000) 45 McGill LJ 347 at 404-06 [emphasis in original].

²⁷⁸ Kakuk, *supra* note 13 at 335.

²⁷⁹ *Ibid.*

²⁸⁰ See generally Mark A Rothstein, Yu Cai & Gary E Marchant, “The Ghost in Our Genes: Legal and Ethical Implications of Epigenetics” (2009) 19 Health Matrix 1.

Conclusion

Through this study, we have pursued several analytical objectives. Primarily, we have catalogued the types of genetic causal statements made in Canadian court and tribunal decisions. The range of these statements — in the relationships they allege among the predisposition in question, the legally significant cause at issue, and the resulting condition — highlights the convenience of using genetic arguments to resolve legal issues. With an awareness of this versatility, individuals can respond more readily to genetic arguments made by other participants in the legal process. Where such arguments merely express a legal conclusion as to causation, it is helpful to look beyond the genetic language and focus on the underlying causal arguments. In some cases it will also be possible to question the scientific validity of alleging that a predisposition exists. Individuals may also choose to direct attention toward the complex interaction of social and environmental causes that are unacknowledged in notions of genetic predisposition, along the lines of the analysis undertaken by Shainblum, Sullivan & Frank.²⁸¹ Doing so may not affect the outcome of the proceeding, as the court or tribunal must ultimately decide whether on a balance of probabilities the condition is related to the legally significant cause. Nonetheless, from a policy development perspective, acknowledging the complexity of causal factors of disease can promote reflection on social determinants of health and disability. It can also counteract the tendency to geneticize health and disease. Geneticization, which is reflected in the results of our survey of case law, has consequences that reach beyond particular legal decisions and affects society at large by shaping understandings of health and disability, as well as responses to them. It is this concern that should motivate policy, as much as that of genetic discrimination.

²⁸¹ *Supra* note 259 at 69-70.

DOUGLAS V INDEPENDENT LIVING CENTER:
LITIGATING ACCESS TO PUBLICLY FUNDED
HEALTH SERVICES IN THE
UNITED STATES AND CANADA

*Lorian Hardcastle**

As health care costs grow, policy-makers face difficult trade-offs between competing demands in order to ensure health system sustainability. Government decisions limiting access to publicly funded health services have prompted a growing number of aggrieved citizens to turn to courts for redress. A recent case before the US Supreme Court asked whether Medicaid beneficiaries have a justiciable right to challenge state budget cuts impeding their access to health services. According to the claimants, cuts to provider reimbursement rates contravened federal conditions on Medicaid funding. Despite the different legal regimes and political structures in Canada and the US, legal claims relating to the accessibility of health services raise similar policy issues. In this paper, I discuss the tension between the judicial competence to adjudicate matters of complex social policy and the need for beneficiaries, who have little choice but to rely on the public system, to have mechanisms to hold governments accountable for their health policy decisions. I conclude that although judges should be reluctant to completely bar beneficiaries from seeking redress before the courts, they should show considerable deference to governmental policy choices in adjudicating the merits of these cases.

Alors que le coût des soins de santé augmente, le gouvernement se doit de faire des compromis entre plusieurs demandes concurrentes afin de maintenir la viabilité du système de santé. Les décisions gouvernementales visant à limiter l'accès au service de santé publique ont provoqué le mécontentement chez un nombre croissant de citoyens, qui se tournent maintenant vers le système judiciaire pour demander des réparations. Un cas récent demanda à la Cour suprême des États-Unis de se prononcer sur la possibilité des ayants droit de l'assurance médicale de contester les réductions budgétaires étatiques responsables compromettant leur accès au système de santé. Les plaignants soutiennent que ces réductions vont à l'encontre des préalables fédéraux du financement des soins de santé. Malgré les différences qui existent entre les juridictions et les institutions américaines et canadiennes, les demandes concernant l'accès aux soins de santé soulèvent des enjeux similaires. Dans cet article, j'examinerai les tensions entre la compétence judiciaire de statuer sur des sujets de politique sociale complexes et le besoin des bénéficiaires du système de santé, qui n'ont d'autre choix que de fier au système public, d'avoir droit à des mécanismes afin de rendre les gouvernements responsables de leurs décisions reli-

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ées à la santé. Je conclus que même si les juges se doivent d'être réticents avant d'exclure toute possibilité pour les bénéficiaires de soins d'aller chercher compensation devant les tribunaux, ils devraient démontrer une déférence considérable faces aux décisions gouvernementales lorsqu'il temps de trancher de tels cas.

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Introduction

Given the proliferation of costly pharmaceuticals, sophisticated diagnostic technologies, and the aging population, policy-makers around the world are increasingly faced with difficult trade-offs between competing demands in order to ensure health system sustainability. Government decisions negatively affecting access to publicly funded health services have prompted a growing number of aggrieved citizens to turn to courts for redress. In this paper, I compare the responses of American and Canadian courts to legal claims challenging policies limiting access to health services in the context of public insurance programs.

A recent case before the US Supreme Court called upon the justices to determine whether Medicaid beneficiaries have a justiciable right to challenge state budget cuts impeding their access to health services. According to the claimants, cuts to provider reimbursement rates contravened federal conditions on Medicaid funding. When faced with similar questions, Canadian courts have determined that litigants cannot bring claims alleging a province breached the requirements of Canada's corresponding federal funding legislation, the *Canada Health Act*.¹ I argue that the denial of a private right of action is less problematic in Canada, due to the greater efficacy of political pressure in the context of a universal health insurance program and to the ability of plaintiffs to indirectly challenge government policies limiting access to publicly funded health services through other legal mechanisms, most notably the *Canadian Charter of Rights and Freedoms* and administrative law.

Despite the different legal regimes and political structures in Canada and the US, legal claims relating to the accessibility of health services raise similar policy issues. In what follows, I discuss the tension between the judicial competence to adjudicate matters of complex social policy and the need for beneficiaries, who have little choice but to rely on the public system, to have mechanisms to hold governments accountable for their health policy decisions. I conclude that although judges should be reluctant to completely bar beneficiaries from seeking redress before the courts, they should show considerable deference to governmental policy choices in adjudicating the merits of these cases.

¹ RSC 1985, c C-6.

I. The US Legal Claim

The Medicaid program, which has 60 million low income beneficiaries,² fills a coverage gap left by the market-based system of health insurance allocation. Cost pressures are particularly acute within a countercyclical, income-tested program such as Medicaid, in which an economic downturn leaves governments with both a reduced tax base and an increased number of eligible beneficiaries. In 2008, the California government sought to address the state's "fiscal crisis" by cutting Medicaid provider reimbursement rates by 10%. Beneficiaries and providers responded by filing a legal claim alleging these rate cuts violated the federal equal access requirement.³ According to this provision, in order to qualify for federal funding, a state Medicaid plan must "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."⁴ In other words, states must ensure provider reimbursement rates are sufficiently high that Medicaid beneficiaries have access to services that is comparable with other individuals (i.e., those insured under private plans and Medicare).

If a state wishes to amend its Medicaid plan, including provider reimbursement rates, it must seek the approval of the federal Department of Health and Human Services ("HHS"). Although HHS had not approved California's 2008 rate cuts, the state nevertheless proceeded with their implementation. In *Douglas v Independent Living Center*, the Ninth Circuit Court granted an injunction enjoining California from continuing with the rate cuts

² Kaiser Commission on Medicaid and the Uninsured, "The Medicaid Program at a Glance", online: The Henry J Kaiser Family Foundation <www.kff.org/medicaid/upload/7235-05.pdf> at 1-3. Federal rules specify that to qualify for Medicaid, an individual must fall below a certain income level and be a member of an eligible group: children, pregnant women, adults with dependent children, people with disabilities, and senior citizens. Many states have expanded these criteria to cover additional beneficiaries. Medicaid covers a variety of services, including hospital services, physician services, laboratory services, and nursing home and home care services. In 2010, Medicaid spending was approximately \$390 billion, with the federal government paying approximately 57% of those costs.

³ See e.g. *Douglas v Independent Living Center*, 572 F 3d 644 (9th Cir 2009) [*Douglas* 2009]; *Independent Living Center of South California v Maxwell-Jolly*, 572 F 3d 644 (2009).

⁴ 42 USC § 1396a(a)(30)(A).

pending the resolution of the litigation.⁵ Last term, the US Supreme Court heard the California government's appeal from the Ninth Circuit decision.⁶ This case was overshadowed by the attention garnered by another health care case heard during the same term, the constitutional challenge to the *Patient Protection and Affordable Care Act*.⁷ However, *Douglas* called upon the Supreme Court to resolve the important issue of whether Medicaid beneficiaries and providers have a right to challenge state Medicaid policies and, more broadly, the scope of the Constitution's Supremacy Clause.

Historically, litigants have challenged state breaches of the equal access provision under § 1983 of the *Civil Rights Act*, which allows individuals to sue the government for deprivations of statutory rights. However, in 2002, in *Gonzaga University v Doe*,⁸ the US Supreme Court narrowed the scope of this provision, finding that a plaintiff must first demonstrate congressional intent to create a legally enforceable right in order to succeed with a § 1983 claim. Most circuit courts have subsequently interpreted *Gonzaga* as precluding private enforcement of the equal access provision through § 1983, since nothing in the legislation suggests that Congress intended to create a privately enforceable right.⁹

Accordingly, the plaintiffs in *Douglas* pursued an alternative legal theory, arguing that because California's rate cuts were inconsistent with the federal equal access provision, they violated the Constitution's Supremacy Clause, which provides for the supremacy of federal laws over state laws.¹⁰ The Supreme Court thus had to determine whether the Supremacy Clause provided an implied right of action to challenge state legislation, or whether the plaintiffs first had to prove the applicable legislation created a privately enforceable right. California argued that if the Court adopted the latter approach, the post-*Gonzaga* § 1983 jurisprudence dictated the claim should fail, due to the absence of congressional intent to create a cause of action in

⁵ *Supra* note 3.

⁶ *Douglas v Independent Living Center of Southern California*, 132 US 1204 (2012) [*Douglas* 2012].

⁷ *National Federation of Independent Business v Sebelius*, 132 US 2566 (2012) [*Sebelius*].

⁸ 536 US 273 (2002) [*Gonzaga*].

⁹ Nicole Huberfeld, "Bizarre Love Triangle: The Spending Clause, Section 1983, and Medicaid Entitlements" (2008) 42 UC Davis L Rev 413 at 426-57.

¹⁰ *Douglas* 2009, *supra* note 3 at 649.

Medicaid legislation.¹¹ Following the Supreme Court's 1908 decision *Ex parte Young*,¹² numerous courts had assumed a freestanding right to invoke the Supremacy Clause to pre-empt state laws (independent of whether the relevant statute contained a private right of action), but California sought to challenge this assumption and to draw a distinction in the context of Congress' use of the Constitution's Spending Clause.¹³

Following oral arguments at the Supreme Court, but before the justices released their opinion, HHS retroactively approved several of the California plan's amendments and the state withdrew the remainder of the proposed changes.¹⁴ The Court was then faced with the question of whether a Supremacy Clause claim could be maintained, given that the federal government had, in effect, affirmed that California's rate cuts did not violate federal law. Because this changed the circumstances of the plaintiffs' claim, the Supreme Court remanded the case to the Ninth Circuit, and the issue of whether beneficiaries can challenge state rate cuts under the Supremacy Clause remains unresolved. A judge may now conclude this case is more appropriately resolved through judicial review of the HHS decision to approve the plan amendments under the *Administrative Procedures Act*. Under this statute, courts would be required to give considerable deference to the agency's decision, with the applicable standard of review being whether the decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."¹⁵

This issue is likely to reach the courts again, because budgetary concerns within state Medicaid plans will become increasingly acute over the next few years. In 2014, the *Patient Protection and Affordable Care Act*¹⁶ will expand Medicaid eligibility to 133% of the poverty level.¹⁷ While federal funds will

¹¹ Douglas 2012, *supra* note 6 (Brief for the Petitioners, online: American Bar Association <www.americanbar.org/content/dam/aba/publishing/previewbriefs/Other_Brief_Updates/09-958_petitioner_douglas.authcheckdam.pdf> at 15-16) [Douglas Brief].

¹² 209 US 123 (1908).

¹³ *Supra* note 11 at 18.

¹⁴ See Douglas 2012, *supra* note 6 at 1206.

¹⁵ 5 USC § 706(2)(a).

¹⁶ Pub L No 111-148, 24 Stat 119 (2010).

¹⁷ Benjamin D Sommers & Arnold M Epstein, "Why States Are So Miffed about Medicaid: Economics, Politics, and the 'Woodwork Effect'" (2011) 365 New Eng J Med 100 at 100. As with the Canadian Constitution, the Tenth Amendment

initially cover the entire cost of newly eligible individuals, this contribution will decrease over time for new beneficiaries.¹⁸ Furthermore, states will only receive the traditional federal contribution (50–75%) for individuals who were eligible for Medicaid prior to the program's expansion.¹⁹ In addition to the 16 million newly enrolled beneficiaries that have been projected,²⁰ more than nine million previously eligible individuals may now enroll in Medicaid due to new federally-mandated simplified application procedures, publicity respecting eligibility criteria, and the individual mandate to obtain health insurance.²¹

II. The Canadian Legal Claims

Similar to American Medicaid, Canadian Medicare is a co-operative federalism program, whereby provincial health insurance plans must meet certain conditions, including accessibility, in order to qualify for federal funding.²² According to the *Canada Health Act*, a province's plan must satisfy four criteria in order to meet the accessibility requirement:

permits the US federal government to impose conditions on federal funding. In *Sebelius*, *supra* note 7, a majority of the Supreme Court accepted the states' argument that it was coercive to make all federal Medicaid funding conditional on the expansion of eligibility, as the states had little choice but to accept the expansion, given that Medicaid is their largest source of federal funding (at 2604–05).

¹⁸ Sommers & Epstein, *ibid* at 100.

¹⁹ *Ibid*.

²⁰ Congressional Budget Office, *Reconciliation Act of 2010 (Final Health Care Legislation)* (HR Doc No 4872) (Washington, DC: US Congress, 20 March 2010) at 9 and Table 4. These figures assume states do not opt out of the Medicaid expansion, as permitted by the Supreme Court's recent finding in *Douglas*, *supra* note 6 at 2608.

²¹ Sommers & Epstein, *supra* note 17 at 100–01. A majority of the US Supreme Court recently upheld the constitutionality of the individual mandate when faced with the question of whether it was a valid exercise of Congress' taxing power or of the Commerce Clause and Necessary and Proper Clause in *Sebelius*, *supra* note 7 at 2608.

²² *Canada Health Act*, *supra* note 1, s 7. Similarly, the scope and legitimacy of the federal spending power has been a source of controversy and debate in both jurisdictions. See e.g. Andrew Petter, "The Myth of the Federal Spending Power Revisited" (2008–09) 34 *Queen's LJ* 163; Jeffrey T Renz, "What Spending Clause? (Or The President's Paramour): An Examination of the Views of

- (a) provide for insured health services on uniform terms and conditions and on a basis that does not impede or preclude ... reasonable access to those services;
- (b) provide for payment for insured health services in accordance with a tariff or system of payment authorized by the law of the province;
- (c) provide for reasonable compensation for all insured health services rendered by medical practitioners or dentists; and
- (d) payment of amounts to hospitals ... in respect of the cost of insured health services.²³

In practice, provincial governments generally determine which physician and hospital services are insured, and the reimbursement rates for those services, through negotiations with provincial medical associations.

As Flood and Choudhry argue, “[f]or most Canadians, the [*Canada Health Act*] has become a document of near constitutional status, emblematic of Canadian values and a guarantee for all Canadians of the security of health insurance.”²⁴ However, despite the public’s perception of the *Act*, the courts have repeatedly held that it is merely a funding statute that does not confer privately enforceable rights. For example, in *Cameron v Nova Scotia (AG)*, the Nova Scotia Court of Appeal held that if provincial legislation “fails to meet the standards or objectives of the Canada Health Act, it does not follow that the appellants would be entitled to relief.”²⁵ The Court went on to state that while “[f]ailure of a province to comply with the Canada Health Act

Hamilton, Madison, and Story on Article I, Section 8, Clause I of the United States Constitution” (1999) 33:1 J Marshall L Rev 81.

²³ *Supra* note 1, s 12.

²⁴ Colleen M Flood & Sujit Choudhry, “Strengthening the Foundations: Modernizing the Canada Health Act” in Tom McIntosh, Pierre-Gerlier Forest & Gregory P Marchildon, eds, *The Governance of Health Care in Canada: The Romanow Papers*, vol 3 (Toronto: University of Toronto Press, 2004) 346 at 346. The authors also argue that “to view the CHA as simply a dry and dusty spending statute, whereby the federal government transfers funds to provinces that comply with certain conditions, belies the importance of the CHA in the hearts and minds of Canadians” (at 346).

²⁵ (1999), 204 NSR (2d) 1 at para 97, 177 DLR (4th) 611 (NSCA).

may result in the Government of Canada imposing a financial penalty on the province ... [this is] a political, not a justiciable issue.”²⁶

III. The Policy Issues

In both Canada and the US, legal challenges to health service accessibility raise several significant policy issues. In the first part of this section, I discuss the importance of an available mechanism through which beneficiaries can hold state or provincial governments accountable for their health policy decisions. In particular, I address three accountability mechanisms: federal enforcement, political pressure, and recourse to the courts. In the second part of this section, I argue that legal accountability must be balanced against a countervailing policy concern—the judiciary’s institutional competence to adjudicate matters of complex social policy. I conclude that while judges should be reluctant to completely foreclose a private right to challenge government decisions, they should show considerable deference to the state’s policy choices in adjudicating the merits of these claims.

A. The Importance of Accountability

Recipients of both Canadian Medicare and US Medicaid have little choice but to rely on their respective governments to provide reasonable access to health services. In the US, this reliance is a function of the inability of beneficiaries to afford private health insurance or to pay for care out-of-pocket. In Canada, reliance is government-mandated, as provinces have implemented a variety of prohibitions and disincentives to prevent or limit the privatization of health care services and the development of duplicate private insurance,²⁷ thereby creating a state monopoly over most hospital and physician services. Because of these regulations, generally only those individuals who are wealthy enough to travel outside of Canada and pay for health ser-

²⁶ *Ibid* at para 97. See also *Brown v British Columbia (AG)* (1997), 41 BCLR (3d) 265, 73 ACWS (3d) 163 (BCSC); *Lexogest Inc v Manitoba (AG)* (1993), 101 DLR (4th) 523, 85 Man R (2d) 8 (Man CA); *Canadian Union of Public Employees v Canada (Minister of Health)*, 2004 FC 1334 at para 44, 244 DLR (4th) 175.

²⁷ For a discussion of these legislative provisions, see Colleen M Flood & Tom Archibald, “The Illegality of Private Health Care in Canada” (2001) 164:6 Can Med Assoc J 825. Duplicate private insurance covers services already insured within the public plan. This can be contrasted with supplementary private insurance, which covers services not included in the public plan (such as dental or optometry services or pharmaceuticals received outside of hospitals).

vices entirely out-of-pocket have an alternative to the public system. This reliance on government necessitates there be mechanisms in place by which the state can be held accountable when the public program fails to provide a reasonable standard of care.

The intergovernmental nature of both countries' public health insurance programs has the potential to facilitate accountability, with the central government acting as a check on state or provincial policies. Indeed, in *Douglas*, the California government argued that the appropriate remedy for breaches of the equal access requirement was federal enforcement rather than litigation by private parties.²⁸ But despite this position, and although HHS arguably has greater institutional competence than the judiciary to assess the adequacy of health service accessibility, California disregarded the requisite federal approval process in implementing its rate cuts, a fact attracting the criticism of Justice Kagan during oral arguments before the Supreme Court. Specifically, she (somewhat rhetorically) asked the Attorney General of California whether the state "end-ran the administrative process" by implementing the regulations and new rates "before [it] submitted them to HHS, and continued them in effect while HHS was considering them, and [then] continued them in effect to the extent that [it was] allowed to do so by the injunction, even after HHS disapproved them."²⁹

In this case, California was clearly far more responsive to judicial sanctions than to the threat of federal enforcement. It is uncertain whether there would have been any meaningful HHS review of California's rate cuts in the absence of an available legal mechanism for beneficiaries to compel such a review, particularly given the federal government's history of lax enforcement against state governments. Instead, HHS has preferred to concentrate its enforcement efforts on the compliance of providers with fraud and abuse laws.³⁰ Furthermore, even if the federal government had taken enforcement action against California by withholding funds for the state's failure to comply with Medicaid's legislative requirements, this blunt remedy could have further impeded beneficiary access to health services by shrinking an already strained state Medicaid budget. During oral arguments in *Douglas*, Justice

²⁸ *Douglas* Brief, *supra* note 11 at 16.

²⁹ *Douglas v Independent Living Center* (3 Oct 2011), Washington 09-958 (USSC), online: USSC <www.supremecourt.gov/oral_arguments/argument_transcripts/09-958.pdf> at 6 [*Douglas* Oral Argument Transcript].

³⁰ Abigail R Moncreiff, "The Supreme Court's Assault on Litigation: Why (and How) It Might Be Good for Health Law" (2010) 90 BUL Rev 2323 at 2341.

Ginsburg referred to this as a “very drastic remedy ... [that would] hurt the people that Medicaid was meant to benefit.”³¹

Until recently, HHS had failed to provide standards or methods for measuring equal access. Nor had it implemented clear state reporting requirements, set out a plan to improve accessibility, or amassed evidence respecting the effect of state policies on beneficiary access to health services.³² Federal enforcement of the equal access provision would have been difficult, given the unclear definition of equal access and the absence of methods for measuring access to health services. Although HHS has recently drafted a rule addressing accessibility, Rosenbaum characterizes it as “a model of inaction” that is primarily “an information-gathering exercise.”³³ State governments must now submit one year of access data if provider rate cuts “could result in access issues,” but a state could unilaterally determine its rate reductions would not raise access issues and therefore not submit this data to HHS.³⁴ This could actually result in less federal scrutiny than the previous status quo, as the federal government may now only examine the rate cuts state governments bring to its attention.

Like its American counterpart, Health Canada can withhold funding for non-compliance with the *Canada Health Act*. It too has been criticized for its

³¹ Douglas Oral Argument Transcript, *supra* note 29 at 5. Although beyond the scope of this paper, a case heard by the US Supreme Court on 8 January 2013 may address the ability of the federal government to enforce conditions on states in the context of spending legislation. In *Delia v EMA*, 133 S Ct 99, 184 L Ed 2d 646, a case challenging North Carolina’s lien on tort recoveries for the purposes of recovering Medicaid expenditures, Texas and 10 other states filed an amicus brief arguing that even if state law is inconsistent with the federal legislation governing Medicaid, *supra* note 4, the law is not pre-empted. Although the *Act* gives the Secretary of Health and Human Services discretion to withhold only a portion of federal reimbursement from a non-compliant state, Texas argued that a state may, without violating any federal law, merely accept the reduced funding while continuing to participate in the Medicaid program. *Delia v EMA*, Brief for Texas, Alabama, Georgia, Hawaii, Idaho, Indiana, Michigan, Nebraska, New Mexico, Ohio and South Carolina in Support of Petitioner, online: American Bar Association <www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs/12-98_pet_amcu_texas-alabama-et-al.authcheckdam.pdf>.

³² Sara Rosenbaum, “Medicaid and Access to Health Care – A Proposal for Continued Inaction?” (2011) 365 New Eng J Med 102 at 103.

³³ *Ibid.*

³⁴ *Ibid.*

similarly permissive approach to provincial breaches of the *Act* and its lack of meaningful guidance with regard to federal funding conditions. For example, Choudhry characterizes “the federal government’s non-enforcement of the *CHA* ... [and] the failure of political actors and the academic community to highlight the federal government’s abdication of its responsibilities ... [as] a national embarrassment.”³⁵ However, unlike in the US system, where there may be more opportunity for the federal government to act as an accountability mechanism to review state health policies, the Canadian federal government’s cash contribution to provincial health budgets may be insufficient to incentivize compliance with conditions of the *Act*, even if Health Canada were to amplify its enforcement efforts. While Medicare was initially predicated on a federal/provincial cost-sharing arrangement, the federal government subsequently shifted to a combination of smaller transfer payments and tax points.³⁶ This leaves provinces to make up the budgetary shortfall in an extremely expensive program that is so popular among the public that it would likely be politically infeasible to limit or abandon it. As Roy Romanow, the former premier of Saskatchewan and head of a major federal commission on Medicare argues, “the relative size of the federal transfer compared to the provincial cost of delivering health services has become a dominant and disruptive theme of contemporary intergovernmental relations in Canada.”³⁷

Although both the Canadian and American federal governments do little to enhance the accountability of provinces or states for their health programs, beneficiaries themselves may exert political pressure to catalyze health policy change. However, Medicaid’s low reimbursement rates and other access

³⁵ Sujit Choudhry, “Bill 11, the Canada Health Act and the Social Union: The Need for Institutions” (2000) 38 Osgoode Hall LJ 39 at 57.

³⁶ For a discussion of the federal government’s shifting financial commitment to Medicare, see Steven Lewis et al, “The Future of Health Care in Canada” (2001) 323 Brit Med J 926 at 926. The authors note that by 1995, through some negotiated and some unilateral changes, the federal government’s 50% contribution was reduced to 16% (according to the provinces) or 32% including tax points (according to the federal government). The transfer payment portion of the federal contribution was grouped together with other social programs (post-secondary education and welfare) in the Canadian Health and Social Transfer, but these programs have since been disaggregated into the Canada Health Transfer and the Canada Social Transfer.

³⁷ Commission on the Future of Health Care in Canada, *Building on Values: The Future of Healthcare in Canada – Final Report*, by Roy J Romanow (Ottawa: CFHCC, 2002) at 5.

barriers suggest vulnerable beneficiaries lack the political power to motivate state governments to maintain robust Medicaid programs. For example, American physicians argue that they are deterred from accepting Medicaid patients by the fact that both Medicare and private insurance reimbursement rates are higher,³⁸ and providers frequently report losing money when treating Medicaid recipients.³⁹ In one widely-reported case that attracted the media's attention, a twelve-year-old Medicaid beneficiary who was unable to access dental care died of brain sepsis after infection spread from an abscessed tooth. Although the tooth extraction would have cost only US\$80, the efforts to treat his infection (including two surgeries and over six weeks of hospitalization) were estimated at over US\$250,000. At the time, only 900 of the state's 5,500 dentists accepted Medicaid patients, and it took months, and dozens of phone calls, to find a dentist who would accept a Medicaid patient.⁴⁰ Financial deterrents to treating Medicaid beneficiaries are extremely concerning, as they may exacerbate existing health disparities linked to income. California's across-the-board budgetary cuts were particularly problematic, as they affected all health services equally, with no regard to the cost or efficacy of particular services, nor to especially acute access concerns for certain types of services or within certain segments of the population.

Although Canadian courts have not permitted individuals to privately enforce the provisions of the *Canada Health Act* against the provinces, this may present less of an accountability concern in the Canadian context, due to the comparative potential for beneficiaries to exert political pressure. In contrast to the US, the universal nature of Canada's health care system means that those with low incomes are not relegated to a separate health insurance plan that politicians consequently have little incentive to adequately resource.⁴¹ It remains to be seen whether expanding Medicaid to cover an addi-

³⁸ Stephen Zuckerman, Aimee F Williams & Karen E Stockley, "Trends in Medicaid Physician Fees, 2003–2008" (2009) 28:3 Health Affairs 510. See also Sandra L Decker, "In 2011 Nearly One-Third of Physicians Said They Would Not Accept New Medicaid Patients, But Rising Fees May Help" (2012) 31:8 Health Affairs 1673.

³⁹ Mark A Rothstein, "Who Will Treat Medicaid and Uninsured Patients? Retired Providers Can Help" (2011) 39:1 JL Med & Ethics 91 at 92.

⁴⁰ Mary Otto, "For Want of a Dentist", *The Washington Post* (28 February 2007), online: Washington Post – The Breaking News Blog <www.washingtonpost.com/wp-dyn/content/article/2007/02/27/AR2007022702116.html>.

⁴¹ Aboriginal health is a notable exception. Due to shared provincial/federal jurisdiction, aboriginal people, in some ways, are relegated to their own health program and have thus far lacked the political capital to compel governments to

tional 25 million individuals⁴² will improve the political clout of beneficiaries, thereby narrowing the gap between their access to health services and that of privately insured individuals and US Medicare recipients. If the expansion does indeed enhance the political power of beneficiaries, this may provide support for Canadian critics of increased privatization who have suggested that a two-tier health care system could erode popular support for a robust public health care system.⁴³

In addition to the deficient federal enforcement efforts and limited political accountability afflicting Medicaid, there are few legal mechanisms available for reviewing policies affecting the accessibility of health services. Although beneficiaries may have recourse to judicial review when HHS approves or denies a state's proposed Medicaid plan amendments, *Douglas* illustrates that states may fail to submit amendments for approval altogether or disregard the federal government's disapproval of proposed amendments. By contrast, although Canadian litigants have been unable to invoke the provisions of the *Canada Health Act* to challenge provincial health policies, they have successfully advanced grievances relating to health service accessibility through other legal arguments. For example, claimants have alleged that the government's failure to fund particular health services constituted discrimination in contravention of section 15 of the *Charter*⁴⁴ and provincial human rights legislation.⁴⁵ Plaintiffs have also invoked section 7 of the *Charter*, arguing that government restrictions on the availability of private insurance, coupled with long wait times, violate the right to life, liberty, and security of the person.⁴⁶ Other individuals have brought claims alleging that long wait

provide adequate health services. For a summary of the laws and policies affecting aboriginal health in Canada, see Constance MacIntosh, "Indigenous Peoples and Health Law and Policy: Responsibilities and Obligations" in Jocelyn Downie, Timothy Caulfield & Colleen M Flood, eds, *Canadian Health Law and Policy*, 4th ed (Markham, Ont: LexisNexis, 2011) 575.

⁴² *Supra* notes 20 and 21.

⁴³ See e.g. Carolyn Tuohy, Mark Stabile & Colleen M Flood, "How Does Private Finance Affect Public Health Care Systems? Marshaling the Evidence from OECD Countries" (2004) 29:3 J Health Pol 359 at 387-90.

⁴⁴ See e.g. *Eldridge v British Columbia (AG)*, [1997] 3 SCR 624, 151 DLR (4th) 577 [Eldridge]. But see *Auton (Guardian ad litem of) v British Columbia (AG)*, 2004 SCC 78, [2004] 3 SCR 657.

⁴⁵ See e.g. *Hogan v Ontario (Minister of Health and Long-Term Care)*, 2006 HRTO 32, [2006] OHRTD no 34 (QL). But see *Armstrong v British Columbia (Ministry of Health)*, 2010 BCCA 56, 2 BCLR (5th) 290.

⁴⁶ *Chaoulli v Quebec (AG)*, 2005 SCC 35, [2005] 1 SCR 791 [Chaoulli].

times in the public system compelled them to obtain health services outside of Canada, for which they are entitled to reimbursement.⁴⁷ Plaintiffs have also framed claims in tort law, alleging that governmental negligence led to unreasonably long waits for health care services.⁴⁸

B. Balancing Accountability Against Concern for Institutional Competence

Although courts serve the important functions of protecting vulnerable beneficiaries and acting as a mechanism to enhance governmental accountability, these considerations must be balanced against the countervailing concern regarding the judiciary's competence to adjudicate complex matters of social policy. An intricate web of variables influences health sector decision making, including the availability of resources (temporal, monetary, and human), public and media pressure, provider and interest group advocacy, bureaucratic self-interest, political factors (for example, the timing of the next election), and technical and often contradictory scientific and policy evidence. As Cohen and Smith argue, "the state is likely to be involved in polycentric disputes in which the determination of any particular factor or issue involves the simultaneous adjustment of numerous other factors and issues, and affects the interests of numerous individual and collective interests."⁴⁹

⁴⁷ See e.g. *Stein c Tribunal administratif du Québec*, [1999] RJQ 2416 (Qc Sup Ct (Civ Div)). But see *Flora v Ontario (Health Insurance Plan, General Manager)*, 2008 ONCA 538, 91 OR (3d) 412.

⁴⁸ See e.g. *Cilinger c Québec (PG)*, [2004] RJQ 2943, 135 ACWS (3d) 775 (Qc CA), leave to appeal to SCC refused, 30703 (December 31, 2004) and *Mitchell (Litigation Administrator of) v Ontario* (2004), 71 OR (3d) 571, 242 DLR (4th) 560 (Ont Sup Ct). Although most of these claims have failed to survive a motion to strike or class certification motion, see *Heaslip Estate v Mansfield Ski Club Inc*, 2009 ONCA 594, 96 OR (3d) 401, in which a boy died waiting for an emergency transfer to a hospital after air ambulance operators failed to follow a policy addressing the prioritization of urgent cases. The Ontario Court of Appeal refused to strike this claim on the basis that the government did not owe a duty of care. I discuss these tort cases in greater detail in Lorian Hardcastle, "Government Tort Liability for Negligence in the Health Sector: A Critique of the Canadian Jurisprudence" (2012) 37:2 Queen's LJ 525. Specifically, I argue that the Canadian judiciary's restrictive approach to health sector tort claims may present its own accountability concerns, as only particular types of claims are captured by the *Charter* or administrative law.

⁴⁹ David Cohen & JC Smith, "Entitlement and the Body Politic: Rethinking Negligence in Public Law" (1986) 64:1 Can Bar Rev 1 at 8.

Judges must account for the complexity of the health system by according government policy choices an appropriate degree of deference.

In the pre-*Gonzaga* § 1983 Medicaid jurisprudence, state courts diverged on whether to adopt what I characterize as a substantive or a procedural approach to adjudicating breaches of the equal access provision. Those that adopted a substantive approach focused primarily on the rates of provider participation in Medicaid and beneficiary health service utilization as indicia of accessibility.⁵⁰ However, these numbers are contingent upon a host of factors independent of reimbursement rates. For example, low-income Medicaid recipients may have difficulty accessing transportation or childcare in order to attend health care appointments, there may be physician shortages in low-income communities, educational or cultural barriers may deter particular groups from seeking health care services, and providers may be reluctant to accept Medicaid patients due to higher rates of co-morbidities and lower patient compliance (stemming from reasons such as an inability to fill prescriptions or attend follow-up appointments). Even in universal health care systems such as Canada's, there is evidence to suggest that after adjustment for disease prevalence, lower income may be associated with reduced health service utilization.⁵¹ It is crucial that policy-makers conduct research to determine the causes and effects of inequitable access to health services and craft solutions to mitigate this disparity. However, it is problematic for courts to take on this role themselves by making legal determinations hinging on the complex array of variables affecting service utilization.

In contrast to this substantive approach, courts adopting a procedural approach to equal access before *Gonzaga* inquired whether a state considered the requisite factors set out in Medicaid legislation (efficiency, economy, and equality of care) and whether the government conducted research to estimate the effect of proposed rate cuts on beneficiaries' access to services. In other words, judges examined the process the state undertook in setting provider reimbursement rates and the factors it weighed in making this decision. In *Douglas*, the California courts favoured this procedural approach, focusing their criticisms on the state's failure to conduct cost studies to analyse the anticipated effects of the rate cuts. Judicial scrutiny of the state's rate-setting process arguably falls more squarely within the institutional competence of

⁵⁰ Sean Jessee, "Fulfilling the Promise of the Medicaid Act: Why the Equal Access Clause Creates Privately Enforceable Rights" (2009) 58:3 Emory LJ 791.

⁵¹ Mark Lemstra et al, "High Health Care Utilization and Costs Associated with Lower Socio-Economic Health Status: Results from a Linked Dataset" (2009) 100:3 Can J Public Health 180.

the courts than does a judicial attempt to analyse health service utilization and provider reimbursement data.

Canadian courts have similarly struggled with the appropriate degree of deference to accord governmental policy decisions. For example, in *Chaouli*, a challenge to limits on the availability of private health insurance, a majority of the Supreme Court of Canada stated that “[t]he fact that the matter is complex, contentious or laden with social values does not mean that the courts can abdicate the responsibility vested in them by our Constitution.”⁵² In contrast, the dissenting justices questioned the ability of the courts to define “the scope and nature of ‘reasonable’ health services,” concluding that “[t]he public cannot know, nor can judges or governments know, how much health care is ‘reasonable’ enough to satisfy [the *Charter*.] ... It is to be hoped that we will know it when we see it.”⁵³

As with their American counterparts, Canadian judges have sometimes focused primarily on the procedure employed by policy-makers, granting greater deference when the decision making process was fair and deliberate and the government weighed the appropriate considerations. For example, in *Eldridge*, a challenge to British Columbia’s refusal to fund sign language interpretation services for individuals receiving insured health services, the Supreme Court of Canada was critical of the Ministry of Health’s ad hoc decision making process. Specifically, the Court noted that the initial request to fund interpreter services “was declined out of hand”⁵⁴ and that the \$150,000 program was characterized as a “strain” on available resources, even though it would consume only 0.0025% of the provincial health care budget.⁵⁵ By contrast, in *Armstrong v British Columbia (Ministry of Health)*, the BC Human Rights Tribunal accepted the government’s refusal to fund prostate cancer screening services. In that decision, which was affirmed by the Court of Appeal, the plaintiff alleged that the government’s failure to these services constituted discrimination because it insured screening for cancers affecting the female reproductive system. In concluding that the complaint was not justified, the Tribunal cited the extensive scientific evidence and expert tes-

⁵² *Supra* note 46 at para 107.

⁵³ *Ibid* at para 163.

⁵⁴ *Supra* note 44 at para 4.

⁵⁵ *Ibid* at para 87.

timony respecting the efficacy and cost of a screening program the government relied on in making its decision.⁵⁶

Conclusion

In light of mounting cost pressures, policy-makers will increasingly be called upon to make difficult choices between competing demands in order to ensure health system sustainability. Although courts should not act as a barrier to necessary cost-containment measures, judicial scrutiny of government policies is a critical component of health sector accountability, particularly for programs like Canadian Medicare and US Medicaid, in which beneficiaries have little alternative but to rely on the government. In the US, *Douglas* has left open the question of whether Medicaid recipients and providers have a private right of action to challenge state budget cuts, the ultimate resolution of which may have profound implications for beneficiaries, who lack the ability to exert political pressure and have limited other recourse against budget cuts, particularly given the climate of lax federal enforcement.

The evolving American jurisprudence in this area will prove interesting for a Canadian audience. Of particular importance will be the judicial approach to reviewing governmental health policy choices, specifically whether courts adopt a substantive approach to equal access or instead focus on ensuring that states employ a fair, deliberate, and evidence-based decision making process. If judicial scrutiny leads to improved state government decision making, this jurisprudence may legitimize the role of courts in facilitating health sector accountability. This may, in turn, motivate Canadian courts to amplify their own scrutiny of government decisions. In addition, if the US jurisprudence prompts increased federal enforcement or oversight of Medicaid, Health Canada may be similarly motivated to take a more active role in setting standards to meet the conditions of the *Canada Health Act* or, perhaps, to enforce the numerous ongoing breaches of the *Act*.⁵⁷

⁵⁶ 2008 BCHRT 19 (available on CanLII), 62 CHRR D/1, aff'd *supra* note 45.

⁵⁷ For a discussion of the numerous unenforced breaches of the *Canada Health Act*, see Choudhry, *supra* note 35.

DATA SHARING, BIOBANKS AND INFORMED CONSENT: A RESEARCH PARADOX?

*Clarissa Allen, Yann Joly & Palmira Granados Moreno**

Population biobanks are research facilities that store human biological material and health data of thousands of participants to facilitate research in the field of personalized medicine. To achieve this goal, biobanks usually collect samples and data from research participants through the process of broad consent. This type of research consent request permission to use data and biological samples collected from a wide range of research projects that are not specifically identified in the consent form (e.g. for genetic research). This article aims to determine if the trend supported by research funding agencies, to require broad consent from biobank participants, meets current Canadian legal and ethical standards. Based on our research, it appears of paramount importance that the requirements of funding agencies could be better harmonized with the current legal and ethical framework. The lack of synchronization identified could have negative impacts on research and the realization of legal objectives. Ideally, rules governing consent in this area of research will have

Les biobanques populationnelles sont des infrastructures de recherche qui conservent le matériel biologique humain et les données de santé de milliers de participants pour faciliter la conduite de la recherche dans le domaine de la médecine personnalisée. Pour atteindre leurs objectifs ces biobanques recueillent généralement des échantillons et des données sur les participants à la recherche par l'entremise d'un processus de consentement large. Ce type de consentement à la recherche requiert la permission d'utiliser les données et le matériel collectés dans un large ensemble de projets de recherche qui ne sont pas identifiés de façon spécifique dans le formulaire de consentement (ex. pour la recherche en génétique). Cet article a pour objectif d'identifier si la tendance soutenue par les organismes subventionnaires de la recherche à requérir un consentement large des participants aux projets de biobanques répond aux normes juridiques et éthiques en vigueur au Canada. À la lumière de nos recherches, il apparaît de toute première importance que les exigences des organis-

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to evolve in order to better respond to the objectives and challenges of contemporary biomedical research. Meanwhile, funding agencies involved in biobank research should make a greater effort to reconcile their scientific requirements with current ethics and legal rules.

mes subventionnaires soient mieux harmonisées avec le cadre juridique et éthique en vigueur. Le manque de synchronisation identifié pourrait nuire à la recherche et à l'atteinte d'objectifs légaux. Idéalement, les règles régissant le consentement dans ce domaine de recherche devront évoluer pour mieux répondre aux objectifs et enjeux de la recherche biomédicale contemporaine. En attendant, les organismes subventionnaires impliqués dans la recherche avec les biobanques devront faire un plus grand effort pour concilier leurs exigences scientifiques avec les règles de droit et d'éthique présentement en vigueur.

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Introduction

Large-scale population biobanks, which store human biological material and link health data to environmental and demographic information for use in biomedical research, are emerging as a promising research tool in many countries around the world.¹ These biobanks promise to be of significant benefit to the development of personalized medicine, since genomic and phenotypic variation across populations must first be catalogued before the features of a given disease can be recognized in individuals.² The vast amounts of data currently being collected and generated by population biobank projects are enabling researchers to elucidate the relationships between environment, socioeconomic status, diet, education, access to healthcare, gender, ethnicity, genetics, and health that in many instances contribute to disease. With sufficient biospecimens and effective governance structures, these biobanks have the potential to serve as valuable resources facilitating research on health and disease for decades to come.³

Governments, funding bodies, and scientists have suggested that the more researchers have access to biobank data and materials, the more quickly the biomedical advances promised by biobanks can be achieved.⁴ Accordingly, researchers often ask research participants contributing biological material and data to biobanks to provide broad consent to research. Subject to ongoing ethics review, broad consent grants the original researchers and sometimes future researchers as well permission to use individuals' materials and data in a wide range of future research projects that are unknown at the time of subject recruitment. While this practice maximizes the value of biobanks by making them accessible to a greater number of researchers for a greater number of projects, opponents of broad consent argue that it does not adequately inform subjects of the specific nature, risks, and benefits of the

¹ See Timothy Caulfield & Bartha Maria Knoppers, "Consent, Privacy & Research Biobanks", Genome Canada GPS Policy Brief No 1 (26 January 2010), online: GC <www.genomecanada.ca/medias/pdf/en/GPS-Policy-Directions-Brief.pdf> at 1; Christopher Heaney et al, "The Perils of Taking Property Too Far" (2009) 1 *Stanf Journal of Law, Science & Policy* 46 at 47.

² See Krishanu Saha & J Benjamin Hurlbut, "Treat Donors as Partners in Biobank Research" (2011) 478 *Nature* 312 at 312.

³ *Ibid.*

⁴ See e.g. Wellcome Trust, "Sharing Research Data to Improve Public Health: Full Joint Statement by Funders of Health Research", online: WT <www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Public-health-and-epidemiology/WTDV030690.htm>.

future research to which they are being asked to consent. Thus, according to these opponents, this type of broad consent meets neither the ethical nor legal requirements put forward to promote the respect of participants' autonomy.⁵ The issue of whether broad consent is an ethically valid consent model to use in the context of biobank research has been widely debated in the academic literature in recent years, but no consensus has been reached.⁶ Nor has there been a comprehensive review of relevant Canadian law to ascertain whether broad consent practices fulfill current legal requirements. Despite these issues, most active population biobanks in Canada seem to be acting on the presumption that broad consent is both a legally and ethically valid practice.⁷

In this paper, we seek to elucidate the legal and policy dimensions of consent in Canadian biobank research. By analyzing relevant legislation, jurisprudence, ethical guidelines, funding policies, and informed-consent documents from ongoing, large-scale Canadian population biobank projects, we determine that Canadian biobank researchers face a complex and often conflicting array of legal, ethical, and financial obligations. In particular, funding organizations that indirectly pressure biomedical researchers to adopt broad consent models through their "open-science" policies make it difficult for researchers to meet current legal and ethical requirements applicable to informed consent. Indeed, as we describe below, funders offer no practical advice on how to reconcile their data sharing and "open-science" policies with their informed consent requirements.

We will explore the issues raised by consent in Canadian large-scale population biobanks by first discussing the growing importance of data sharing in contemporary health research. In the context of biobanking, open data sharing is facilitated by obtaining broad consent from research participants who donate samples, so our discussion will segue into the notion of broad consent and how it differs from the traditional informed-consent model. Following this introduction to the benefits of data sharing and the debate around the ethical and legal status of broad consent, we will present the methodology and results of our review of relevant Canadian legislation and jurisprudence, research ethics guidelines, funding policies, and biobank consent

⁵ See Christian M Simon et al, "Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models" (2011) 13:9 *Genet Med* 821 at 822.

⁶ For a review of the literature on this topic, see Zubin Master et al, "Biobanks, Consent and Claims of Consensus" (2012) 9 *Nat Methods* 885.

⁷ Refer to the section entitled "Consent Forms" for the evidence we have collected supporting this claim.

forms. In our discussion, we conclude that there is a tension between the current practice of large-scale population biobanks asking participants for broad consent (as required by funding policies) and the legal and ethical requirements of a more traditional informed consent. Though this tension can be lessened by mechanisms such as public engagement and more sophisticated biobank governance models, it will become apparent from our review that clarification of the legal and ethical thresholds for obtaining truly informed consent in the context of large-scale population biobanks, and in biomedical research in general, is needed.

I. Data Sharing

In recent years, the importance of data sharing to the advancement of health research has become increasingly well recognized. Since the late 1990s, several national and international statements have been made on behalf of a variety of stakeholders, including government representatives,⁸ scientists⁹, journal editors,¹⁰ and research funders,¹¹ emphasizing a commitment to the rapid and open sharing of data in order to help maximize the public benefit to be gained from biomedical research. Though early statements focused on the pre-publication release of genomic data sets, stakeholders have since expanded their outlook to recommend that proteomic, metabolomic, chemical structure, and RNA interference data sets, as well as annotated clinical resources such as birth cohorts and tissue banks, be rapidly and openly shared in publicly accessible databases.¹² The recommendations made in these statements have subsequently been imposed on researchers by major health-research funding bodies, both public and private, including the Bill and Melinda Gates Foundation, Wellcome Trust, National Institute of

⁸ The White House, Office of the Press Secretary, Press Release, "Joint Statement by President Clinton and Prime Minister Tony Blair of the UK" (14 March 2000), online: National Archives <clinton4.nara.gov/WH/EOP/OSTP/html/00314.html>.

⁹ Toronto International Data Release Workshop Authors, "Prepublication Data Sharing" (2009) 461 *Nature* 168.

¹⁰ BioMed Central, "BioMed Central's Position Statement on Open Data (Draft)" (8 September 2010), online: BioMed Central <blogs.biomedcentral.com/bmc_blog/files/2010/09/opendatastatementdraft.pdf>.

¹¹ Wellcome Trust, *supra* note 4.

¹² See e.g. Henry Rodriguez et al, "Recommendations from the 2008 International Summit on Proteomics Data Release and Sharing Policy: The Amsterdam Principles" (2009) 8:7 *J Proteome Res* 3689 at 3690.

Health, Canadian Institute of Health Research, UK Medical Research Council, and many others.¹³

The benefits of rapid, open data sharing in health research have been most clearly illustrated by the Human Genome Project. During the development of the entire draft human genome sequence, the data was shared on an ongoing basis, such that each sequence of 1000 base pairs was generally made public within 24 hours of being read. As a result of this rapid sharing, new information on 30 disease genes was published before the genome draft was even complete, representing many new insights and discoveries that were made much earlier than would otherwise have been achieved.¹⁴

In addition to the evident advantage of making fundamental research data and tools quickly available for general use, data-sharing models have been associated with a number of scientific, economic, and social benefits. With regard to science, open data sharing by its nature involves a significant degree of transparency. Consequently, it allows peer evaluation and validation of findings, thereby encouraging open, critical discussion of results and increasing the quality of scientific work overall.¹⁵ In economic terms, open sharing of data reduces duplication, allowing researchers to share the financial burden of generating fundamental data and tools. Additionally, the standardization of sharing agreements arising from uniform data release policies reduces the need for costly and time-consuming case-by-case data-sharing negotiations.¹⁶ Finally, open data sharing represents significant social benefits. Firstly, the transparency engendered by open access promotes public trust. This is particularly essential to projects such as biobanks, which rely on the altruistic participation of many thousands of individuals.¹⁷ Secondly, it respects the normative claim that “research with human materials is valuable to all, ... [and consequently] requires unhindered distribution of research materials to all qualified investigators... and the dissemination of its benefits to

¹³ See Jane Kaye et al, “Data Sharing in Genomics – Re-shaping Scientific Practice” (2009) 10 Nat Rev Genet 331 at 332; Wellcome Trust, “Signatories to the Joint Statement”, online: WT <www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Public-health-and-epidemiology/Signatories-to-the-joint-statement/index.htm>.

¹⁴ Toronto International Data Release Workshop Authors, *supra* note 9 at 168.

¹⁵ Yann Joly, “Open Source Approaches in Biotechnology: Utopia Revisited” (2007) 59:2 Me L Rev 385 at 398.

¹⁶ *Ibid* at 400-02.

¹⁷ See Heaney et al, *supra* note 1 at 47.

humanity at large on just and reasonable terms.”¹⁸ The benefits of rapid, open data sharing are therefore substantial and may be key to ensuring the realization of the full clinical potential of the genomic revolution.

Data sharing can, however, create tensions for researchers, especially when it is required by funding organizations. Data sharing as an alternative to ownership and commercialization of research tools and genetic materials has received considerable attention in recent years.¹⁹ Researchers need to be concerned with the ethical requirements imposed by various regulatory bodies. The fundamental normative obligation of respecting subject autonomy, as traditionally defined, is a particularly challenging issue in the context of data sharing.²⁰ Sharing data openly means that researchers cannot be aware, at the time they recruit subjects for research, of the full extent of future uses of the data those subjects provide, or of the psychosocial risks involved. This is particularly true in the context of biobanking, in which data and tissue samples are collected for the purpose of creating an accessible resource that any researcher may access. Given this indeterminacy, some argue that data sharing inhibits researchers from fully respecting subject autonomy, as it prevents the consent process – the primary locus of subject self-governance in the context of health research – from being sufficiently informed.²¹ Thus, while broad consent supports a central purpose of biobanking insofar as it optimally allows for the open sharing of subject data and materials between researchers, there is a question as to whether it truly satisfies the current legal and ethical norms regarding consent. This is the issue with which we are primarily concerned.

¹⁸ Patrick L Taylor, “Research Sharing, Ethics and Public Benefit” (2007) 25:4 Nat Biotechnol 398 at 398, citing International Society for Stem Cell Research, *Guidelines for the Conduct of Human Embryonic Stem Cell Research*, version 1 (21 December 2006), online: ISSCR <www.isscr.org/docs/default-source/hesc-guidelines/isscrhescguidelines2006.pdf>.

¹⁹ Jeremy de Beer, Richard Gold & Mauricio Guaranga, “Intellectual Property Management: Policy Issues and Options”, Genome Canada GPS Policy Brief No 4 (August 2011), online: GC <www.genomecanada.ca/medias/pdf/en/Research_Policy-Directions-Brief.pdf> at 5-6.

²⁰ Timothy Caulfield, “Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales” (2007) 18 King’s Law Journal 209 at 212-15.

²¹ *Ibid.*

II. Consent

(For a description of different models of consent, see Table 1.)

In the context of biobanking, open data sharing is facilitated by broad consent. Broad consent describes a process in which subjects are asked to provide researchers with permission to use their data and biological samples for a wide range of research activities, such as genetic research. Though the terms are not uniformly defined in the literature, broad consent may be said to differ from blanket consent (also known as “open consent”) in that there remains some minimal delimitation of what data and samples may be used for; for example, the consent may be limited to medical research on a particular condition such as cancer, or research on a particular population, such as children. Subjects are also often made aware that the specific future use(s) to which data and samples will be put must be approved by a designated oversight body or ethics committee, and must conform to the general principles governing the biobanking endeavor.²² Under broad consent, biobankers are therefore free to maximize the utility of data and samples and can make them available to a variety of researchers, as long as the general aims and governing structure of the biobank, as described to subjects, are respected.

Broad consent appears to deviate from the hallmarks of informed consent as enshrined in case law, legislation, and research ethics.²³ Traditionally, respecting subject autonomy through consent is thought to require that decisions regarding whether or not to participate in research be informed by the relevant details of the specific research project, such as the identity of the researcher(s), the project objectives, the potential risks and benefits, the anticipated outcomes, and so on.²⁴ The concern with this traditional model, as alluded to above, is that it places significant limits on the realization of the benefits of data sharing that can otherwise be effectively achieved through biobanking. If biobanks are to serve as research platforms to be used over several decades for a variety of initiatives that are not fully known at the time of data and material collection, it is extremely difficult and impractical to provide subjects upon their enrolment with all the details needed to satisfy traditional consent norms. Recontacting subjects to provide information on each proposed study has been suggested as a way of respecting subjects’ autonomy, but would likely be too expensive and time-consuming to provide a feasible solution to this chal-

²² Simon et al, *supra* note 5 at 822.

²³ Master et al, *supra* note 6 at 886.

²⁴ Mark Sheehan, “Can Broad Consent Be Informed Consent?” (2011) 4:3 Public Health Ethics 226 at 226.

lenge.²⁵ As an intermediate solution, several population biobanks have adopted ongoing consent mechanisms (e.x. CARTaGÈNE) that allow biobanks to re-contact the participants thus keeping the initial consent alive. These mechanisms can be used to ask new data/samples from the participants and to provide important updates regarding the biobank (thus making the participant's decision process more informed). The tension that exists between the significant scientific and social benefits to be gained from open data sharing, facilitated by broad consent, on one hand, and the requirements imposed by traditional informed consent, on the other, has engendered a growing body of academic literature arguing that the traditional informed-consent model is too restrictive and burdensome in the context of biobank research, and should therefore be amended.²⁶ However, even in the case of large-scale population biobanking, this proposal has not met with unanimous approval either in public opinion or among scholars.²⁷

A recent literature review by Master et al (2012)²⁸ found that while there are many academic articles that favour a broad consent approach,²⁹ there is no consensus on the topic outside of the population biobank community. Those in favour of broad consent tend to argue that the great social utility and scientific value of biobanking and the absence of physical risks justify the alteration of consent norms they perceive as socially and technologically outdated. Seeking reconsent for each research project has been described as "extremely arduous or impossible,"³⁰ while the risks to donor subjects are ar-

²⁵ Carlo Petrini, "'Broad Consent', Exceptions to Consent and the Question of Using Biological Samples for Research Purposes Different from the Initial Collection Purpose" (2010) 70:2 Soc Sci Med 217 at 217.

²⁶ Caulfield, *supra* note 20 at 213.

²⁷ Master et al, *supra* note 6 at 885, 887.

²⁸ *Ibid* at 887-88. It is important to note that a limitation of the study by Master et al is that they do not distinguish between different types of research in which broad consent is considered by the authors they cite. Nevertheless, their study provides a fairly comprehensive review of the debate around broad consent, which itself is not a uniformly used term. See also Bartha Maria Knoppers, Ma'n Zawati & Emily Kirby, "Sampling Populations of Humans Across the World: ELSI Issues" (2012) 13 Annu Rev Genomics Hum Genet 395.

²⁹ See e.g. Mats G Hansson, "Ethics and Biobanks" (2009) 100:1 Br J Cancer 8; Bartha M Knoppers & Rosario Isasi, "Stem Cell Banking: Between Traceability and Identifiability" (2010) 2:73 Genome Med 1; Mats G Hansson et al, "Should Donors Be Allowed to Give Broad Consent to Future Biobank Research?" (2006) 7:3 Lancet Oncol 266.

³⁰ Petrini, *supra* note 25 at 217

guably extremely small. In light of the analysis of benefits compared to burdens it would appear that broad consent might be justified. As long as privacy is protected and ethical oversight is in place, proponents argue that subjects should be allowed to consent to permitting biobanks to make future decisions for them regarding the data and samples they donate.³¹

On the other hand, those who argue against broad consent question whether consent that is not adequately informed can really be autonomous, and therefore legally and ethically acceptable.³² Since, according to critics, consent by its nature presupposes the communication of complete and precise information, broad consent is said to undermine the meaning of this practice.³³ Allowing scientific goals to take precedence over individual rights is contrary to traditional bioethics norms, which developed in a context of human-subject research abuses.³⁴ These same opponents argue that even if public opinion data, which itself reflects a variety of preferences,³⁵ were to suggest a general acceptance of, or preference for, broad consent, this would not in itself justify overturning fundamental normative principles requiring that the interests of research subjects prevail over the interests of science and

³¹ Sheehan, *supra* note 24 at 231.

³² See e.g. Timothy Caulfield, Ross EG Upshur & Abdallah Daar, "DNA Databanks and Consent: A Suggested Policy Option Involving an Authorization Model" (2003) 4:1 BMC Med Ethics E1; Vilhjálmur Árnason, "Coding and Consent: Moral Challenges of the Database Project in Iceland" (2004) 18:1 Bioethics 27; B Hofmann, "Broadening Consent – and Diluting Ethics?" (2009) 35 J Med Ethics 125; David Hunter, "Letter: One-time General Consent for Research on Biological Samples: Autonomy and Majority Rules Have Been Misunderstood" (2006) 332 Brit Med J 665.

³³ Petrini, *supra* note 25 at 218.

³⁴ Caulfield, *supra* note 20 at 216.

³⁵ See e.g. David Wendler, "One-time Consent for Research on Biological Samples" (2006) 332 Brit Med J 544 at 546 (in favour of broad consent); Geraldine M McQuillan et al, "Consent for Genetic Research in a General Population: The NHANES Experience" (2003) 5 Genetics in Medicine 35 at 40 (in favour of specific consent); Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Mapping the Future* (30 November 2001), online: Ontario, Ministry of Health <www.health.gov.on.ca/en/common/ministry/publications/reports/geneticsrep01/genetic_report.pdf> (in a 2001 survey conducted in Ontario, "87% believed that consent must be given for each specific new research initiative for which a sample is to be used" at 17).

society.³⁶ The divergence of opinions surrounding this issue is reflected in international research ethics instruments, which also variably reject³⁷ or condone³⁸ a broad consent approach. Clearly, more in-depth investigations of what type of consent is ethically and socially acceptable in the context of biobanking, as well as a systematic analysis of legal requirements are needed.

III. Methodology

As there is no consensus in academic literature, public opinion data, or international research ethics instruments, the collection and analysis of additional empirical evidence can serve to advance the debate regarding consent in the large-scale population-biobanking context. To this end, we conducted a comparative, qualitative review of a variety of relevant documents, in order first to identify Canadian legal, ethical, and policy-imposed obligations of researchers in regard to consent for biobanking research and second, to compare these obligations to consent practices used by Canadian biobank researchers, as documented by their respective consent forms.

To identify Canadian legislation and jurisprudence relevant to the regulation of consent to health research and the use of personal health information, we searched legal resource databases such as Westlaw Canada, Quicklaw, HeinOnline, and HumGen, an international database of laws and policies concerning ethical, legal, and social issues in human genetics, using key terms such as “informed consent” and “medical research.” We also searched provincial Ministry of Health websites for relevant legislation, and additionally consulted experts in medical and biotechnology law from various Canadian provinces. Finally, we referred to secondary sources, such as

³⁶ World Medical Association, *WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (Helsinki, Finland: WMA, 1964), online: WMA <www.wma.net/en/30publications/10policies/b3/> at para 6 [*Declaration of Helsinki*].

³⁷ See *Universal Declaration on Bioethics and Human Rights*, UNESCO General Conference Res 36, UNESCOOR, 32d Sess (2005), at art 6; Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Epidemiological Studies* (Geneva: CIOMS, 2008) at 2, guideline 5.

³⁸ Organization for Economic Co-operation and Development, *OECD Guidelines on Human Biobanks and Genetic Research Databases* (OECD, 2009) at 10, best practices, section 4.6.

*Halsbury's Laws of Canada*³⁹ and *Canadian Health Law and Policy*⁴⁰ to ensure that relevant documents had been identified.

To research ethical guidelines discussing consent to health research, we again used HumGen, and also searched both the websites of Canadian federal and provincial governmental research oversight bodies, such as the Canadian Institutes of Health Research ("CIHR") and the Fonds de recherche du Québec – Santé ("FRQS"), and those of professional organizations, such as the Canadian College of Medical Geneticists () and the Réseau de médecine génétique appliquée. All documents providing ethical guidelines for obtaining consent for health research generally, and genetic research and/or biobanking specifically, were included. Similarly, to determine what requirements funding bodies impose on researchers in relation to data sharing, we searched the websites of major Canadian funding bodies such as CIHR and Genome Canada. Policies containing requirements imposed as a condition of funding that related to access or to sharing of research materials and data were included.

To gather data on how researchers are managing the various requirements imposed upon them in relation to consenting subjects, we collected informed-consent documents from major large-scale population biobanks in Canada. There are currently different categories of biobank projects in existence in Canada (eg. disease specific biobanks, public health biobanks, collections of residual samples, the National DNA databank of Canada) each raising its own particular set of legal and ethical challenges. We chose to focus on population biobank projects as opposed to other endeavours, as the former represent the most recent trends in biobanking projects currently taking place in the field of genomics in Canada. Furthermore, because of their very nature, they are also the type of biobanks that are the most susceptible of collecting data for a broad range of purposes and of archiving it for extensive periods of time. By undertaking internet searches and consulting experts in the area, we identified biobanks representing both Canada's various regions and the nation as a whole. We obtained the model informed-consent documents used by these projects when recruiting subjects, and performed a qualitative analysis to determine the nature of the consent being requested. The conclusions that we drew from comparing the consent forms to the various normative guidelines are discussed below.

³⁹ *Halsbury's Laws of Canada* (Markham, Ont: LexisNexis, 2006).

⁴⁰ Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds, *Canadian Health Law and Policy*, 3d ed (Markham, Ont: LexisNexis, 2007).

IV. Results

A. Legislation and Jurisprudence

Canadian law generally requires health care professionals and researchers to obtain informed consent from individuals before performing any health interventions or human subject research. This is the case both in the context of research involving human data and in that of research using human samples, although the legal regime applicable in both cases is slightly different. Both situations will be discussed below.

In clinical research, a consent based on anything but “precise information” has been found by the courts to be insufficient to provide the necessary elements of true and valid informed consent.⁴¹ A “full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent”,⁴² as well as “information about ... the specific risks”⁴³ including those that are “rare or remote”⁴⁴ must be communicated for consent to be considered informed.

This high threshold of disclosure is explained by a number of factors. Firstly, researchers and physicians have an obligation to respect the patient/participant’s autonomy, dignity, and privacy in relation to his or her

⁴¹ For examples of cases where broad consent was found not to meet the informed threshold in clinical care, see e.g. *Pridham v Nash Estate* (1986), 57 OR (2d) 347, (sub nom *Pridham v Nash*) 33 DLR (4th) 304 (Ont H Ct J); *Brushett v Cowan* (1990), 83 Nfld & PEIR 66, 69 DLR (4th) 743 (Nfld CA). As Caulfield and Ries describe, “‘In *Pridham*, a patient signed a consent form agreeing to an abdominal procedure and “additional or alternative procedures as may be necessary or medically advisable during the course of such procedures.’ The Court ruled that this language only permits a physician to carry out additional, *minor* procedures and specific patient consent must be obtained before engaging in additional serious or major interventions.” (Timothy Caulfield & Nola M Ries, “Consent, Privacy and Confidentiality in Longitudinal, Population Health Research: The Canadian Legal Context” (2004) 11 Health LJ Supplement 1 at 31, n 141).

⁴² *Halushka v University of Saskatchewan* (1965), 53 DLR (2d) 436 at 444, 52 WWR 608 (Sask CA) [*Halushka*].

⁴³ Caulfield & Ries, *supra* note 41 at 31.

⁴⁴ *Weiss c Solomon*, [1989] RJQ 731 at 743, CCLT 280 (“risques... rares ou éloignés” [translated by authors]) [*Weiss*].

body and his or her personal health information.⁴⁵ Secondly, a non-standard medical treatment that occurs during clinical research is not considered to be for the (exclusive) benefit of the individual participant, but rather for the benefit of science,⁴⁶ which creates a risk of conflict of interest. This potential for a conflict of interest militates in favour of the patient/participant knowing the specific details of the project in order to protect his or her own interests.

In biobank research, other than a possible feeling of altruism arising from a contribution to the advancement of science, there are few, if any, direct benefits for the individual.⁴⁷ As in the case of clinical research, there is an obligation for biobank researchers to respect the participant's autonomy, dignity, and privacy with respect to his or her body and his or her personal and health information.⁴⁸ Because research platforms or longitudinal studies such as biobanks are even farther from the medical care end of the spectrum than clinical research, the disclosure obligation is arguably higher in this context than in the clinical research context.⁴⁹

Two provinces have enacted specific legislation that regulates consent to research. In Québec, the *Civil Code of Québec* states that biological specimens may be taken for research purposes only with free and enlightened consent from participants,⁵⁰ which must be given in writing unless an ethics committee stipulates otherwise.⁵¹ In Newfoundland, the *Health Research Ethics Authority Act* requires research to be authorized by research ethics boards ("REBs") applying either the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* ("TCPS 2"),⁵² which provides

⁴⁵ Patricia Kosseim & Megan Brady, "Policy by Procrastination: Secondary Use of Electronic Health Records for Health Research Purposes" (2008) 2 McGill JL & Health 6 at 14.

⁴⁶ Caulfield & Ries, *supra* note 41 at 3, 7, 34.

⁴⁷ *Ibid* at 34.

⁴⁸ Kosseim & Brady, *supra* note 45 at 15.

⁴⁹ Caulfield & Ries, *supra* note 41 at 33; Edith Deleury & Dominique Goubau, *Le droit des personnes physiques*, (Cowansville (Qc): Yvon Blais, 2008) at 147.

⁵⁰ Arts 10, 11, 20, 22 CCQ. This reference to the CCQ and the subsequent ones refer to the latest version of the *Code* including the changes introduced by Bill 30, *An Act to amend the Civil Code and other legislative provisions with respect to research*, 1st Sess, 40th Leg, Québec, 2013 (assented to 14 June 2013), 2013, c 17.

⁵¹ Art 24 CCQ.

⁵² Interagency Advisory Panel on Research Ethics (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and

guidelines for obtaining informed consent to health research, or a similar guideline that has been approved by the Health Research Ethics Authority.⁵³ Elsewhere in Canada, consent to research is regulated predominantly by case law.⁵⁴ The Supreme Court of Canada has repeatedly indicated, on the grounds of autonomy and human dignity, that individuals should be able to make their own decisions about undergoing medical interventions.⁵⁵ There is, however, less case law addressing biomedical research.⁵⁶ In one of the two cases relevant to our discussion, *Halushka*, Justice Hall stated that “[t]he subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.”⁵⁷ In *Weiss*, the second relevant case, Justice De Blois reiterated Justice Hall’s position and stated that, “in the case of purely experimental research, the doctor must disclose [to the patient/research subject] all the known risks, even those that are rare or remote, and all the more so when they entail serious consequences.”⁵⁸

Although these decisions do not provide an explicit definition of what constitutes “full,” “frank,” “fair,” and/or “reasonable” disclosure, they underscore that participants must be provided with the information necessary to allow them to freely and truly determine if they want to participate in the research prior to actually giving consent. The elements of disclosure may therefore include (a) facts related to the study/test, (b) probabilities, (c) opin-

Social Sciences and Humanities Research Council of Canada), *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 2d ed (2010), online: IAPRE <www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf> [TCPS 2]. See next section for further discussion of the TCPS 2.

⁵³ Health Research Ethics Authority Act, SNL 2006, c H-1.2, s 9(5).

⁵⁴ For an extensive discussion of the regulatory landscape and case law around consent in biomedical research, see Michael Hadskis, “The Regulation of Human Biomedical Research in Canada” in Jocelyn Downie, Timothy Caulfield & Colleen M Flood, eds, *Canadian Health Law and Policy*, 4th ed (Markham, Ont: LexisNexis, 2011) 437 at 441-50, 468ff.

⁵⁵ See *Ciarlariello v Schacter*, [1993] 2 SCR 119, 100 DLR (4th) 609; *Starson v Swayze*, 2003 SCC 2002, [2003] 1 SCR 722, 225 DLR (4th) 385.

⁵⁶ Hadskis, *supra* note 54 at 469.

⁵⁷ *Supra* note 42 at 444.

⁵⁸ *Supra* note 44 (“en matière de recherche purement expérimentale, le médecin doit révéler tous les risques connus même rares ou éloignés et, à plus forte raison, si ceux-ci sont d’une conséquence grave” at 743 [translated by the authors]).

ions, (d) potential risks and effects associated with any stage of the research, and (e) inconveniences or discomforts related to the research.⁵⁹

As alluded to above, the assessment in these cases of the type of information that is necessary to enable participants to freely determine whether they want to participate in research is based on the standard of what a “reasonable man might be expected to consider before giving his consent.”⁶⁰ This idea of a “reasonable man” needs to take into account that the research participant is not an expert in the medical field or the study, and that he or she relies on the researcher’s “special skill, knowledge and experience,” which puts the researcher in a fiduciary position.⁶¹ This fiduciary position, which requires the researcher to fairly and reasonably inform the research participant, stems from two sources. Firstly, it arises from the transposition of the duty owed by a physician to his patient in ordinary medical practice. This duty is made more exacting in the biomedical research context, where “there can be no exception to the ordinary requirements of disclosure” needed in order to enable research subjects to adequately judge the implications of participation.⁶² Secondly, the fiduciary duty arises from a duty to ensure, at all times, the right of the research subject to safeguard his or her integrity, which is an ethical obligation arising from the *Declaration of Helsinki*.⁶³

The obligation to obtain informed consent for research should be viewed in conjunction with more general privacy norms that cover the use of health information. This would apply to the collection and use of health data in the context of a biobank, in addition to the specific norms applicable to the use

⁵⁹ *C.f. Halushka, supra* note 42 at 442-44; *Weiss, supra* note 44 at 740-43. In the context of population biobanks, it has been argued by some researchers that the information provided is consequent with the longitudinal nature of the research. According to this theory, the information provided is material and reasonable and thus the consent informed. Bartha Maria Knoppers, Ma'n H Abdul-Rahman & Karine Bédard, "Genomic Databases and International Collaboration", (2007) 18 *King's Law Journal* 291 at 305.

⁶⁰ *Halushka, supra* note 42 at 444; *Weiss, supra* note 44 at 742.

⁶¹ *Halushka, supra* note 42 at 444; *Weiss, supra* note 44 at 741-42. A slight distinction can be made regarding the “reasonable” patient test in civil law and in common law. For more on this see *Pelletier v Roberge*, [1991] RRA 726, EYB 1991-63575 (REJB) (Qc CA), *Marcoux c Bouchard*, 2001 SCC 50, [2001] 2 SCR 726; Deleury & Goubau, *supra* note 49 at 119-20.

⁶² *Halushka, supra* note 42 at 444; see also *Weiss, supra* note 44 at 742-43.

⁶³ See *Weiss, supra* note 44 at 741, 743; *Declaration of Helsinki, supra* note 36, arts 25-29.

of health data and human tissues in research described above. In Canada, apart from narrowly defined exceptions, personal health information can generally only be used for research purposes with the consent of the individual to whom it pertains.⁶⁴

In Ontario, for example, individual personal health information generally may not be collected, used, or disclosed without the individual's consent.⁶⁵ Such consent must be knowledgeable, meaning that it must be reasonable in the circumstances to believe that the individual knows the purpose of the collection, use, or disclosure, and that they are able to give or withhold consent.⁶⁶ Nova Scotia's legislation uses similar wording, requiring express consent for the use of personal health information for the purpose of research, unless an REB determines that it is not required.⁶⁷ In the latter case, the information must be de-identified, confidentiality must be ensured, and it must be impracticable to obtain consent.⁶⁸ In Alberta, the collection and disclosure of individually identifying health information requires the informed consent of the individual who is the subject of the information.⁶⁹ Custodians of individually identifying health information may then use that information to conduct research or perform services to facilitate the research of others, as long as there is REB approval, which may require that researchers obtain individual consent.⁷⁰ Judicial decisions such as *McInerney v MacDonald*,⁷¹ a civil case regarding a patient's access to her own medical files, support the position adopted by the federal and provincial legislatures. In the Supreme Court's judgment, Justice La Forest quoted a policy report stating that indi-

⁶⁴ *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5, ss 7(2)(c), (3)(f) (exceptions provided for "purposes that cannot be achieved without using the information, [when] the information is used in a manner that will ensure its confidentiality, it is impracticable to obtain consent and the organization informs the Commissioner of the use before the information is used") [*PIPEDA*].

⁶⁵ *Personal Health Information Protection Act*, SO 2004, c 3, s 29 [PHIPA].

⁶⁶ *Ibid*, s 18.

⁶⁷ *Personal Health Information Act*, SNS 2010, c 41, as amended by SNS 2012, c 31.

⁶⁸ *Ibid*, s 57.

⁶⁹ *Health Information Act*, RSA 2000, c H-5, ss 34 (with respect to disclosure), 20(b), 27(1)(d)(iv) (with respect to collection).

⁷⁰ *Ibid*, s 27(1)(d).

⁷¹ [1992] 2 SCR 138, 93 DLR (4th) 415 [*McInerney*].

viduals have a “basic and continuing interest in what happens to [their personal health] information, and in controlling access to it.”⁷²

In conclusion, it is clear from Canadian legislation and jurisprudence that, to be valid, consent to health research must be voluntarily given by a capable person who has been thoroughly informed of the goals, risks, and benefits associated with the research.⁷³ However, jurisprudence and legislation relating to this topic is fairly sparse, which means that the precise quantity and quality of information that is necessary to ensure that consent is “informed” in a variety of contexts remains subject to debate. That said, it would appear that broad consent, as described above, may not meet the legal requirements in several Canadian provinces, in light of legislation such as the *Civil Code of Québec*, Newfoundland and Labrador’s *Health Research Ethics Authority Act*,⁷⁴ and jurisprudence such as *Weiss*⁷⁵ indicating that extensive information is required for a participant’s consent to experimental research to be considered informed.

B. Ethical Guidelines

Canada’s national and provincial guidelines on consent to biomedical research generally require that subjects be substantively informed of the nature of the research to which they are consenting. The *TCPS 2*⁷⁶ is a prominent research ethics document, national in scope, which provides guidance on the process of informed consent. This document is a joint project of the primary three federal research funding agencies in Canada (CIHR, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council), that asserts that “the commitment to participation in research, including participation through the use of one’s data or biological materials, should be a matter of choice and that, to be meaningful, the choice must be informed”.⁷⁷ Accordingly, Article 3.2 of the *TCPS 2* states that “[r]esearchers shall provide to prospective participants, or authorized

⁷² Canada, *Privacy and Computers*, report of a Task Force established jointly by the Department of Communications and the Department of Justice (Ottawa: Information Canada, 1972) at 14. See also *R v Dyment* [1988] 2 SCR 417 at 429, 55 DLR (4th) 503 (on the importance of informational privacy).

⁷³ See Caulfield & Ries, *supra* note 41.

⁷⁴ *Supra* note 53.

⁷⁵ *Supra* note 44.

⁷⁶ *Supra* note 52.

⁷⁷ *Ibid* at 9.

third parties, full disclosure of all information necessary for making an informed decision to participate in a research project”.⁷⁸ Such information includes “the purpose of the research, what it entails, and its foreseeable risks and potential benefits”.⁷⁹ Furthermore, Article 3.3 asserts that the provision of this information must be ongoing during the research, so as to ensure that consent is maintained throughout the project.⁸⁰ An exception to this rule, articulated in Article 5.5, is provided for when an REB gives approval for the *secondary* use of personal data without consent, as may occur in the context of biobanks. In order for this to occur, several conditions must be met:⁸¹ the material must be essential to the research, the research must be unlikely to have a negative effect on the welfare of the participant, the privacy of the subject must be safeguarded, the researchers must comply with any known preferences of the subject, it must be impossible or impracticable to seek consent from individuals,⁸² and any necessary permissions, for example from local ethics boards, must be obtained. The *TCPS 2* also contains, in Article 12.3, a similarly framed exception that applies to biological samples.⁸³

The Canadian College of Medical Geneticists and the Canadian Association of Genetic Counsellors have also developed guidelines requiring that consent in the context of biomedical research be substantively informed. In their *Joint Statement on the Process of Informed Consent for Research* (“*Joint Statement*”), they assert that consent should be a dialogue between the researcher and the participant, including discussion of the scope of the project, potential health-related and/or social risks and benefits, the participant’s ability to withdraw from research, privacy and confidentiality protec-

⁷⁸ *Ibid* at 30.

⁷⁹ *Ibid* at 9.

⁸⁰ *Ibid* at 33-34.

⁸¹ *Ibid* at 62-63.

⁸² According to the *TCPS 2*,

“Impracticable” refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience. Consent may be impossible or impracticable when the group is very large or its members are likely to be deceased, geographically dispersed or difficult to track. Attempting to track and contact members of the group may raise additional privacy concerns. Financial, human and other resources required to contact individuals and seek consent may impose undue hardship on the researcher” (*ibid* at 63).

⁸³ *Ibid* at 172-74.

tions, and whether/how results will be disclosed.⁸⁴ Additionally, the *Joint Statement* recommends that “[p]rior to participation in a genetic research project, when applicable, participants should be asked to provide consent for future use [of samples] that includes as much detail as possible.”⁸⁵ Also, if biological material is collected for banking purposes, the use of the specimens must be discussed with the donors. Banked material may be used for additional research without consent as long as the specimens are “anonymously and irretrievably unlinked from the source,” and the process is otherwise in keeping with any “local REB approval requirements.”⁸⁶ The *Joint Statement* concludes by reiterating the importance in genetic research of ensuring that “participants have all access to all of the information they need to make a truly informed decision to participate in a particular research project.”⁸⁷

A number of provincial organizations in Québec provide a broader spectrum of guidelines for informed consent in the biobank context. The *Final Report: Advisory Group on a Governance Framework for Data Banks and Biobanks Used for Health Research*, prepared for the FRQS, draws on the first edition of the *TCPS*, the *Civil Code of Québec*, and international guidelines such as the *Declaration of Helsinki* to articulate consent requirements.⁸⁸ The FRQS Advisory Group argues, however, that these normative tools do not provide the flexibility needed to maximize the scientific value that biobanks promise.⁸⁹ According to the FRQS Advisory Group, if participants are informed of the main themes and general objectives of the biobank and the research for which their samples might be used, as well as the properties of the biobank’s governance system, then broad consent is an acceptable way of

⁸⁴ Diane J Allingham-Hawkins et al, *Joint Statement on the Process of Informed Consent for Genetic Research* (Canadian College of Medical Geneticists and Canadian Association of Genetic Counsellors, July 2008), online: CCMG-CAGC <www.ccmg-ccgm.org/documents/Policies_etc/Pos_Statements/PosStmnt_EPP_CAGCInformedConsent_16Jul2008.pdf> at 3-5 [Joint Statement].

⁸⁵ *Ibid* at 6.

⁸⁶ *Ibid* at 7.

⁸⁷ *Ibid*.

⁸⁸ Fonds de la recherche en santé du Québec, *Final Report: Advisory Group on a Governance Framework for Data Banks and Biobanks Used for Health Research* (Québec: FRSQ, 2006) online: Fonds de recherche du Québec – Santé <www.frsq.gouv.qc.ca/en/ethique/pdfs_ethique/Rapport_groupe_conseil_anglais.pdf> at 12 [FRQS].

⁸⁹ *Ibid* at 60.

respecting participant autonomy.⁹⁰ In contrast, the Réseau de médecine génétique appliquée, which published several early statements on genetic research, has recommended that participants be informed of “the research team, the goals of the research, its nature, its length, the method followed as well as the tests used, where and how the research data/information and samples will be kept, ... the risks and the benefits to the participant or society..., the actual limitations and future of the project as well as the right to withdraw from research.”⁹¹ In relation to the scope of consent obtained, Québec’s Commission de l’éthique de la science et de la technologie has published *The Ethical Issues of Genetic Databases: Towards Democratic and Responsible Regulation*, which recommends that participants’ samples not be used for secondary research at all. Instead, researchers should ask participants whether they consent to being recontacted for the purpose of being asked to participate in new research projects.⁹²

In summary, with the exception of the report of Québec’s FRQS Advisory Group, pertinent ethical guidelines in Canada require the disclosure of specific information concerning research in the consent process. The guidelines provide some specificity regarding what is meant by the term “informed”; participants require a significant amount of information regarding the nature and scope of the research for which their data and genetic material will be used in order for their consent to be considered informed. In the population biobanking context, it is possible for participants to be informed regarding the nature and scope of the biobank project itself but at the time of consent, researchers are unable to provide participants with significantly de-

⁹⁰ *Ibid* at 59-60.

⁹¹ Réseau de médecine génétique appliquée/Network of Applied Genetic Medicine, *Statement of Principles: Human Genome Research* (2000), online: RMGA <www.rmga.qc.ca/en/documents/Enoncedeprincipesrechercheengénomiquehumaine_en_000.pdf> at 5. In a more recent statement, the RMGA encouraged the adoption of an ongoing research consent process where patients would be informed of significant changes to the research protocol. They also encouraged the development of a biobank governance committee to oversee the management and creation of the bank; Réseau de médecine génétique appliquée/Network of Applied Genetic Medicine, *Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations* (2003), online: RMGA <www.rmga.qc.ca/en/documents/encartANG_2609_2e_000.pdf>.

⁹² Commission de l’éthique de la science et de la technologie, *The Ethical Issues of Genetic Databases: Towards Democratic and Responsible Regulation* (2003), online: CEST <www.ethique.gouv.qc.ca/index.php?option=com_docman&task=doc_download&gid=121&Itemid=16&lang=fr> at 11.

tailed information regarding the future uses to which their samples may be put, and the associated prospective risks. Accordingly, consent at this stage is inevitably broad, and essentially involves asking participants to agree to having their samples used in research for which information such as anticipated risks and benefits, outcomes, and the identity of the future researchers is not presently available. This does not seem to meet ethical requirements put forward in a substantial subset of the ethics texts reviewed. Additionally, it is unlikely that biobanking research, which in the case of coded samples benefits from linking data to personally identifying information, would meet the conditions needed in order to obtain an REB exception to informed consent as presented in the *TCPS 2*.

C. *Funding Policies*

Organizations that provide the majority of public funding for genetic research in Canada predominantly require researchers to share their data and biological materials broadly. Genome Canada, for example, which since 2000 has received \$915 million from the Canadian government to support large-scale genomics and proteomics research projects,⁹³ requires funded projects to share data and resources, including biological specimens, “as rapidly as possible” and “with minimal or no restrictions.”⁹⁴ This data-sharing norm is reinforced by the requirement that publications supported by Genome Canada be made freely accessible online as quickly as possible.⁹⁵ Similarly, CIHR, which in 2012 financially supported over 13,639 health researchers and trainees across the country,⁹⁶ requires grant recipients to make both publications and related biomedical research data freely accessible in public databases, and has committed to improving open access to “research materials and other research data in the future.”⁹⁷ Grand Challenges Canada,

⁹³ Genome Canada, “Research Portfolio”, online: GC <www.genomecanada.ca/en/portfolio/>.

⁹⁴ Genome Canada, “Data Release and Resource Sharing Policy” (2008), online: GC <www.genomecanada.ca/medias/PDF/EN/DataReleaseandResourceSharingPolicy.pdf> at 1.

⁹⁵ Genome Canada, “Policy on Access to Research Publications” (2008), online: GC <www.genomecanada.ca/medias/PDF/EN/DataReleaseandResourceSharingPolicy.pdf> at 1.

⁹⁶ Canadian Institutes of Health Research, *CIHR Three-Year Implementation Plan and Progress Report 2012–15*, online: CIHR <www.cihr-irsc.gc.ca/e/documents/cihr_impl_plan_2012-15-en.pdf> at 3.

⁹⁷ Canadian Institutes of Health Research, “CIHR Open Access Policy” (2013), online: CIHR <www.cihr-irsc.gc.ca/e/46068.html> at s 5.1.

an initiative launched by the federal government in 2010 that has awarded \$93 million in peer reviewed grants as of March 2013,⁹⁸ reserves itself the discretionary right to impose data access agreements to its grantees and directs that “grantees should ensure that relevant aspects of their grant proposal are conducive to data access, i.e. permissions to share data are included in informed consent documents, and in collaboration and consortia agreements.”⁹⁹

Together, the policies of all of these research agencies indicate that genetic researchers in Canada supported by public funding have a strong incentive, linked to the receipt of their grants, to rapidly and openly share research data, results and materials. That being said, the precise scope of these policies and any possible exceptions are not always clear, and vary from one organization to another.

D. Consent Forms

We reviewed consent forms for large-scale biobanking projects that are members of the Canadian Partnership for Tomorrow Project (“CPTP”), an initiative funded by Health Canada as well as the formerly privately owned Genizon Biobank.¹⁰⁰ See Table 2 for a description of each of the projects examined in this study. The CPTP projects include the Ontario Health Study, the British Columbia Generations Project, Alberta’s The Tomorrow Project, Québec’s CARTaGENE, and the Atlantic Partnership for Tomorrow Project, which is taking place across the four Atlantic provinces. We also obtained a model consent form for use in biobanking research from the Public Population Project in Genomics (P³G), a non-profit consortium with administrative headquarters in Montréal that was created to facilitate collaboration between researchers and projects in the area of population genomics. These consent forms differ from one another in a number of ways, for example in terms of whether and how individual results will be returned to participants and the period of time during which samples and data will be stored. They are re-

⁹⁸ Grand Challenges Canada, “Bold Ideas with Big Impact” (May 2013), online: GCC <www.grandchallenges.ca/wordpress/wp-content/uploads/2013-CEO-Letter-EN.pdf> at 1.

⁹⁹ Grand Challenges Canada, “Data Access Policy” (September 2012) online: GCC <www.grandchallenges.ca/wordpress/wp-content/uploads/data-access-policy-2012Sep06-EN.pdf> at 2.

¹⁰⁰ Although the Genizon Biosciences Inc. research model was principally disease-based, the company also developed a biobank for more prospective research initiatives.

markably similar, however, in that they uniformly require that participants provide broad consent, albeit with ongoing ethical monitoring of new projects.

Each of the forms we reviewed was seeking consent for collection of, at minimum, urine and blood or saliva samples. They all asked for access to past, current, and future health information, either contained in medical records or collected by organizations such as provincial cancer registries. The forms explained that the samples and data collected would be used in unspecified studies, using general language such as “health research projects” (the British Columbia Generations Project) and “future health-related research” (the Atlantic Partnership). Some forms explicitly stated that the samples and data would be used in ways currently unknown, for example explaining: “It is impossible to predict all the studies that could use the blood and urine samples over the course of the next 50 years. They will be used, among other biomedical projects, for research on the structure and the functioning of the genome” (CARTaGENE).¹⁰¹ Each project stated that the samples and data would be used by researchers both within and outside of Canada. Participants were uniformly assured, however, that researchers would not receive identifying information and that the proposed projects would need to be approved by an REB before data and samples would be provided. It is clear from this substantial sample of current consent forms, therefore, that seeking broad consent is a common practice in large-scale Canadian population biobanking research.

IV. Discussion

Analysis of Canadian legislation, jurisprudence, ethical guidelines, and funding policies indicates that researchers are facing a complex array of conflicting requirements when it comes to informed consent in the context of biobanking. In congruence with traditional consent norms, both legal instruments and ethical guidelines require researchers to provide subjects with substantive information regarding the uses to which samples and data will be put. Funding policies, on the other hand, expect researchers to make the materials and data they collect widely available with minimal restrictions on their use by other scientists, thereby indirectly pressuring the researchers they support to adopt broad consent policies. Unsurprisingly, Canadian researchers are fulfilling the requirements imposed upon them by funding bodies at the expense of those currently imposed by legal and ethical instruments. This is problematic.

A. Legal Implications

While no known suits have yet been brought against Canadian biobanks in relation to the nature of their consenting practices, it is possible that such a suit may arise in the future. Parallels may be drawn to a recent case in British Columbia, *LD (Guardian ad litem of) v Provincial Health Services Authority*, in which governmental health agencies were sued for banking newborn bloodspots without obtaining explicit parental consent.¹⁰²

In *LD*, a mother of two infants sought to commence class proceedings against the Provincial Health Services Authority in relation to their policy of taking and storing newborn bloodspots for 19 years for, among other purposes, medical research. The chambers judge dismissed the appellant's claims on the basis that she had no genuine issue for trial, ruling that the Authority's failure to disclose its intentions to maintain and store the samples would not have vitiated the original consent given for the collection of the samples, as any reasonable person in the position of the parent would have consented to having their children's samples collected and tested, even knowing of their storage intentions.¹⁰³ The British Columbia Court of Appeal overturned this decision. Ryan JA, delivering judgment for the Court, agreed with the chambers judge that "consent to the taking of the samples [was] central to the appellants' case."¹⁰⁴ But he ruled that, "[i]t is very much an open question as to what the test for consent should be when the plaintiff or claimant seeks damages alleging that his privacy rights have been breached under s. 8 of the *Charter*. The same can be said about the *Privacy Act*."¹⁰⁵ The appellant's statement of claim was reinstated, so that the "proper factual foundation on which to explore, develop and apply the tests" for articulating the scope of the parents' consent could be debated in court.¹⁰⁶

Although, the primary purpose of the banking was a different one (for population newborn screening), this case is relevant to the biobank context as it also deals with the issue of consent to the storage of human biological sam-

¹⁰² 2012 BCCA 491, 331 BCAC 43, 225 ACWS (3d) 401 [*LD* 2012]. For two US cases where the issue of consent to newborn bloodspot banking was discussed, see *Higgins v Texas Department of Health Services*, 801 F Supp (2d) 541 (WD Tex 2011); *Bearder v Minnesota*, 806 NW (2d) 766 (2011).

¹⁰³ *LD (Guardian ad litem of) v Provincial Health Services Authority*, 2011 BCSC 628 at paras 38, 42, 234 CRR (2d) 84, 201 ACWS (3d) 1071.

¹⁰⁴ *LD* 2012, *supra* note 102 at para 13.

¹⁰⁵ *Ibid* at para 18.

¹⁰⁶ *Ibid* at para 19.

ples on a population scale for long-term research purposes. The decision concerned only whether the appellant had a genuine issue for trial, and so left extended discussion of the type and amount of information that would need to be provided to obtain adequately informed consent for the lower court to decide. That said, *LD* confirms that the meaning of informed consent in the context of the storage of human biological tissues for research purposes is still very much up for debate. Though the eventual outcome of *LD* has yet to be decided, the existence of this consent-related case indicates that there are members of the public who are willing to take legal action to ensure that consent norms in biomedical research are respected. If this were to occur in the context of large-scale population biobanking, it could lead to the loss of thousands of research samples and other data in the event that the consent that had been provided by subjects to collect, store, and use the human biological samples were found to be invalid.

B. Policy Implications

There are a number of approaches that may be pursued in an effort to dispel the tension that exists between legal and ethical informed consent requirements and the practice of obtaining broad consent for the purposes of data sharing. Firstly, clarification of what the “informed” criterion for consent in Canadian law and policy substantively requires is needed. The Québec Ministry of Health and Social Services has recently reviewed the section of the Québec Civil Code on medical research, including article 22 CCQ which deals with consent to the removal of tissues and bodily substances for research purposes. It was reported that a priority objective of this revision was to improve the legislative framework of biobanks and databases.¹⁰⁷ Sadly, the new revision will have little impact on consent to research involving biobanks. Although the new provisions bring some welcome changes to the Québec research framework, they address more traditional issues (e.g. research with minors, formal requirement of research consent, substitute consent for deceased individuals) and do not propose innovative solutions to the current dilemma in biobank research that would provide some flexibility to consent requirements. Given the low prevalence of psychosocial risk associated with biobank research, relative to the much more concrete prevalence of physical risk in clinical research, and in view of the eminently social dimension of biobank projects, such legal reform seems desirable. The challenge

¹⁰⁷ Denis Lalumière, “Pour que l’éthique de la recherche continue de prendre des forces” in *Peut-on se faire confiance? Actes de la 5e édition des Journées d’étude des comités d’éthique de la recherche et de leurs partenaires* (Québec: Ministère de la santé et des services sociaux du Québec, Direction des communications, 2011) 4 at 8.

for the legislature will be to adopt more progressive consent requirements for the research context that will not vitiate the informed-consent process. One option worthy of consideration may be an exception to the strict consent requirement in the form of a proportionate approach that would allow broad consent for biobanks. This exception would require the researcher to justify the use of broad consent and to meet well-delineated privacy and governance requirements. Such an exception could also promote a more active role for research participants, for example via the inclusion of various preferences in consent documents, greater communication with the biobank and ongoing ethics review.

In the meantime, however, little doctrine exists in regard to the meaning of “informed” for legal purposes in the context of human subject research, and what does exist does not address recent technological developments that challenge traditional conceptions of consent. The principle that the farther from the medical care end of the research spectrum, the more complete the subject’s knowledge and understanding of the research must be¹⁰⁸ and the importance of promoting individual autonomy and respecting the subject’s right to self-determination¹⁰⁹ have been invoked to justify strict informed consent requirements. Yet, the low level of risk generally associated with participation in biobank projects and the impracticability of carrying out such research with narrowly framed informed consent requirements seem to suggest that a more nuanced position could be more appropriate.

In this paper, we have suggested that a preliminary analysis indicates that broad consent does not seem to fulfill legal and ethical informational requirements. However, current research regulation is largely based on a narrow view of the research enterprise, contemplating individual consent for well-delineated research projects.¹¹⁰ This regulation, we argue, needs to be reconceptualized in the context of the increasing prevalence of biobanking. Future work providing more sustained consideration of what information is legally and ethically required for consent to be valid, especially in the novel context of large-scale population biobanking, would help researchers and policy makers navigate these diverging considerations.

¹⁰⁸ See *Weiss*, *supra* note 44 at 741.

¹⁰⁹ JG Castel, “Nature and Effects of Consent with Respect to the Right to Life and the Right to Physical and Mental Integrity in the Medical Field: Criminal and Private Law Aspects” (1978) 16 *Alta L Rev* 293 at 301.

¹¹⁰ See Mark A Rothstein, “Expanding the Ethical Analysis of Biobanks” (2007) 33:1 *JL Med & Ethics* 89 at 91.

One response to this claim might be to argue that research done using anonymized samples¹¹¹ from biobanks may be interpreted as not involving human subjects, which would obviate the need for human subject protections such as informed consent. In the US, for example, where human subject research is defined by the “Common Rule,” some have argued that when biobankers collect anonymized samples from third-party researchers, and thus have no contact with subjects, this “secondary” research might not be subject to Common Rule regulations.¹¹² However, in Canada, human subject research is defined as any research involving living human participants or human biological materials, derived from living or deceased individuals.¹¹³ Additionally, the use of individual personal health information for research purposes generally requires informed consent, even if such information is not directly derived from medical intervention by the researcher.¹¹⁴ Privacy norms will therefore generally apply to biobank research with anonymized biological samples, and/or with anonymized health data in Canada. However, there are a number of narrow exceptions provided for where it is possible to use health information without obtaining informed consent.¹¹⁵

More importantly, anonymization does not represent a realistic solution to the problem of informed consent. Firstly, as the genomic literature demonstrates, it is misleading to claim that information contained in biobanks can be fully anonymized, thereby completely negating the risks of discrimination or psychosocial harm to individuals.¹¹⁶ Moreover, this approach takes too

¹¹¹ Anonymized human biological materials are materials that have been “irrevocably stripped of direct identifiers, a code is not kept to follow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.” *TCPS 2*, *supra* note 52 at 170. The word anonymized is often used with a similar meaning in the context of health data.

¹¹² See Henry T Greely, “The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks” (2007) 8 *Annu Rev Genomics Hum Genet* 343 at 353-55.

¹¹³ See *TCPS 2*, *supra* note 52 at 15, article 2.1; see also art 22 CCQ.

¹¹⁴ PIPEDA, *supra* note 64 at Schedule 1, Principle 4.3.

¹¹⁵ See e.g. *ibid*, s 7(2)(c).

¹¹⁶ See e.g. Nils Homer et al, “Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays” (2008) 4:8 *PLoS Genetics* 1 at 9; Zhen Lin, Art B Owen & Russ B Altman, “Genomic Research and Human Subject Privacy” (2004) 305 *Science* 183; Eric E Schadt, Sangsoo Woo & Ke Hao, “Bayesian Method to Predict Individual SNP Genotypes from Gene Expression Data” (2012) 44:5 *Nat Genet*

narrow a view of the interests of research subjects. Individuals have an inherent interest in the decision to consent to research, even when their participation is limited to previously collected, anonymized data, as a result of their fundamental right to self-determination. They may object to having their samples used for particular types of research, irrespective of what risks this research poses to them personally. Additionally, biobanks with anonymized information have a very limited value for researchers, as a result of the limitations that anonymization puts on the health and environmental data available. This indicates that it is both ethically and scientifically undesirable that biobanks be anonymized in an attempt to circumvent informed consent requirements.¹¹⁷

An alternative way in which the tension between informed consent requirements and broad consent practices might be alleviated is to increase the inclusion of subjects as partners in biobank research. This can happen both at a community level, through public engagement, and at the level of the individual subject. In Canada, public engagement exercises seeking to obtain diverse input on policy issues in biobanking have been undertaken in British Columbia and Québec with significant success.¹¹⁸ Such initiatives increase public knowledge and understanding while providing policy-makers with information regarding public concerns, and so improve the background conditions out of which specific informed-consent processes arise. On the individual level, while it may be impractical and unduly burdensome for researchers to contact subjects for every new research project, it is not unreasonable for large-scale population biobanks to keep subjects apprised of ongoing activities, for example through regular newsletters and/or interactive websites that provide information on how samples are being used. Given appropriate privacy safeguards, subjects could be provided individual online accounts to which they could log on in order to update their health information and research preferences, and review the details of the research projects in which their personal samples are being used, with the option of opting out if de-

603 at 607; Melissa Gymrek et al, "Identifying Personal Genomes by Surname Inference" (2013) 339:6117 *Science* 321.

¹¹⁷ See Greely, *supra* note 112 at 356.

¹¹⁸ See KC O'Doherty & MM Burgess, "Engaging the Public on Biobanks: Outcomes of the BC Biobank Deliberation" (2009) 12:4 *Public Health Genomics* 203; Béatrice Godard, Jennifer Marshall & Claude Laberge, "Community Engagement in Genetic Research: Results of the First Public Consultation for the Quebec CARTaGENE Project" (2007) 10:3 *Community Genetics* 147.

sired.¹¹⁹ Options for participants to take an even more active role in the development of a public biobank project have been proposed.¹²⁰ Such initiatives would honour the spirit of informed consent as an ongoing, dynamic process and ensure that subjects have access to relevant information regarding their participation in research as it arises. Increasing the level of subject participation in the biobank endeavour via these methods will contribute to reducing the existing tension between legal and ethical informed consent requirements and data sharing initiatives.

In response to problems of consent and concerns around public involvement in the context of biobanking, David and Richard Winickoff have proposed the legal solution of a “charitable trust” model for biobank governance.¹²¹ Under such a model, research subjects would transfer their property interest in donated tissue to a trust. The trustee of this property would have legal fiduciary duties to manage the property to the advantage of the beneficiary, which in the case of a charitable trust, is the general public. According to the Winickoffs, such a model is superior to the usual governance framework of private biobanks for a number of reasons. It can be structured so as to provide the donor groups with an advisory role in the governance of the trust, which would promote a sense of community amongst donors. It also recognizes tissue donation as an altruistic gift intended to benefit mankind, which fits the normative conception of the human genome as a universally shared resource. The charitable trust model aims to promote donor participation in research governance and stimulate research that will benefit the public at large, and so could contribute to alleviating many of the tensions currently associated with broad consent in the biobank context.¹²²

¹¹⁹ For a description of a “[w]eb-based, interoperable personally controlled health record” system supporting a research regime, see Isaac S Kohane et al, “Reestablishing the Researcher-Patient Compact” (2007) 316 *Science* 836 at 836-37.

¹²⁰ Edward S Dove, Yann Joly & Bartha M Knoppers, “Power to the People: A Wiki-governance Model for Biobanks” (2012) 13 *Genome Biology* 158.

¹²¹ David E Winickoff & Richard N Winickoff, “The Charitable Trust as a Model for Genomics Biobanks” (2003) 349:12 *New England Journal of Medicine* 1180 at 1182-83.

¹²² *Ibid* at 1182-83. For a broader discussion of governance, see Robert O Keohane, “Governance in a Partially Globalized World (Presidential Address, American Political Science Association, 2000)” (2001) 95:1 *American Political Science Review* 1.

However, even if inclusionary measures are adopted, whether in the form of public engagement or through formal legal structures such as the charitable trust, it will remain the case that more communication is needed between the various funding bodies and professional associations that finance, regulate and oversee biomedical research in order to develop harmonized policies that are more connected to the contemporary research challenges. Funding bodies in particular are currently promoting open data-sharing practices while ignoring the fact that this encourages the adoption of consent practices that may conflict with traditional legal and ethical norms. While the promotion of data sharing and open access to biomedical research resources is an admirable goal that could very well procure valuable benefits to health research, it is important that it be pursued in a way that is congruent with legal and ethical requirements. The legal and ethical obligations requiring that consent to biobank research be substantively informed may eventually be modified, but in the meantime, the bodies providing funding and oversight for this research must present researchers with clearer and less contradictory policies, as well as guidance and options on how to undertake these responsibilities in the Canadian legal context.

Table 1: Types of Consent

There is little consistency or consensus in the literature regarding the definition for different types of consent, when they are even defined at all. The following table provides some examples of types of consent that have been described.

Type of Consent	Example of Descriptions from the Literature	Defined in
Narrow or Traditional	This model presents an incredibly exacting standard, requiring at minimum that researchers “provide information about all potential risks, no matter how remote, and material information about the nature of the research protocol.” ¹²³	Caulfield, Upshur & Daar (2003) ¹²⁴
Dynamic	Participants are continuously recontacted and, each time, they are asked to provide “real-time” consent for the use of their data in every new research project as it arises. The model allows research participants to have an interactive relationship with the custodians of biobanks and the research community, and to easily provide or revoke their consent at any time. ¹²⁵	Pawlikowski, Sak & Marczewski (2009) ¹²⁶ Steinsbekk, Myskja & Solberg (2013) ¹²⁷
Tiered	This model allows research participants to choose from a checklist of items on the consent form, such as the types of research in which they are willing to participate. ¹²⁸ Participants may permit only some use, thereby requiring new consent for other studies. ¹²⁹	Ram (2004) ¹³⁰ Bunnik, Janssens, and Schermer (2012) ¹³¹ Master et al (2012) ¹³²
Broad	“[P]articipants must be clearly informed that that they are consenting to future, unspecified research with their biospecimen and genomic data.” ¹³³ Within this framework for future research, participants may be reassured that each research project involved will undergo independent ethical review. They will be contacted to provide new consent if this framework is significantly modified. ¹³⁴	Salvaterra et al (2008) ¹³⁵ Wallace, Lazor & Knoppers (2009) ¹³⁶ Steinsbekk, Myskja & Solberg (2013) ¹³⁷
Blanket	Potential research participants may be asked, for example, simply if they consent to having their samples used for research purposes, without being given any additional information about what that research may involve. ¹³⁸	Shickle (2006) ¹³⁹ Caulfield (2007) ¹⁴⁰
Presumed (opt out)	Opt out systems assume the subject understands the information, freely chooses, and takes action if he or she does not want to participate. ¹⁴¹ When consenting to medical treatment, individuals can opt out of having their DNA included in the biobank by checking a box on the consent to treatment form. ¹⁴²	Wendler & Emanuel (2002) ¹⁴³ Árnason (2004) ¹⁴⁴ Petrini (2010) ¹⁴⁵ Pulley et al (2010) ¹⁴⁶

Table 2: Examples of Population Biobanks in Canada

Population Biobank	Atlantic Partnership for Tomorrow's Health*	BC Generations Project*	CARTaGENE*	Ontario Health Study*	The Tomorrow Project*	Biobanque de Genizon (currently Genome Quebec, acting as trustee)
Territory Covered	Atlantic Canada (Nova Scotia, New Brunswick, Newfoundland & Labrador, Prince Edward Island)	British Columbia	Québec	Ontario	Alberta	Québec
Year Created	2009 ¹⁴⁷	2009 ¹⁴⁸	2009 ¹⁴⁹	2010 ¹⁵⁰	2000 ¹⁵¹	1999
Number of Projected Participants	30 000 ¹⁵²	40 000 ¹⁵³	37 000 ¹⁵⁴	225 000 (current number of participants) ¹⁵⁵	50 000 ¹⁵⁶	50 000 (final number of samples) ¹⁵⁷
Privacy Measures	Coded ¹⁵⁸	Coded ¹⁵⁹	Coded ¹⁶⁰	Coded ¹⁶¹	Coded ¹⁶²	Coded
Consent Language	“We will be keeping the blood and toenail samples, along with the physical measures and information from the questionnaires to allow them to be used for future health related research. The samples and all of the information gathered for the study will be stored for 30 years, during which time they will be made available to researchers.” ¹⁶³	“If you volunteer to take part, you will be asked to agree to the following: ...Allow storage of your samples and health-related information obtained for this study in a coded form which does not identify individuals. This information may be used for health research projects until the year 2058.” ¹⁶⁴	“Participants in CARTaGENE accept that data and samples collected from them will be used for health and genomic studies in the future... It is impossible to predict all the studies that could use the blood and urine samples over the course of the next 50 years. They will be used, among other biomedical projects, for research on the structure and the functioning of the genome.” ¹⁶⁵	“I understand that most of my blood sample will be coded and stored for future research. I recognize that it will be possible for components of my blood to be examined for research purposes. I understand that my DNA may be used for genetic research. I recognize that in the future, my blood and/or DNA could be analyzed in ways that are currently unknown.” ¹⁶⁶	“I accept that my data and samples will be stored for at least 50 years to support research related to cancer, and potentially other health conditions... I accept that my data and samples may be used, in coded form, by approved researchers from Canada and other countries for research related to cancer, and potentially other health conditions.” ¹⁶⁷	“By accepting to participate in the Biobank, you are authorizing Genizon to use part of your DNA already collected as part of the research project to which you initially consented, for purposes of achieving Biobanks’ goal (finding the genes associated to common genetic diseases) ... Your information and genetic material may be accessed by researchers located inside and outside Canada.” ¹⁶⁸
Possibility to Re-Contact	Yes ¹⁶⁹	Yes ¹⁷⁰	Yes ¹⁷¹	Yes ¹⁷²	Yes ¹⁷³	Yes

This table was developed by the authors of this article using a number of sources including the biobanks’ websites and consent forms and CTP Project Catalogue at Public Population Project in Genomics and Society online. *Member of the Canadian Partnership for Tomorrow Project

Table References

- ¹²³ Caulfield, Upshur & Daar, *supra* note 32 at 2.
- ¹²⁴ *Ibid.*
- ¹²⁵ Kristin Solum Steinsbekk, Bjørn Kåre Myskja & Berge Solberg, “Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?” (2013) *European Journal of Human Genetics*, advance online publication, doi: 1018-4813/13 at 2.
- ¹²⁶ Jakub Pawlikowski, Jaroslaw Sak & Krzysztof Marczewski, “The Analysis of the Ethical, Organizational, and Legal Aspects of Polish Biobanks Activities” (2009) 20:6 *European Journal of Public Health* 707 at 709.
- ¹²⁷ *Supra* note 125.
- ¹²⁸ Master et al, *supra* note 6 at 885.
- ¹²⁹ Natalie Ram, “Tiered Consent and the Tyranny of Choice” (2008) 48 *Jurimetrics J* 253 at 254-55.
- ¹³⁰ *Ibid.*
- ¹³¹ Eline M Bunnik, A Cecile JW Janssens & Maartje HN Schermer, “A Tiered Layered-Staged Model for Informed Consent in Personal Genome Testing” (2013) 21 *European Journal of Human Genetics* 596 at 597-98.
- ¹³² *Supra* note 6 at 885.
- ¹³³ Susan Wallace, Stephanie Lazor & Bartha Maria Knoppers, “Consent and Population Genomics: The Creation of Generic Tools” (2009) 31:2 *IRB: Ethics and Human Research* 15 at 16.
- ¹³⁴ Steinsbekk, Myskja & Solberg, *supra* note 125 at 1.
- ¹³⁵ Elena Salvaterra et al, “Banking Together. A Unified Model of Informed Consent for Biobanking” (2008) 9:4 *European Molecular Biology Organization Report* 307 at 309-10.
- ¹³⁶ Wallace, Lazor & Knoppers, *supra* note 133 at 16.
- ¹³⁷ Steinsbekk, Myskja & Solberg, *supra* note 125 at 1.
- ¹³⁸ Darren Shickle, “The Consent Problem Within DNA Biobanks” (2006) 37 *Studies in History and Philosophy of Biological and Biomedical Sciences* 503 at 510.
- ¹³⁹ *Ibid.*
- ¹⁴⁰ Caulfield, *supra* note 20, at 213-14.
- ¹⁴¹ Petrini, *supra* note 25 at 219
- ¹⁴² Jill Pulley et al, “Principles of Human Subject Protections Applied in An Opt-Out, De-identified Biobank” (2010) 3:1 *Clinical and Translational Science* 42 at 43.

- ¹⁴³ David Wendler & Ezekiel Emanuel, “The Debate Over Research On Stored Biological Samples: What Do Sources Think?” (2002) 162:13 Archives of Internal Medicine 1457 at 1461-62.
- ¹⁴⁴ Vilhjálmur Árnason, “Coding and Consent: Moral Challenges of the Database Project in Iceland” (2004) 18:1 Bioethics 27 at 33.
- ¹⁴⁵ *Supra* note 25.
- ¹⁴⁶ *Supra* note 142 at 43.
- ¹⁴⁷ Atlantic PATH, Media Release, “Landmark Cancer Study Gets Underway in Nova Scotia” (5 March 2009), online: AP <atlanticpath.ca/supportfiles/PATH_March_5_09.pdf> [Atlantic PATH, Media Release].
- ¹⁴⁸ BC Generations Project, News Release, “Are You Eligible? Largest-Ever BC Health Research Project to Benefit Future Generations” (14 October 2009), online: BCGP <www.bcgenerationsproject.ca/2009/10/are-you-eligible-largest-ever-bc-health-research-project-to-benefit-future-generations>.
- ¹⁴⁹ CARTaGENE, *Brochure for Participants*, online: CARTaGENE <cartagene.qc.ca/sites/default/files/brochure_25_oct_finale_en_sans_salive.pdf> at 3.
- ¹⁵⁰ Ontario Health Study, “The Ontario Health Study Invites All Ontario Adults to join Research Effort to Fight Cancer, Heart Disease, Asthma, Diabetes and Other Common Diseases” (Toronto, September 2010), online: OHS <www.ontariohealthstudy.ca/files/field_file/OHS%20-%20Media%20Release%20-%20Sept%2028%202010%20-%20FNL.pdf>.
- ¹⁵¹ The Tomorrow Project, “Brief History & Summary”, online: TTP <www.in4tomorrow.ca/AboutTheStudy.aspx>.
- ¹⁵² Atlantic PATH, Media Release, *supra* note 147.
- ¹⁵³ BC Generations Project, “BC Generations Project Protocol” (4 April 2011), online: BCGP <www.bcgenerationsproject.ca/wp-content/uploads/BCGP-Study-Protocol-Version2.2.pdf> at 8 [BC Generations, “BC Generations Project Protocol”].
- ¹⁵⁴ CARTaGENE, *supra* note 149.
- ¹⁵⁵ Ontario Health Study, “Ontario Health Study Enters Next Phase of Research with Groundbreaking Blood Collection Program” Press Release (Toronto: November 21, 2012), online: OHS <www.ontariohealthstudy.ca/files/field_file/OHS%20news%20release%2021%20Nov%202012.pdf>.
- ¹⁵⁶ The Tomorrow Project, Brochure, “Enroll in Alberta’s Tomorrow Project Now”, online: TTP <www.in4tomorrow.ca/Portals/0/In4Tomorrow%20Brochure.pdf>.
- ¹⁵⁷ Genome Quebec, “Public Notice: Genizon Biosciences Inc.” Press Release (12 December 2012), online: Genome Quebec <www.genomequebec.com/81-researchers-details-news-public-notice-genizon-biosciences-inc-.html>.

- ¹⁵⁸ Atlantic PATH, “FAQs: Confidentiality”, online: AP <atlanticpath.ca/faq/faq-confidentiality.html>.
- ¹⁵⁹ BC Generations, “BC Generations Project Protocol”, *supra* note 153 at 9.
- ¹⁶⁰ CARTaGENE, *supra* note 149 at 6.
- ¹⁶¹ Ontario Health Study, “Privacy”, online: OHS <www.ontariohealthstudy.ca/en/privacy> [Ontario Health Study, “Privacy”].
- ¹⁶² The Tomorrow Project, “Frequently Asked Questions by Section: Privacy & Confidentiality Questions”, online: TTP <www.in4tomorrow.ca/FAQ.aspx>.
- ¹⁶³ Atlantic PATH, “Consent to Take Part in a Research Study – Participant Information” CBDHA REB, Version 8 CBDHA, September 16, 2009, online: Atlantic PATH <http://atlanticpath.ca/supportfiles/Appendix%20VII%20-%20Consent%20Form%20-%20Version%208CBDHA.pdf> [Atlantic PATH, “Consent”].
- ¹⁶⁴ BC Generations Project/BC Cancer Agency, “Participant Information and Consent Form: BC Generations Project” (27 February 2012), online: BCGP <www.bcgenerationsproject.ca/wp-content/uploads/BCGP-Consent-and-Information-Version3.9.pdf> at 3.
- ¹⁶⁵ CARTaGENE, *supra* note 149 at 2, 6.
- ¹⁶⁶ Ontario Health Study, “Appendix 1: Assessment Centre Consent Form”, Version 4, 8 June 2012 at 3.
- ¹⁶⁷ Alberta Health Services, “The Tomorrow Project – Consent Form” DS-3008Av3 CPTP Combined Consent, May 2011 at 2, 3.
- ¹⁶⁸ This quote was translated from the French version by the authors. See Genizon Bioscience, “Formulaire de Consentement de la biobanque”, CL-CRF-OP-FRMB.00, 24 May 2007 at 1.
- ¹⁶⁹ Atlantic PATH, “Consent”, *supra* note 163.
- ¹⁷⁰ BC Generations, “BC Generations Project Protocol”, *supra* note 149 at 4, 23-24.
- ¹⁷¹ CARTaGENE, *supra* note 149 at 10.
- ¹⁷² Ontario Health Study, “Privacy”, *supra* note 161.
- ¹⁷³ The Tomorrow Project, “Join the Study”, online: <www.in4tomorrow.ca/JoinTheStudy.aspx>.

**SPECIAL SECTION: DEVELOPMENTS IN THE LAW OF
INFORMED CONSENT**

INFORMED CONSENT AND PATIENT COMPREHENSION: THE LAW AND THE EVIDENCE

*Sarah Burningham, Christen Rachul & Timothy
Caulfield**

Introduction

Few areas of health law attract as much attention as informed consent. In Canada, several well-known Supreme Court cases,¹ and, in some provinces, health care consent laws,² provide that physicians must obtain the informed consent of patients prior to providing medical treatment. While the basic parameters of informed consent law are clear, confusion remains about the extent of the duty of physicians to ensure that patients understand the information provided. The need for patient comprehension is self-evident: providing patients with information facilitates decision making and promotes autonomy only if patients are able to understand that information. However, it may be challenging for physicians in practice to meet legal or ethical obliga-

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¹ *Reibl v Hughes*, [1980] 2 SCR 880, 114 DLR (3d) 1 [*Reibl*]; *Hopp v Lepp*, [1980] 2 SCR 192, 112 DLR (3d) 67.

² Health Care Consent Act, 1996, SO 1996, c 2, Schedule A; Health Care (Consent) and Care Facility (Admission) Act, RSBC 1996, c 181; Consent to Treatment and Health Care Directives Act, RSPEI 1988, c C-17.2.

tions to ensure patient comprehension, as evidence suggests that many patients do not understand complex medical information or risk information. Reviewing relevant jurisprudence and professional ethics, we examine the nature of this obligation, followed by a discussion of empirical evidence relating to patient comprehension. Based on this review, we suggest that there is a disconnect between what the law expects and what patients experience during the informed consent process.

I. The Law

The breadth of what should be provided as part of the consent process is significant and, in general, includes anything a reasonable person in the patient's position would want to know.³ Over the years, judicial interpretation of consent law has consistently expanded the parameters of the disclosure obligation to include, for example, even relatively remote risks.⁴ As a result, meeting this significant legal obligation can, from a practical perspective, be a challenge.⁵

But merely providing patients with relevant information is not the only challenging component of the informed consent process. Canadian law clearly imposes some responsibility on physicians to ensure patients understand what they have been told. In *Reibl v Hughes*, and later in *Ciarlariello v Schacter*,⁶ the Supreme Court appeared to place a burden on physicians to ensure patients understood the information provided to them. In *Ciarlariello v Schacter*, Cory J for the Court held:

Prior to *Reibl v. Hughes*, there was some doubt as to whether the doctor had the duty to ensure that he was understood. However, Laskin C.J. made it quite clear in that case that it was incumbent on the doctor to make sure that he was understood, particularly

³ *Reibl*, *supra* note 1.

⁴ See e.g. *Malinowski v Schneider*, 2012 ABCA 125, 71 Alta LR (5th) 34 (finding that "a rare but potentially catastrophic consequence" ought to have been disclosed to the patient); *White v Turner* (1981), 31 OR (2d) 773, 120 DLR (3d) 269 (HCT) (finding that, "[w]here an operation is elective, ...even minimal risks must be disclosed to patients").

⁵ Colleen M Flood, "Conundrums in Causation and Informed Medical Consent" (2000) 23 *Advocates' Q* 217 at 220; Ellen I Picard & Gerald B Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed (Toronto: Thomson Canada Limited, 2007) at 135-41.

⁶ [1993] 2 SCR 119, 100 DLR (4th) 609.

where it appears that the patient had some difficulty with the language spoken by the doctor.

Indeed, it is appropriate that the burden should be placed on the doctor to show that the patient comprehended the explanation and instructions given.⁷

The burden described by Cory J in *Ciarlariello* has been criticized by both academics and judges. In their influential text, *Legal Liability of Doctors and Hospitals in Canada*,⁸ Picard and Robertson suggest that the burden in *Ciarlariello* is “too onerous and impractical[1].”⁹ Rather, they propose, physicians should “take reasonable steps to ensure that the patient understands” what he or she is told.¹⁰

Lower courts have similarly criticized *Ciarlariello*.¹¹ For example, in *Byciuk v Hollingsworth*, the Alberta Court of Queen’s Bench stated:

That expansive burden [in *Ciarlariello*] has been criticized as unrealistic. See Ellen I. Picard and Gerald B. Robertson *Legal Liabilities of Doctors and Hospitals in Canada* (3d edition) Toronto: Carswell, 1996 at 137.

I agree that the burden described by Cory, J. is too onerous. I prefer the proposal of the above authors. It is sufficient if the physician takes reasonable steps to ascertain whether the patient understood the message being conveyed.¹²

Lower courts have interpreted *Ciarlariello* narrowly, holding that physicians have a duty to take reasonable steps to ensure that patients understand what they are told if patients are older, are distressed, or have trouble with lan-

⁷ *Ibid* at paras 54-55.

⁸ Picard & Robertson, *supra* note 5.

⁹ *Ibid* at 161. See also Kevin Williams, “Comprehending Disclosure: Must Patients Understand the Risks They Run?” (2000) 4 *Medical Law International* 97 at 101-02; Margaret A Somerville, “Structuring the Issues in Informed Consent” (1981) 26:4 *McGill LJ* 740 at 780.

¹⁰ Picard & Robertson, *supra* note 5 at 161.

¹¹ *Byciuk v Hollingsworth*, 2004 ABQB 370, 358 AR 312 at paras 32-33 [*Byciuk*]; *Sadlowski v Yeung*, 2008 BCSC 456, 57 CCLT (3d) 305 at para 104 [*Sadlowski*]; *Loffler v Cosman*, 2010 ABQB 177 at paras 206-09 [*Loffler*].

¹² *Byciuk*, *ibid* at paras 32-33.

guage.¹³ But, it should be noted that the courts have, when asked, consistently confirmed that this obligation does in fact reside with the physicians.¹⁴ While the lengths to which physicians must go to discharge the duty continues to be debated, there is little doubt that physicians do indeed have such a duty. The responsibility is confirmed by relevant professional guidelines. In particular, the Canadian Medical Association's Code of Ethics provides that physicians must "[m]ake every reasonable effort to communicate with...patients in such a way that information exchanged is understood."¹⁵

The main point is clear: physicians have an ethical and legal obligation to take reasonable steps, at minimum, to ensure patients understand the information provided to them. The duty rests with physicians and what "reasonable steps" will discharge the duty "depend[s] on the particular circumstances of each case."¹⁶

II. The Evidence about Patient Understanding

The practicality of this obligation, and how it can best be operationalized, must be considered, given the mounting social science evidence that suggests that many patients do not understand the information they are given during the informed consent process.¹⁷ In particular, patients have trouble understanding probability data, as they often do not understand information in-

¹³ *Martin v Findlay*, 2008 ABCA 161 at para 38; *Byciuk*, *ibid* at paras 31-34; *Sadlowski*, *supra* note 11; *Loffler*, *supra* note 11 at para 208; Kenneth G Evans, "Consent: A Guide for Canadian Physicians", 4th ed, (The Canadian Medical Protective Association, 2006) online: CMPA <www.cmpa-acpm.ca>.

¹⁴ *Reibl*, *supra* note 1; *Gilberds v Sobey*, 2011 ABQB 491 at para 95.

¹⁵ Canadian Medical Association, *Code of Ethics* (Ottawa: Canadian Medical Association, 2004), online: Canadian Medical Association <<http://policybase.cma.ca/dbtw-wpd/PolicyPDF/PD04-06.pdf>>.

¹⁶ Picard & Robertson, *supra* note 5 at 161; *Byciuk*, *supra* note 11 at para 33.

¹⁷ BM Stanley, DJ Walters & GJ Maddern, "Informed Consent: How Much is Enough?" (1998) 68 *Australian & New Zealand Journal of Surgery* 788; Allison E Crepeau et al, "Prospective Evaluation of Patient Comprehension of Informed Consent" (2011) 93:19 *Journal of Bone & Joint Surgery American Volume* e114; Jürgen JW Mulrow, T Martin Feeley & Sean Tierney, "Beyond Consent: Improving Understanding in Surgical Patients" (2012) 203:1 *American Journal of Surgery* 112; Jeff Whittle et al, "Understanding of the Benefits of Coronary Revascularization Procedures Among Patients Who Are Offered Such Procedures" (2007) 154 *American Heart Journal* 662; Sonu Pathak et al, "Consent for Gynaecological Procedure: What Do Women Understand and Remember?" (2013) 287 *Archives of Gynecology & Obstetrics* 59.

volving numbers.¹⁸ Additionally, evidence suggests that the “framing” of numerical information can influence decision making.¹⁹

The fact that patients have difficulty understanding risk information and other medical information suggests that physicians may not easily discharge their duty regarding patient comprehension. For example, teaching patients to understand probability data may take an extensive time commitment beyond what can be reasonably expected of physicians. Even with education, patients may still have trouble understanding some concepts.

The matter is made more complex by two additional factors. First, physicians have trouble recognizing that patients do not understand information or have not received sufficient information necessary to make a decision.²⁰ Second, patients struggle to identify their own misunderstanding. Patients overwhelmingly believe they are well informed and understand the information provided to them.²¹ How can physicians meet their obligation respecting patient comprehension when neither physician nor patient can properly identify misunderstanding? Additionally, patient misunderstanding cannot be corrected simply by encouraging patients to ask questions, because

¹⁸ Lisa M Schwartz et al, “The Role of Numeracy in Understanding the Benefit of Screening Mammography” (1997) 127:11 *Annals of Internal Medicine* 966; R Fuller, N Dudley & J Blacktop, “How Informed is Consent? Understanding of Pictorial and Verbal Probability Information by Medical Inpatients” (2002) 78:923 *Postgraduate Medical Journal* 543; Richard Fuller, Nigel Dudley & Jon Blacktop, “Risk Communication and Older People: Understanding of Probability and Risk Information by Inpatients Aged 75 Years and Older” (2001) 30:6 *Age & Aging* 473; Isaac M Lipkus, Greg Samsa & Barbara K Rimer, “General Performance on a Numeracy Scale among Highly Educated Samples” (2001) 21:1 *Medical Decision Making* 37.

¹⁹ Schwartz et al, *ibid*; Judith Covey, “A Meta-analysis of the Effects of Presenting Treatment Benefits in Different Formats” (2007) 27:5 *Medical Decision Making* 638.

²⁰ Marko Jukic et al, “Physicians Overestimate Patient’s Knowledge of the Process of Informed Consent: A Cross-Sectional Study” (2011) 8:1 *Medicinski Glasnik* 39; M Gattellari et al, “Misunderstanding in Cancer Patients: Why Shoot the Messenger?” (1999) 10 *Annals of Oncology* 39.

²¹ Mulsow, Feeley & Tierney, *supra* note 17; PJD Dawes, L O’Keefe & S Adcock, “Informed Consent: The Assessment of Two Structured Interview Approaches Compared to the Current Approach” (1992) 106 *Journal of Laryngology & Otology* 420.

they “may not know enough to enable them to frame specific or even general questions.”²²

Clearly, a gap exists between what the law expects and what actually occurs during the informed consent process. Indeed, the evidence regarding patient comprehension may undermine bedrock principles of informed consent. Informed consent is based on the notion that medical decisions are properly within the realm of patient autonomy. Patients should be provided with sufficient information to enable them to make informed decisions. Courts often assume that patients understand this information.²³ A review of the evidence challenges this assumption.

Conclusion

Informed consent, built on a long and well-developed body of jurisprudence and bioethics literature, is a foundational cornerstone of health law in Canada. For this reason, we do not advocate in this article revisiting the theoretical principles underlying informed consent law. Rather, we suggest that, given the practical problems associated with implementation, physicians, lawyers, and policy makers consider methods and approaches to ensure informed consent works in practice.

For example, there are several interventions identified in the academic literature that may improve patient comprehension. The evidence suggests that interventions—such as leaflets, multimedia, or testing—are generally helpful, especially in improving patients’ knowledge of risks.²⁴ Additionally, providing physicians with communication skills training may improve patient understanding.²⁵ Such interventions may help physicians meet their ethical and legal obligations.

²² Picard & Robertson, *supra* note 5 at 164-65.

²³ Williams, *supra* note 9.

²⁴ Yael Schenker et al, “Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: A Systematic Review” (2011) 31:1 *Medical Decision Making* 151; Mulsow, Feeley & Tierney, *supra* note 17. *Contra* H Brown et al, “Are Patient Information Leaflets Contributing to Informed Consent for Cataract Surgery?” (2004) 30 *Journal of Medical Ethics* 218.

²⁵ Pranitha Naini et al, “Evaluation of a Method to Improve the Consent Process: Improved Data Retention with Stagnant Comprehension” (2013) 28 *Journal of Cancer Education* 38.

LEGAL LIABILITY IN INFORMED CONSENT CASES: WHAT ARE THE RULES OF THE GAME?

*Paul McGivern & Natalia Ivolgina**

Introduction

Informed consent is an important tenet of the Western medical care system, serving a number of functions. Firstly, it addresses the imbalance of knowledge between physicians and patients about the complexities of medical care. Secondly, it protects the patient's right to self-determination when choosing medical treatment. Thirdly, it imposes a duty on the physician to pass the material information about the proposed treatment to his or her patient, emphasizing the importance of effective physician-patient communication.

This paper discusses the evolution of the doctrine of informed consent. It will outline how informed consent cases are properly pled, the parameters of the physician's duty to disclose, and what the scope of this duty is. It will examine the legal test of causation in informed consent cases and discuss the latest cases from the Supreme Court of Canada considering this cause of action.

I. In the Beginning

Prior to the decisions in *Hopp v Lepp*¹ and *Reibl v Hughes*,² there was considerable debate in the medical and legal community about the amount and content of medical information a doctor should disclose to his or her patient.

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¹ [1980] 2 SCR 192, 112 DLR (3d) 67, 22 AR 361 [*Hopp v Lepp* cited to SCR].

² [1980] 2 SCR 880, 114 DLR (3d) 1, 33 NR 361, 14 CCLT 1 [*Reibl v Hughes* cited to SCR].

Should these cases be pled as actions in battery or in negligence? What was the scope of the duty to disclose information to patients? Should the courts defer to the standards set by the medical community, as occurs in most other aspects of medical malpractice law?

II. Battery or Negligence?

Does a physician's failure to inform the patient of the risks involved in a treatment or procedure invalidate consent and result in liability based in battery? This issue was settled in *Hopp v Lepp*, *Reibl v Hughes*, and the decisions that followed.³ The Supreme Court determined, and repeatedly affirmed, that non-disclosure of risks or medical information was to be subsumed into the law of negligence, not battery. In the words of the Supreme Court of Canada in *Reibl v Hughes*, an action in battery would only be appropriate "where surgery or treatment has been performed or given to which there has been no consent at all or where, emergency situations aside, ... there was misrepresentation of the surgery or treatment for which consent was elicited and a different surgical procedure or treatment was carried out."⁴

These principles are still at play today, as illustrated in *Mohsina v Ornstein*,⁵ where the plaintiff succeeded in her action in battery against her gynecologist. Here, the plaintiff consented to surgery to remove her right ovary, which had a cyst. The signed consent form authorized such measures as were "immediately necessary" during the operation.⁶ During the surgery, the plaintiff experienced bleeding in the area of both the right and left fallopian tubes, requiring stitching. The doctor was concerned that the stitches on the left side could lead to a future ectopic pregnancy, and decided to apply clips (i.e. perform a tubal ligation) to prevent this occurrence; the tubal ligation resulted in the plaintiff's infertility. The defendant argued that the procedure fell within the terms of the consent form. Citing *Reibl v Hughes*, the court found for the plaintiff, explaining that while claims in negligence are suitable where the patient is not advised of the material risks, a claim in battery is available in "cir-

³ See *Ciarlariello v Schacter*, [1993] 2 SCR 119, 100 DLR (4th) 609, 62 OAC 161 [cited to SCR]; *Hollis v Dow Corning Corp.*, [1995] 4 SCR 634, 129 DLR (4th) 609, 14 BCLR (3d) 1 [*Hollis* cited to SCR]; *Arndt v Smith*, [1997] 2 SCR 539, 148 DLR (4th) 48, BCLR (3d) 187 [cited to SCR]. These cases are discussed later in the paper.

⁴ *Supra* note 2 at 890-91.

⁵ 2012 ONSC 6678, 99 CCLT (3d) 247, 225 ACWS (3d) 576.

⁶ *Ibid* at para 30 (quoting the consent form).

cumstances [such as this] where informed consent is given for a particular procedure and another procedure for which consent has not been given is performed.”⁷

III. The Duty to Disclose and the Standard of Disclosure

The legal parameters of a physician’s duty to disclose were articulated in *Hopp v Lepp*, a case in which a 66 year-old retired man suffered a spinal disc injury and underwent a hemilaminectomy operation in Lethbridge, Alberta. The case was pled in both negligence and battery, alleging that the patient’s consent was not informed because the surgeon failed to advise the plaintiff that it was his first operation since becoming a qualified orthopaedic surgeon, and because his assertion that the surgery could be performed just as competently in Lethbridge as in Calgary was supposedly incorrect.

The Court found that the surgeon did not have to disclose to the patient that it was his first operation since becoming qualified and that the routine operation could be performed just as well in Lethbridge as in Calgary. In describing the duty to disclose, Laskin CJ stated the following for the Court:

[I]n obtaining the consent of a patient for the performance upon him of a surgical operation, a surgeon, generally, should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation. However, having said that, it should be added that the scope of the duty of disclosure and whether or not it has been breached are matters which must be decided in relation to the circumstances of each particular case.⁸

With these words, Laskin CJ laid the foundation for the test on informed consent that is still in use today.

Laskin CJ expanded on the framework enunciated in *Hopp v Lepp* in *Reibl v Hughes*.⁹ In that case, the plaintiff suffered a stroke during or immediately after an elective operation that was performed solely to reduce the risk of a lat-

⁷ *Ibid* at para 31.

⁸ *Hopp v Lepp*, *supra* note 1 at 210.

⁹ *Supra* note 2; for a fuller presentation of the facts, see the decision of the Court of Appeal, *Reibl v Hughes*, 21 OR (2d) 14, 89 DLR (3d) 112.

er stroke. The plaintiff's pension was scheduled to vest 18 months after the surgery. As a result of the stroke he suffered during the surgery, he became partially paralyzed, was unable to return to work, and therefore did not become eligible for pension benefits. Laskin CJ repeated the principles set out in *Hopp v Lepp* that required all material risks to be disclosed to the patient, and added that "even if a certain risk is a mere possibility which ordinarily need not be disclosed, yet if its occurrence carries serious consequences, as for example, paralysis or even death, it should be regarded as a material risk requiring disclosure."¹⁰

IV. The Scope of the Duty: What Information Must Be Disclosed?

Reibl v Hughes also changed the scope of the duty to disclose information to patients. Previously, courts had relied on the medical profession to determine the scope of disclosure to a patient. *Reibl v Hughes* rejected that approach and adopted a new objective standard that focused on what a reasonable patient would want to know, which broadened the scope beyond what the medical standards of the day considered appropriate. Laskin CJ commented as follows:

To allow expert medical evidence to determine what risks are material and, hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty. *Expert medical evidence is, of course, relevant to findings as to the risks that reside in or are a result of recommended surgery or other treatment. It will also have a bearing on their materiality but this is not a question that is to be concluded on the basis of the expert medical evidence alone.* The issue under consideration is a different issue from that involved where the question is whether the doctor carried out his professional activities by applicable professional standards. *What is under consideration here is the patient's right to know what risks are involved in undergoing or foregoing certain surgery or other treatment.*¹¹

Reibl v Hughes also narrowed the test for determining causation in informed consent cases, which will be discussed in further detail later in this paper.

¹⁰ *Reibl v Hughes*, *supra* note 2 at 884-85.

¹¹ *Ibid* at 894-95 [emphasis added].

V. Patient's Right to Bodily Autonomy and the Right to Withdraw Consent

The judgments of the Supreme Court of Canada concerning the scope of disclosure that subsequently came out in the 1990s emphasized the patient's right to make decisions regarding his or her own body. This right was recognized as one of the main purposes of the "duty to disclose" doctrine.

This principle is illustrated in *Ciarlariello v Schacter*.¹² In that case, an angiogram was performed to determine the exact location and extent of the plaintiff's aneurism. The risks were adequately explained and consent was given. The patient withdrew consent during the procedure upon experiencing hyperventilation, but consented once again upon calming down after a discussion. When the procedure was resumed, the patient suffered an immediate adverse reaction, which rendered her a quadriplegic. The Supreme Court reiterated the principles enunciated in *Reibl v Hughes*, underscoring that every patient has the right to bodily integrity, including the right not only to consent to a procedure, but also to withdraw that consent and halt the procedure. Cory J, writing for the Court, said:

It should not be forgotten that every patient has a right to bodily integrity. ... This concept of individual autonomy is fundamental to the common law and is the basis for the requirement that disclosure be made to a patient. *If, during the course of a medical procedure a patient withdraws the consent to that procedure, then the doctors must halt the process. This duty to stop does no more than recognize every individual's basic right to make decisions concerning his or her own body.*¹³

Two years later, in *Hollis v Dow Corning Corp*,¹⁴ a case that examined the duty of the manufacturer of breast implants to warn physicians and patients of the risks associated with the use of the implants, La Forest J, speaking for the Court (on this issue), stated:

there is an important analogy to be drawn in this context between the manufacturer's duty to warn and the doctrine of "informed consent" developed by this Court in recent years with respect to the doctor-patient relationship. ... *The doctrine of "informed*

¹² *Supra* note 3.

¹³ *Ibid* at 135 [emphasis added].

¹⁴ *Supra* note 3.

*consent” dictates that every individual has a right to know what risks are involved in undergoing or foregoing medical treatment and a concomitant right to make meaningful decisions based on a full understanding of those risks.*¹⁵

VI. What Information is Material and What is Not?

The duty of disclosure does not require a physician to disclose all potential risks to a patient. Only risks that are “material” need to be disclosed. A useful starting point for courts in determining which risks must be disclosed is found in *Rawlings v Lindsay*,¹⁶ where McLachlin J (as she then was) stated:

[A] medical person must disclose those risks to which a reasonable patient would be likely to attach significance in deciding whether or not to undergo the proposed treatment. In making this determination, the degree of probability of the risk and its seriousness are relevant factors.¹⁷

In *Brito (Guardian ad litem of) v Woolley*,¹⁸ a case involving injuries that occurred to the infant plaintiff during his birth, the governing legal principles relating to determination of what risks are material were summarized as follows by Sinclair Prowse J:

What constitutes a special, material, or unusual risk will depend on the particular facts of the case. A mere possibility will be included as a material risk if the occurrence of that mere possibility is serious, for example, if it can result in paralysis or death ... *Material risks include those risks which the doctor knows, or ought to know, that a reasonable person in the patient’s position would consider in deciding whether to undergo a procedure or treatment.*¹⁹

Although we usually think of the disclosure of material *risks* as the key to the provision of information to patients, other information can also be material to a patient’s decision making. In *Seney v Crooks*, Conrad JA, writing for the majority of the Alberta Court of Appeal, upheld the trial judge’s finding that

¹⁵ *Ibid* at para 24 [emphasis added].

¹⁶ (1982), 20 CCLT 301, 13 ACWS (2d) 376 (BCSC) [cited to CCLT].

¹⁷ *Ibid* at 306.

¹⁸ 2001 BCSC 1178, 107 ACWS (3d) 518, [2001] BCTC 1178.

¹⁹ *Ibid* at para 133 [emphasis added].

the defendant surgeon owed a duty to inform the patient that there was an alternative method of treatment of her broken wrist that was preferred by some specialists and might have prevented the damage she sustained. Included in the duty to inform is information on both an alternative mode of treatment and the material risks of that treatment.²⁰

VII. What if the Risk of Injury to the Patient is Small?

Almost all procedures and treatments involve risks; some of these risks are inherent in the procedure itself and occur regularly, and others may be statistically unlikely to occur. The clinical significance of the risks may also vary, for example, from short-term minor pain created by a surgical incision to paralysis. This range of risks presents an interesting exercise in judicial discrimination.

How significant must the risk be before the duty to disclose is triggered? An answer to that question is offered in *Bryan v Hicks*.²¹ In that case, the defendant orthopaedic surgeon removed an annoying and painful ganglion from the plaintiff's wrist. The surgery was done appropriately, but the plaintiff developed a recognized potential complication: reflex sympathetic dystrophy. The plaintiff's hand became permanently disfigured and essentially useless. She sued, and the court found the defendant liable for failing to properly inform her of the risks of this complication. The defendant appealed on the basis that the risk was so low that there was no duty to disclose it. In rejecting that submission, Ryan JA, speaking for the Court, stated that "[A] risk may be remote, yet considered to be material. ..."²² The judge relied on Justice McLachlin's reasons in *Rawlings v Lindsay*:

... an "unusual" or improbable risk should be disclosed if its effects are serious. Conversely, a minor result should be disclosed if it is inherent in or a probable result of the process.

Other factors which may be relevant in determining a reasonable standard of disclosure include the gravity of the condition to be treated, the importance of the benefits expected to flow from the treatment and the intellectual and emotional capacity of the

²⁰ 1998 ABCA 316, 223 AR 145, 166 DLR (4th) 337 at paras 53, 55.

²¹ [1995] 10 WWR 145, 10 BCLR (3d) 239, 1995 CanLII 172 (BCCA).

²² *Ibid* at paras 22-23.

patient to accept the information without such distortion as to prevent any rational decision at all.²³

VIII. Causation in Informed Consent Cases: The Modified Objective Test

In order to succeed in an “informed consent” case, the plaintiff must satisfy two causation tests – the modified objective test, outlined here, and the “but for” causation test that applies to all tort cases. The “but for” causation test will be described further below.

The modified objective causation test in informed consent cases is established by demonstrating that a reasonable person in the patient’s circumstances would have declined the treatment had full disclosure been made.²⁴ This test imports a certain level of subjectivity into the assessment of what a reasonable person would do. The question then becomes: how far do courts go in allowing a particular patient’s circumstances to influence the application of an objective test?

Impact of the Plaintiff’s Circumstances on the Modified Objective Test

In the past 15 years or so, there has been a judicial trend towards giving more weight to the plaintiff’s personal circumstances when applying the “modified objective test” in informed consent cases. Perhaps this trend was predictable in light of its point of origin: the modified objective test for causation was adopted in *Arndt v Smith*,²⁵ although a purely subjective test was favoured in the concurring reasons of Justice McLachlin (now Chief Justice) and the dissenting judgment of Justices Sopinka and Iacobucci.

In that case, the plaintiff sued her physician for costs incurred in raising her daughter, who was born with injuries caused by chickenpox that the plaintiff had contracted during her pregnancy. The plaintiff asserted that she would have terminated her pregnancy had she been advised of the risks of congenital defects. The trial judge found that the plaintiff would have continued with the pregnancy based on her personal circumstances: the pregnancy was carefully planned, the baby was much wanted, and the plaintiff was sceptical of “mainstream” medical intervention. In addition, the evidence was that the risk of injury to the foetus was small and that the medical doctors would have advised

²³ *Ibid*; *Rawlings v Lindsay*, *supra* note 18 at 306.

²⁴ *Reibl v Hughes*, *supra* note 2 at 898-99, 928.

²⁵ *Supra* note 3.

against the abortion.²⁶ The Court of Appeal found that the trial judge applied the wrong test and ordered a new trial, but the Supreme Court of Canada restored the trial judge's dismissal of the claim.

Cory J had the following to say on behalf of the majority on the issue of how personal circumstances should be appropriately considered in application of the modified objective test:

In my view this means that the "reasonable person" who sets the standard for the objective test must be taken to possess *the patient's reasonable beliefs, fears, desires and expectations*. Further, the patient's expectations and concerns will usually be revealed by the questions posed. Certainly, they will indicate the specific concerns of the particular patient at the time consent was given to a proposed course of treatment. The questions, by revealing the patient's concerns, will provide an indication of the patient's state of mind, which can be relevant in considering and applying the modified objective test.²⁷

The recent Ontario case of *Husain v Daly*²⁸ illustrates just how much weight the trial courts are willing to allocate to the personal circumstances of a particular plaintiff. In that case, a gynecologist was sued for wrongful hysterectomy. The plaintiff and her husband were desperate to have a baby and had plans to see a fertility specialist. However, the plaintiff suffered from excessive bleeding and considerable pelvic pain, and was suspected to have uterine fibroids that needed to be addressed first. While performing a myomectomy to remove the suspected uterine fibroids, the defendant gynecologist discovered that the source of the plaintiff's symptoms was instead a uterine condition called adenomyosis. Having diagnosed this condition intra-operatively, the defendant decided to remove the plaintiff's uterus, thereby rendering her incapable of becoming pregnant.

Prior to the procedure, the risk of excessive bleeding during the procedure that would necessitate an emergency hysterectomy was discussed with the plaintiff and she accepted it. However, the hysterectomy was performed to treat the discovered condition, and not to deal with an intra-operative emergency. The defendant argued that even if there was no consent, a reasonable

²⁶ *Ibid* at para 69, citing the trial decision, *Arndt v Smith*, [1994] 8 WWR 568, 93 BCLR (2d) 220.

²⁷ *Ibid* at para 9 [emphasis added].

²⁸ 2012 ONSC 919, 214 ACWS (3d) 285.

person in the plaintiff's circumstances would have agreed to a non-emergency hysterectomy due to her age and the debilitating symptoms she was suffering. The plaintiff argued that she had not been ready to give up on her hope to have children yet, and would not have agreed to a non-emergency hysterectomy simply to relieve her symptoms of pain and bleeding. The court found that a reasonable person in the plaintiff's shoes would have lived with the pain if it meant that there was still a possibility of becoming pregnant through artificial methods. In assessing the reasonableness of the plaintiff's beliefs, fears, desires and expectations, the court found that it was not unreasonable for the plaintiff to want to have a baby at age 46, even though it was statistically unlikely.²⁹

Another example where the court focused on the patient's circumstances is *Cojocar v British Columbia Women's Hospital and Health Centre*.³⁰ In that case, the infant plaintiff suffered brain damage during his birth. His mother had previously given birth to a child by Caesarean section ("C-section") and wanted to deliver her second baby by the same method since that was the recommendation of her previous obstetrician.

Dr. Yue, Ms. Cojocar's prenatal care obstetrician, advised Ms. Cojocar to attempt to deliver her second baby by vaginal birth after C-section or "VBAC." During labour, Ms. Cojocar experienced a uterine rupture and an emergency C-section was performed. The baby was born with brain damage, which led to cerebral palsy. The trial judge found Dr. Yue liable for failing to obtain Ms. Cojocar's informed consent to the VBAC procedure. He included evidence of the plaintiff's unique circumstances in the factors that led him to conclude that had she been advised of the risks of uterine rupture, she would have never consented to VBAC. These circumstances included the fact that her first child had been born with a cleft palate and the cultural stigmas of her home country associated with children with disabilities.³¹

²⁹ *Ibid* at paras 26-27.

³⁰ *Cojocar (Guardian Ad Litem) v British Columbia Women's Hospital*, 2009 BCSC 494, 65 CCLT (3d) [*Cojocar*], aff'd 2013 SCC 30, 357 DLR (4th) 585, 226 ACWS (3d) 838 [*Cojocar* SCC] (Author Paul McGivern was lead counsel at trial and on appeal to the SCC).

³¹ *Cojocar*, *supra* note 30 at paras 20-21, 100. On appeal, the Supreme Court upheld the trial judge's finding of negligence on the informed consent issue (*Cojocar* SCC, *supra* note 30 at para 88).

A patient's level of comprehension is perhaps the most important personal circumstance to be considered. In *Tiglao v Sleightholm*,³² the plaintiff who spoke minimal English underwent a breast augmentation and a tummy tuck with liposuction. The plaintiff argued that the risk that the procedure would lead to undesirable results was never fully explained to her. All the consultations and office visits at the clinic were conducted in English. The plaintiff's husband, a native English-speaker, attended with the plaintiff at most of her consultations. The court found that "a doctor cannot relegate his obligation to ensure informed consent is given to an employee or a spouse of the patient."³³ The court quoted Justice Shelley in *Malinowski v Schneider*,³⁴ where she stated:

When faced with a patient whose personal characteristics might suggest there is a language barrier to his or her understanding of a consent form, the medical practitioner ought to take steps to ensure that language limitations have not prevented or limited the patient's understanding of the form that the patient has been asked to read and sign.... When faced with such a patient, medical practitioners should ensure that the patient understands the meaning of the words and expressions as well as the overall meaning of the document.³⁵

The court in *Tiglao* concluded: "There is a 'special duty' placed on the doctor in these circumstances to be certain that his/her patient understands the risks and the alternatives available to the patient."³⁶

As will be discussed below, the Supreme Court of Canada recently affirmed that a patient's capacity to comprehend is a vitally important personal characteristic that raises the bar for a physician in making sure that all the information that is given is understood by the patient. This duty to ensure the patient understands extends beyond problems due to language barriers; the patient must not only be informed of the risks, they also need to understand the implications of those risks.

³² 2012 ONSC 3092, 219 ACWS (3d) 217.

³³ *Ibid* at para 46.

³⁴ 2010 ABQB 734, 494 AR 201, 79 CCLT (3d) 36.

³⁵ *Ibid* at para 70, cited in *Tiglao v Sleightholm*, *supra* note 32 at para 32.

³⁶ *Tiglao v Sleightholm*, *supra* note 32 at para 45.

IX. Latest Word from the Supreme Court of Canada

In two decisions in the spring of 2013, the Supreme Court again addressed the informed consent issue and the scope of the duty to disclose. Essentially, the Court has stated that it is not enough for a physician to tell a patient of the material risks and their statistical probability. A physician must ensure that the significance of these risks is impressed upon a patient, that is, that the patient understands what would happen if a risk were to materialize.

In *Ediger (Guardian ad litem) v Johnston*,³⁷ the Supreme Court of Canada dealt with a question of causation that turned on the proper interpretation of the standard of care. Although the issue of informed consent was considered only peripherally, the case illustrates the need to inform the patient of the risk and ensure that they understand what would happen if the risk materialized. In that case, Cassidy Ediger was born with severe and permanent brain damage. She sued the obstetrician who delivered her for negligence. During her mother's labour, the defendant decided to attempt a mid-level forceps procedure to deliver Cassidy. The obstetrician did not warn the mother of the risks; one such risk was compression of the baby's umbilical cord, which could lead to persistent foetal bradycardia, and in turn cause severe brain damage. The obstetrician did not determine the availability of medical personnel to assist with an emergency C-section in case these complications occurred. On this basis, the trial judge found the obstetrician liable for Cassidy's injuries. She also found that he had failed to obtain informed consent from Cassidy's mother. The Supreme Court of Canada upheld the trial judge's finding that in order for there to have been informed consent to the procedure in the absence of a surgical team on standby, the obstetrician would have had to tell the mother that "proceeding with the mid-level forceps delivery included the risk of bradycardia, and that in the event that the risk materialized, her baby would necessarily be born with severe and permanent brain damage because of the time required to arrange for surgical back-up."³⁸

In this way, the Supreme Court set the stage for the decision discussed earlier, *Cojocar*,³⁹ which came out a month later. In that case, the Supreme Court upheld the finding of the learned trial judge that insufficient information had been provided to Ms. Cojocar. There was evidence that the methods of deliv-

³⁷ 2013 SCC 18, 356 DLR (4th) 575, 100 CCLT (3d) 1 [*Ediger*] (Author Paul McGivern was also counsel at trial and on appeal to the SCC in this case).

³⁸ *Ibid* at para 58.

³⁹ *Cojocar* SCC, *supra* note 30.

ery were discussed, and that Ms. Cojocaru may have been informed that the chance of success with VBAC was 80% and that the risk of uterine rupture was 1 in 200. However, there was no evidence that anything more than the statistical risks of uterine rupture were conveyed to Ms. Cojocaru, and there was “no indication that the significance of that statistic was brought home to Ms. Cojocaru.”⁴⁰ Moreover, the trial judge found that even if Dr. Yue did convey the risk of 1 in 200 to Ms. Cojocaru, it was not enough to meet the duty of disclosure.⁴¹

“But for” Causation – The Second Test

It is important not to overlook the requirement for “but for” causation in informed consent cases. It is not sufficient for a plaintiff to establish, using the modified objective test, that the plaintiff would not have consented to the medical treatment had the risks associated with the treatment been properly outlined. It is necessary to go further and establish that “but for” the treatment rendered, the injury would have been avoided. Thus, in *Cojocaru*, the Supreme Court set aside the finding of the learned trial judge that Dr. Yue should be held liable for failure to obtain Ms. Cojocaru’s informed consent to the induction. The court held that there was no proper causation analysis conducted by the trial judge regarding this claim, and no evidence that the uterine rupture would not have occurred but for the induction. Absent evidence capable of supporting a causal link between the induction and the uterine rupture, that aspect of the claim could not be sustained.⁴²

Conclusion: Where Are We Now?

The legal principles of informed consent or the physician’s duty to disclose can be summarized as follows:

- (i) A physician owes a duty to his or her patient to disclose any special, material, or unusual risks associated with the treatment or procedure and, in certain circumstances, to disclose alternative treatments reasonably available to the patient. The duty to disclose is a patient-oriented test, the determining factor being what a reasonable person in the patient’s circumstances would want to know.

⁴⁰ *Cojocaru*, *supra* note 30 at para 93.

⁴¹ *Ibid* at para 107.

⁴² *Ibid* at paras 97-101.

(ii) Although a particular risk may only be a mere possibility, if its occurrence carries serious consequences (e.g. paralysis or death), it is a “material risk” and requires disclosure. Conversely, a risk that carries only minor consequences requires disclosure if it is a probable result.

(iii) Expert medical evidence as to whether a particular risk is or is not normally explained to a patient is relevant, but the determination must be made on the basis of what the reasonable patient in the circumstances of the plaintiff would want to know, not on the basis of what a reasonable physician thinks ought to be disclosed.

(iv) A physician must not only relay to a patient the material risks and their relative likelihood of occurrence, but must also explain the consequences of what would happen if the risks were to materialize.

(v) Causation is established by satisfying two tests – the usual “but for” test (which applies to almost all negligence litigation), and the modified objective test specific to informed consent litigation.

Informed consent litigation, more often than not, turns on the question of causation. The defence is successful in the majority of cases, not because the risks of the medical treatment have been disclosed, but because the plaintiff is unable to prove that a reasonable person in the situation of the plaintiff would have refused treatment. This is because:

- a) Patients have medical conditions they want treated;
- b) Patients, when asked, will concede that they trust their treating physicians and will normally abide by the advice given;
- c) When remote risks are outlined to patients, they usually conclude that the material risks will happen to other people, not to them.

In order to overcome this defence, it is necessary to have a “hook” – something specific about the client that distinguishes him or her from the “usual patient” who will usually consent. Examples of successful cases where counsel were able to differentiate their clients from the usual patient include *Husain*⁴³ and *Cojocar*.⁴⁴

⁴³ *Supra* note 28.

⁴⁴ *Supra* note 30.

It may also be necessary to ensure that the patient's refusal is specific to the risk that materialized. In other words, the plaintiff must prove that he or she would have refused treatment if the risks associated with the specific complication that arose had been explained. The Australian High Court decision in *Wallace v Kam*⁴⁵ highlights this point. In that case, the plaintiff underwent a surgical procedure that had various inherent risks. One of these risks – bilateral femoral neurapraxia – materialized. The evidence indicated that the plaintiff likely would have consented if the only risk was neurapraxia and it had been disclosed, but would not have consented to the procedure if another inherent risk, the risk of paralysis, had been explained to him. He did not experience paralysis, but argued that he had not provided an informed consent because he was not advised of the risk of paralysis, and had he been so advised he would have refused treatment, thereby avoiding the complication that did arise.

The case was dismissed, and the High Court upheld the dismissal. The case was argued within the context of the local legislation (which is similar in many respects to the common law regarding the duty of disclosure). The High Court found that the duty of disclosure had been breached. Nevertheless, liability was not imposed because a plaintiff “is not to be compensated for the occurrence of physical injury the risk of which he was prepared to accept.”⁴⁶ This judgment has, to date, not been considered in any Canadian court, but is in accord with the earlier judgment of the PEI Court of Appeal in *Knickle v Rayner*,⁴⁷ where the court suggested that the plaintiff must prove that the specific risk that materialized is a foreseeable risk of which he or she was not advised. It remains to be seen whether the Canadian courts will follow the restrictive course laid down in Australia.

⁴⁵ [2013] HCA 19, 297 ALR 383.

⁴⁶ *Ibid* at para 39.

⁴⁷ (1991), 88 Nfld & PEIR 214, 25 ACWS (3d) 967.

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